



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, 412, 413, 416, 419, and 424

[CMS-1772-P]

RIN 0938-AU82

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for Calendar Year (CY) 2023 based on our continuing experience with these systems. In this proposed rule, we describe the changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment system. Also, this proposed rule would update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program, the ASC Quality Reporting (ASCQR) Program, and the Rural Emergency Hospital Quality Reporting (REH) Program. We are also proposing updates to the requirements for Organ Acquisition, Rural Emergency Hospitals, Prior Authorization, and Overall Hospital Quality Star Rating. We are establishing a new provider type for rural emergency hospitals (REHs), and we have proposals regarding payment policy, quality measures, and enrollment policy for REHs. Finally, we are soliciting comments on the use of

CMS data to drive competition in healthcare marketplaces, and an alternative methodology for counting organs.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by September 13, 2022.

ADDRESSES: In commenting, please refer to file code CMS-1772-P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to

<http://www.regulations.gov>. Follow the "Submit a comment" instructions.

2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1772-P,

P.O. Box 8010,

Baltimore, MD 21244-1810.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following

address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1772-P,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT: Elise Barringer,
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Ambulatory Surgical Center Quality Reporting (ASCQR) Program Measures, contact Cyra Duncan via email Cyra.Duncan@cms.hhs.gov.

Blood and Blood Products, contact Josh McFeeters via email at Joshua.McFeeters@cms.hhs.gov.

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Composite APCs (Low Dose Brachytherapy and Multiple Imaging), contact Au'Sha Washington via email at AuSha.Washington@cms.hhs.gov.

Comprehensive APCs (C-APCs), contact Mitali Dayal via email at Mitali.Dayal2@cms.hhs.gov.

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Mental Health Services Furnished Remotely by Hospital Staff To Beneficiaries in Their Homes, Emily Yoder at Emily.Yoder@cms.hhs.gov.

New Technology Intraocular Lenses (NTIOLs), contact Scott Talaga via email at Scott.Talaga@cms.hhs.gov.

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OPPS New Technology Procedures/Services, contact the New Technology APC mailbox at NewTechAPCapplications@cms.hhs.gov.

OPPS Packaged Items/Services, contact Mitali Dayal via email at Mitali.Dayal2@cms.hhs.gov or Cory Duke via email at Cory.Duke@cms.hhs.gov.

OPPS Pass-Through Devices, contact the Device Pass-Through mailbox at DevicePTapplications@cms.hhs.gov.

OPPS Status Indicators (SI) and Comment Indicators (CI), contact Marina Kushnirova via email at Marina.Kushnirova@cms.hhs.gov.

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Outpatient Department Prior Authorization Process, contact Yuliya Cook via email at Yuliya.Cook@cms.hhs.gov.

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Partial Hospitalization Program (PHP) and Community Mental Health Center (CMHC) Issues, contact the PHP Payment Policy Mailbox at PHPPaymentPolicy@cms.hhs.gov.

Request for Information on Use of CMS Data to Drive Competition in Healthcare Marketplaces, contact Terri Postma via email at Terri.Postma@cms.hhs.gov.

Rural Emergency Hospital Provider Enrollment, contact Frank Whelan via email at Frank.Whelan@cms.hhs.gov.

Rural Emergency Hospital Quality Reporting (REHQR) Program Issues, contact Anita Bhatia via email at Anita.Bhatia@cms.hhs.gov.

Rural Emergency Hospitals (REH) Physician Self-Referral Law Update Issues, contact Lisa O. Wilson via email at Lisa.Wilson2@cms.hhs.gov or Matthew Edgar via email at Matthew.Edgar@cms.hhs.gov.

Skin Substitutes, contact Josh McFeeters via email at Joshua.McFeeters@cms.hhs.gov.

Use of the Medicare Outpatient Observation Notice by REHs, contact Nishamarie Sherry via email at Nishamarie.Sherry@cms.hhs.gov or Janet Miller via email at Janet.Miller@cms.hhs.gov.

All Other Issues Related to Hospital Outpatient Payments Not Previously Identified, contact the OPPS mailbox at OutpatientPPS@cms.hhs.gov.

All Other Issues Related to the Ambulatory Surgical Center Payments Not Previously Identified, contact the ASC mailbox at ASCPPS@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments. CMS will not post on Regulations.gov public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

Addenda Available Only Through the Internet on the CMS Website

In the past, a majority of the Addenda referred to in our OPPS/ASC proposed and final rules were published in the **Federal Register** as part of the annual rulemakings. However, beginning with the CY 2012 OPPS/ASC proposed rule, all of the Addenda no longer appear in the **Federal Register** as part of the annual OPPS/ASC proposed and final rules to decrease administrative burden and reduce costs associated with publishing lengthy tables. Instead, these Addenda are published and available only on the CMS website. The Addenda relating to the

OPPS are available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices>.

The Addenda relating to the ASC payment system are available at:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices>.

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I. Summary and Background

A. Executive Summary of This Document

1. Purpose

In this proposed rule, we propose to update the payment policies and payment rates for services furnished to Medicare beneficiaries in hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs), beginning January 1, 2023. Section 1833(t) of the Social Security Act (the Act) requires us to annually review and update the payment rates for services payable under the Hospital Outpatient Prospective Payment System (OPPS). Specifically, section 1833(t)(9)(A) of the Act requires the Secretary of the Department of Health and Human Services (the Secretary) to review certain components of the OPPS not less often than annually, and to revise the groups, the relative payment weights, and the wage and other adjustments that take into account changes in medical practice, changes in technology, and the addition of new services, new cost data, and other relevant information and factors. In addition, under section 1833(i)(D)(v) of the Act, we annually review and update the ASC payment rates. This proposed rule also includes additional policy changes made in accordance with our experience with the OPPS and the ASC payment system and recent changes in our statutory authority. We describe these and various other statutory authorities in the relevant sections of this proposed rule. In addition, this proposed rule would update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program. We are also proposing updates to the requirements for Organ Acquisition, Prior Authorization, and

Overall Hospital Quality Star Rating. We are also proposing new regulatory requirements to codify payment policy, quality measures, and enrollment policy for Rural Emergency Hospitals. Finally, we are soliciting comments on the use of CMS data to drive competition in healthcare marketplaces, and a Request for Information on an alternative methodology for counting organs.

2. Summary of the Major Provisions

- *OPPS Update:* For 2023, we propose to increase the payment rates under the OPSS by an Outpatient Department (OPD) fee schedule increase factor of 2.7 percent. This proposed increase factor is based on the proposed hospital inpatient market basket percentage increase of 3.1 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS) reduced by a proposed productivity adjustment of 0.4 percentage point. Based on this update, we estimate that total payments to OPSS providers (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix) for calendar year (CY) 2023 would be approximately \$86.2 billion, an increase of approximately \$6.2 billion compared to estimated CY 2022 OPSS payments.

We propose to continue to implement the statutory 2.0 percentage point reduction in payments for hospitals that fail to meet the hospital outpatient quality reporting requirements by applying a reporting factor of 0.9805 to the OPSS payments and copayments for all applicable services.

- *Data used in CY 2023 OPSS/ASC Ratesetting:* To set CY 2023 OPSS and ASC payment rates, we would normally use the most updated claims and cost report data available. The best available claims data is the most recent set of data which would be from 2 years prior to the calendar year that is the subject of rulemaking. Therefore, we are proposing to use the CY 2021 claims data to set CY 2023 OPSS and ASC rates. However, cost report data usually lags the claims data by a year and CMS believes that the CY 2020 cost report data are not the best overall approximation of expected outpatient hospital services as the majority of the cost reports we would typically use for CY 2023 rate setting have cost reporting periods that overlap

with parts of the CY 2020 Public Health Emergency (PHE). In order to mitigate the impact of some of the temporary changes in hospitals cost report data from CY 2020, we propose to use cost report data from the June 2020 extract from Healthcare Cost Report Information System (HCRIS), which includes cost report data from prior to the PHE. This is the same cost report extract we used to set OPPS rates for CY 2022. We believe using the CY 2021 claims data with cost reports data through CY 2019 (prior to the PHE) for CY 2023 OPPS ratesetting is the best approximation of expected costs for CY 2023 hospital outpatient services for ratesetting purposes. As a result, CMS is proposing to use CY 2021 claims data with cost reports with cost reporting periods prior to the PHE to set CY 2023 OPPS and ASC payment system rates.

- *Partial Hospitalization Update:* For CY 2023, we propose to calculate the CMHC and hospital-based PHP (HB PHP) geometric mean per diem costs consistent with our existing methodology, except that while we propose to use the latest available CY 2021 claims data, we propose to continue to use the cost data that was available for the CY 2021 rulemaking.

- *Changes to the Inpatient Only (IPO) List:* For 2023, we propose to remove ten services from the Inpatient Only list.

- *340B-Acquired Drugs:* For CY 2023, we formally propose at this time to continue our current policy of paying ASP minus 22.5 percent for 340B-acquired drugs and biologicals, including when furnished in nonexcepted off-campus PBDs paid under the PFS. This proposal is in accordance with the policy choices and calculations that CMS made in the months leading up to publication of this proposed rule before the Supreme Court issued its decision in *American Hospital Association v. Becerra* (Docket 20-1114). However, we note that, in light of the Supreme Court's recent decision in *American Hospital Association v. Becerra*, we fully anticipate applying a rate of ASP + 6 percent to such drugs and biologicals in the final rule for CY 2023 and making a corresponding decrease to the conversion factor consistent with the OPPS statute and our longstanding policy that this adjustment is made in a budget neutral manner. We are still evaluating how to apply the Supreme Court's recent decision to prior

calendar years. In that decision, the Court summarized the parties' arguments regarding budget neutrality and stated that, "[a]t this stage, we need not address potential remedies." We are interested in public comments on the best way to craft any potential remedies affecting cost years 2018-2022 given that the Court did not resolve that issue.

- *Device Pass-Through Payment Applications:* For CY 2023, we received 8 applications for device pass-through payments. We solicit public comment on these applications and will make final determinations on these applications in the CY 2023 OPPS/ASC final rule. Beginning for OPPS device pass-through applications received on or after January 1, 2023, we propose to publicly post online the completed application forms and related materials that we receive from applicants, excluding certain copyrighted or other materials that applicants indicate cannot otherwise be released to the public.

- *Cancer Hospital Payment Adjustment:* For CY 2023, we propose to continue providing additional payments to cancer hospitals so that a cancer hospital's payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average PCR for the other OPPS hospitals using the most recently submitted or settled cost report data. However, section 16002(b) of the 21st Century Cures Act requires that this weighted average PCR be reduced by 1.0 percentage point. Based on the data and the required 1.0 percentage point reduction, we proposed to use a target PCR of 0.89 to determine the CY 2023 cancer hospital payment adjustment to be paid at cost report settlement. That is, the payment adjustments would be the additional payments needed to result in a PCR equal to 0.89 for each cancer hospital.

- *ASC Payment Update:* For CYs 2019 through 2023, we propose to adopt a policy to update the ASC payment system using the hospital market basket update. Using the hospital market basket methodology, for CY 2023, we propose to increase payment rates under the ASC payment system by 2.7 percent for ASCs that meet the quality reporting requirements under the ASCQR Program. This proposed increase is based on a hospital market basket percentage increase of 3.1 percent reduced by a productivity adjustment of 0.4 percentage point. Based on

this proposed update, we estimate that total payments to ASCs (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix) for CY 2023 would be approximately 5.4 billion, an increase of approximately 130 million compared to estimated CY 2022 Medicare payments.

- *Changes to the List of ASC Covered Surgical Procedures:* For CY 2023, we propose to add one procedure, a lymph node biopsy or excision, to the ASC CPL based upon existing criteria at § 416.166.

- *Hospital Outpatient Quality Reporting (OQR) Program:* For the Hospital OQR Program measure set, we are proposing to: (1) add a data validation targeting criterion to our existing four targeting criteria that reads: “Any hospital with a two-tailed confidence interval that is less than 75 percent, and that had less than four quarters of data due to receiving an ECE for one or more quarters,” beginning with the CY 2023 reporting period/ CY 2025 payment determination; (2) align patient encounter quarters with the calendar year, beginning with the CY 2024 reporting period/ CY 2026 payment determination; and (3) change the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (OP-31) Measure from Mandatory to Voluntary Beginning with the CY 2027 Payment Determination. We are requesting comment on the future readoption of the Hospital Outpatient Volume on Selected Outpatient Surgical Procedures (OP-26) measure or another volume indicator in the Hospital OQR Program.

- *Ambulatory Surgical Center Quality Reporting (ASCQR) Program:* For the ASCQR Program measure set, we are proposing to change the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (ASC-11) Measure from Mandatory to Voluntary Beginning with the CY 2027 Payment Determination. We are also requesting comment on: (1) the potential future implementation of a measures value pathways approach in the ASCQR Program; (2) the status and feasibility of interoperability initiatives in the ASCQR Program; and (3) the potential readoption of the ASC Facility Volume Data on Selected ASC

Surgical Procedures (ASC-7) measure or another volume indicator in the ASCQR Program. We are also proposing to suspend mandatory implementation of the ASC-11 measure.

- *Organ acquisition payment policy*: We are issuing a Request for Information on counting Medicare organs for use in calculating Medicare's share of organ acquisition costs, rather than making a proposal, and will use the information to inform potential future rulemaking. Also, we propose to exclude research organs from the calculation of Medicare's share of organ acquisition costs and require a cost offset; these proposals would help ensure that Medicare does not share in the cost of research, and would lower the cost of procuring and providing research organs to the research community. Finally, we propose to cover as organ acquisition costs certain hospital costs typically incurred when donors die from cardiac death, to promote organ procurement and enhance equity.

- *Rural Emergency Hospitals (REH): Provider Enrollment*: We are outlining provider enrollment requirements for REHs. The most important of these is that REHs must comply with all applicable provider enrollment provisions in 42 CFR Part 424, subpart P in order to enroll in Medicare.

- *Rural Emergency Hospitals (REH) Physician Self-Referral Law Update*: We propose (1) a new exception for ownership or investment interests in an REH; and (2) revisions to certain existing exceptions to make them applicable to compensation arrangements to which an REH is a party.

- *Rural Emergency Hospital Quality Reporting (REHQR) Program*: For the REHQR Program, we are proposing to require a QualityNet account and Security Official (SO) requirement in line with other quality programs for purposes of data submission and access of facility level reports. We are also requesting information on: (1) measures recommended by the National Advisory Committee on Rural Health and Human Services and additional suggested measures for the REHQR Program, and (2) and comments on rural telehealth, behavioral and mental health, and maternal health services.

- *Overall Hospital Quality Star Ratings*: For the Overall Hospital Quality Star Ratings, we are: (1) providing information on the previously finalized policy for inclusion of quality measure data from Veteran’s Health Administration hospitals; (2) proposing to amend § 412.190(c) to state the use of publicly available measure results on Hospital Compare or its successor websites from a quarter within the prior 12 months (instead of the “prior year”); and (3) conveying that although CMS intends to publish Overall Hospital Quality Star Ratings in 2023, we may apply the suppression policy discussed in the CY 2021 OPPTS/ASC proposed rule (85 FR 48996 through 49027) should data analysis demonstrate that the COVID-19 Public Health Emergency (PHE) substantially affects the underlying measure data.

- *REH Payment Policy*: Section 125 of the Consolidated Appropriations Act of 2021 (CAA) established a new provider type called Rural Emergency Hospitals (REHs), effective January 1, 2023.

REHs are facilities that convert from either a critical access hospital (CAH) or a rural hospital (or one treated as such under section 1886(d)(8)(E) of the Social Security Act) with less than 50 beds, and that do not provide acute care inpatient services with the exception of post-hospital extended care services furnished in a unit of the facility that is a distinct part licensed as a skilled nursing facility. By statute, REH services include emergency department services and observation care and, at the election of the REH, other outpatient medical and health services furnished on an outpatient basis, as specified by the Secretary through rulemaking.

By statute, covered outpatient department services provided by REHs will receive an additional 5 percent payment for each service. Beneficiaries will not be charged a copayment on the additional 5 percent payment.

We are proposing to consider all covered outpatient department services, other than inpatient hospital services as described in section 1833(t)(1)(B)(ii), that would otherwise be paid under the OPPTS as REH services. REHs would be paid for furnishing REH services at a rate that is equal to the OPPTS payment rate for the equivalent covered outpatient department service

increased by 5 percent. We are also proposing that REHs may provide outpatient services that are not otherwise paid under the OPPS (such as services paid under the Clinical Lab Fee Schedule) as well as post-hospital extended care services furnished in a unit of the facility that is a distinct part of the facility licensed as a skilled nursing facility; however, these services would not be considered REH services and therefore would be paid under the applicable fee schedule and would not receive the additional 5 percent payment increase that CMS proposes to apply to REH services.

Finally, we are proposing that REHs would also receive a monthly facility payment. After the initial payment is established in CY 2023, the payment amount will increase in subsequent years by the hospital market basket percentage increase.

- *Proposed Addition of a New Service Category for Hospital Outpatient Department Prior Authorization Process:* We propose to add facet joint interventions as a category of services to the prior authorization process for hospital outpatient departments beginning for dates of service on or after March 1, 2023.

- *Mental Health Services Furnished Remotely by Hospital Staff to Beneficiaries in Their Homes:* For CY 2023, CMS is proposing to consider mental health services furnished remotely by hospital staff using communications technology to beneficiaries in their homes as covered outpatient department services payable under the OPPS and would create OPPS-specific coding for these services. We are proposing to require an in-person service within 6 months prior to the initiation of the remote service and then every 12 months thereafter, that exceptions to the in-person visit requirement may be made based on beneficiary circumstances (with the reason documented in the patient's medical record), and that more frequent visits are also allowed under our policy, as driven by clinical needs on a case-by-case basis. We are also proposing that audio-only interactive telecommunications systems may be used to furnish these services in instances where the beneficiary is not capable of, or does not consent to, the use of two-way, audio/video technology.

- *Supervision by Nonphysician Practitioners of Hospital and CAH Diagnostic Services*

Furnished to Outpatients: For CY 2023, to improve clarity, we propose to replace cross-references at § 410.27(a)(1)(iv)(A) and (B) and § 410.28(e) to the definitions of general and personal supervision at § 410.32(b)(3)(i) and (iii) with the text of those definitions. We also propose to revise § 410.28(e) to clarify that certain nonphysician practitioners (nurse practitioners, physician assistants, clinical nurse specialists and certified nurse midwives) may supervise the performance of diagnostic tests to the extent they are authorized to do so under their scope of practice and applicable State law.

- *Exemption of Rural Sole Community Hospitals (SCH) from the Method to Control*

Unnecessary Increases in the Volume of Clinic Visit Services Furnished in Excepted Off-Campus Provider-Based Departments (PBDs): We are proposing to exempt rural Sole Community Hospitals (rural SCHs) from the site-specific Medicare Physician Fee Schedule (PFS)-equivalent payment for the clinic visit service, as described by HCPCS code G0463, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act (departments that bill the modifier “PO” on claim lines).

- *Proposed Payment Adjustments under the IPPS and OPFS for Domestic NIOSH-*

Approved Surgical N95 Respirators: As discussed in section X.H of the preamble of this proposed rule, the Biden-Harris Administration has made it a priority to ensure America is prepared to continue to respond to COVID-19, and to combat future pandemics. To improve hospital preparedness and readiness for future threats, we are proposing to provide payment adjustments to hospitals under the IPPS and OPFS for the additional resource costs they incur to acquire domestic NIOSH-approved surgical N95 respirators. These surgical respirators, which faced severe shortage at the onset of the COVID-19 pandemic, are essential for the protection of beneficiaries and hospital personnel that interface with patients. The Department of Health and Human Services (HHS) recognizes that procurement of domestic NIOSH-approved surgical N95 respirators, while critical to pandemic preparedness and protecting health care workers and

patients, can result in additional resource costs for hospitals. The proposed payment adjustments would account for these additional resource costs.

We believe the proposed payment adjustments would help achieve a strategic policy goal, namely, sustaining a level of supply resilience for surgical N95 respirators that is critical to protect the health and safety of personnel and patients in a public health emergency. We are proposing that the payment adjustments would commence for cost reporting periods beginning on or after January 1, 2023.

3. Summary of Costs and Benefits

In section XXIII of this proposed rule, we set forth a detailed analysis of the regulatory and federalism impacts that the changes would have on affected entities and beneficiaries. Key estimated impacts are described below.

a. Impacts of All OPPS Changes

Table 84 in section XXIII.C of this proposed rule displays the distributional impact of all the OPPS changes on various groups of hospitals and CMHCs for CY 2023 compared to all estimated OPPS payments in CY 2022. We estimate that the policies in this proposed rule would result in a 2.9 percent overall increase in OPPS payments to providers. We estimate that total OPPS payments for CY 2023, including beneficiary cost-sharing, to the approximately 3,502 facilities paid under the OPPS (including general acute care hospitals, children's hospitals, cancer hospitals, and CMHCs) will increase by approximately \$1.8 billion compared to CY 2022 payments, excluding our estimated changes in enrollment, utilization, and case-mix.

We estimated the isolated impact of our OPPS policies on CMHCs because CMHCs are only paid for partial hospitalization services under the OPPS. Continuing the provider-specific structure we adopted beginning in CY 2011, and basing payment fully on the type of provider furnishing the service, we estimate an 8.4 percent decrease in CY 2023 payments to CMHCs relative to their CY 2022 payments.

b. Impacts of the Updated Wage Indexes

We estimate that our update of the wage indexes based on the FY 2023 IPPS proposed rule wage indexes would result in no change for urban hospitals under the OPPIs and no change for rural hospitals. These wage indexes include the continued implementation of the OMB labor market area delineations based on 2010 Decennial Census data, with updates, as discussed in section II.C of this proposed rule.

c. Impacts of the Rural Adjustment and the Cancer Hospital Payment Adjustment

There are no significant impacts of our CY 2023 payment policies for hospitals that are eligible for the rural adjustment or for the cancer hospital payment adjustment. We are not making any change in policies for determining the rural hospital payment adjustments. While we are implementing the reduction to the cancer hospital payment adjustment for CY 2023 required by section 1833(t)(18)(C) of the Act, as added by section 16002(b) of the 21st Century Cures Act, the target payment-to-cost ratio (PCR) for CY 2023 is 0.89, equivalent to the 0.89 target PCR for CY 2022, and therefore has no budget neutrality adjustment.

d. Impacts of the OPD Fee Schedule Increase Factor

For the CY 2023 OPPIs/ASC, we are establishing an OPD fee schedule increase factor of 2.7 percent and applying that increase factor to the conversion factor for CY 2023. We note that the following estimated changes are based on the formal proposal discussed in V.B of this proposed rule. However, we are making available online alternative impact tables and other supporting data associated with the alternative policy for 340B-acquired drugs.

As a result of the OPD fee schedule increase factor and other budget neutrality adjustments, we estimate that urban hospitals would experience an increase in payments of approximately 3.0 percent and that rural hospitals would experience an increase in payments of 2.6 percent. Classifying hospitals by teaching status, we estimate nonteaching hospitals will experience an increase in payments of 3.2 percent, minor teaching hospitals would experience an increase in payments of 3.0 percent, and major teaching hospitals would experience an increase

in payments of 2.6 percent. We also classified hospitals by the type of ownership. We estimate that hospitals with voluntary ownership would experience an increase of 2.8 percent in payments, while hospitals with government ownership would experience an increase of 2.8 percent in payments. We estimate that hospitals with proprietary ownership would experience an increase of 3.5 percent in payments.

e. Impacts of the Proposed ASC Payment Update

For impact purposes, the surgical procedures on the ASC covered surgical procedure list are aggregated into surgical specialty groups using CPT and HCPCS code range definitions. The percentage change in estimated total payments by specialty groups under the CY 2023 payment rates, compared to estimated CY 2022 payment rates, generally ranges between an increase of 1 and 6 percent, depending on the service, with some exceptions. We estimate the impact of applying the hospital market basket update to ASC payment rates would increase payments by \$130 million under the ASC payment system in CY 2023.

B. Legislative and Regulatory Authority for the Hospital OPPS

When Title XVIII of the Act was enacted, Medicare payment for hospital outpatient services was based on hospital-specific costs. In an effort to ensure that Medicare and its beneficiaries pay appropriately for services and to encourage more efficient delivery of care, the Congress mandated replacement of the reasonable cost-based payment methodology with a prospective payment system (PPS). The Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33) added section 1833(t) to the Act, authorizing implementation of a PPS for hospital outpatient services. The OPPS was first implemented for services furnished on or after August 1, 2000. Implementing regulations for the OPPS are located at 42 CFR parts 410 and 419.

The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106-113) made major changes in the hospital OPPS. The following Acts made

additional changes to the OPPI: the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106-554); the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173); the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109-171), enacted on February 8, 2006; the Medicare Improvements and Extension Act under Division B of Title I of the Tax Relief and Health Care Act of 2006 (MIEA-TRHCA) (Pub. L. 109-432), enacted on December 20, 2006; the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) (Pub. L. 110-173), enacted on December 29, 2007; the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110-275), enacted on July 15, 2008; the Patient Protection and Affordable Care Act (Pub. L. 111-148), enacted on March 23, 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152), enacted on March 30, 2010 (these two public laws are collectively known as the Affordable Care Act); the Medicare and Medicaid Extenders Act of 2010 (MMEA, Pub. L. 111-309); the Temporary Payroll Tax Cut Continuation Act of 2011 (TPTCCA, Pub. L. 112-78), enacted on December 23, 2011; the Middle Class Tax Relief and Job Creation Act of 2012 (MCTRJCA, Pub. L. 112-96), enacted on February 22, 2012; the American Taxpayer Relief Act of 2012 (Pub. L. 112-240), enacted January 2, 2013; the Pathway for SGR Reform Act of 2013 (Pub. L. 113-67) enacted on December 26, 2013; the Protecting Access to Medicare Act of 2014 (PAMA, Pub. L. 113-93), enacted on March 27, 2014; the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 (Pub. L. 114-10), enacted April 16, 2015; the Bipartisan Budget Act of 2015 (Pub. L. 114-74), enacted November 2, 2015; the Consolidated Appropriations Act, 2016 (Pub. L. 114-113), enacted on December 18, 2015, the 21st Century Cures Act (Pub. L. 114-255), enacted on December 13, 2016; the Consolidated Appropriations Act, 2018 (Pub. L. 115-141), enacted on March 23, 2018; the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (Pub. L. 115-271), enacted on October 24, 2018; the Further Consolidated Appropriations Act, 2020 (Pub. L. 116-94), enacted on December 20, 2019; the Coronavirus

Aid, Relief, and Economic Security Act (Pub. L. 116-136), enacted on March 27, 2020; and the Consolidated Appropriations Act, 2021 (Pub. L. 116-260), enacted on December 27, 2020.

Under the OPSS, we generally pay for hospital Part B services on a rate-per-service basis that varies according to the APC group to which the service is assigned. We use the Healthcare Common Procedure Coding System (HCPCS) (which includes certain Current Procedural Terminology (CPT) codes) to identify and group the services within each APC. The OPSS includes payment for most hospital outpatient services, except those identified in section I.C of this proposed rule. Section 1833(t)(1)(B) of the Act provides for payment under the OPSS for hospital outpatient services designated by the Secretary (which includes partial hospitalization services furnished by CMHCs), and certain inpatient hospital services that are paid under Medicare Part B.

The OPSS rate is an unadjusted national payment amount that includes the Medicare payment and the beneficiary copayment. This rate is divided into a labor-related amount and a nonlabor-related amount. The labor-related amount is adjusted for area wage differences using the hospital inpatient wage index value for the locality in which the hospital or CMHC is located.

All services and items within an APC group are comparable clinically and with respect to resource use, as required by section 1833(t)(2)(B) of the Act. In accordance with section 1833(t)(2)(B) of the Act, subject to certain exceptions, items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest median cost (or mean cost, if elected by the Secretary) for an item or service in the APC group is more than 2 times greater than the lowest median cost (or mean cost, if elected by the Secretary) for an item or service within the same APC group (referred to as the “2 times rule”). In implementing this provision, we generally use the cost of the item or service assigned to an APC group.

For new technology items and services, special payments under the OPSS may be made in one of two ways. Section 1833(t)(6) of the Act provides for temporary additional payments, which we refer to as “transitional pass-through payments,” for at least 2 but not more than

3 years for certain drugs, biological agents, brachytherapy devices used for the treatment of cancer, and categories of other medical devices. For new technology services that are not eligible for transitional pass-through payments, and for which we lack sufficient clinical information and cost data to appropriately assign them to a clinical APC group, we have established special APC groups based on costs, which we refer to as New Technology APCs. These New Technology APCs are designated by cost bands which allow us to provide appropriate and consistent payment for designated new procedures that are not yet reflected in our claims data. Similar to pass-through payments, an assignment to a New Technology APC is temporary; that is, we retain a service within a New Technology APC until we acquire sufficient data to assign it to a clinically appropriate APC group.

C. Excluded OPPS Services and Hospitals

Section 1833(t)(1)(B)(i) of the Act authorizes the Secretary to designate the hospital outpatient services that are paid under the OPPS. While most hospital outpatient services are payable under the OPPS, section 1833(t)(1)(B)(iv) of the Act excludes payment for ambulance, physical and occupational therapy, and speech-language pathology services, for which payment is made under a fee schedule. It also excludes screening mammography, diagnostic mammography, and effective January 1, 2011, an annual wellness visit providing personalized prevention plan services. The Secretary exercises the authority granted under the statute to also exclude from the OPPS certain services that are paid under fee schedules or other payment systems. Such excluded services include, for example, the professional services of physicians and nonphysician practitioners paid under the Medicare Physician Fee Schedule (MPFS); certain laboratory services paid under the Clinical Laboratory Fee Schedule (CLFS); services for beneficiaries with end-stage renal disease (ESRD) that are paid under the ESRD prospective payment system; and services and procedures that require an inpatient stay that are paid under the hospital IPPS. In addition, section 1833(t)(1)(B)(v) of the Act does not include applicable items and services (as defined in subparagraph (A) of paragraph (21)) that are furnished on or

after January 1, 2017 by an off-campus outpatient department of a provider (as defined in subparagraph (B) of paragraph (21)). We set forth the services that are excluded from payment under the OPSS in regulations at 42 CFR 419.22.

Under § 419.20(b) of the regulations, we specify the types of hospitals that are excluded from payment under the OPSS. These excluded hospitals are:

- Critical access hospitals (CAHs);
 - Hospitals located in Maryland and paid under Maryland's All-Payer or Total Cost of Care Model;
 - Hospitals located outside of the 50 States, the District of Columbia, and Puerto Rico;
- and
- Indian Health Service (IHS) hospitals.

D. Prior Rulemaking

On April 7, 2000, we published in the **Federal Register** a final rule with comment period (65 FR 18434) to implement a prospective payment system for hospital outpatient services. The hospital OPSS was first implemented for services furnished on or after August 1, 2000. Section 1833(t)(9)(A) of the Act requires the Secretary to review certain components of the OPSS, not less often than annually, and to revise the groups, the relative payment weights, and the wage and other adjustments to take into account changes in medical practices, changes in technology, the addition of new services, new cost data, and other relevant information and factors.

Since initially implementing the OPSS, we have published final rules in the **Federal Register** annually to implement statutory requirements and changes arising from our continuing experience with this system. These rules can be viewed on the CMS website at:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html>.

E. Advisory Panel on Hospital Outpatient Payment (the HOP Panel or the Panel)

1. Authority of the Panel

Section 1833(t)(9)(A) of the Act, as amended by section 201(h) of Pub. L. 106-113, and redesignated by section 202(a)(2) of Pub. L. 106-113, requires that we consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to annually review (and advise the Secretary concerning) the clinical integrity of the payment groups and their weights under the OPPTS. In CY 2000, based on section 1833(t)(9)(A) of the Act, the Secretary established the Advisory Panel on Ambulatory Payment Classification Groups (APC Panel) to fulfill this requirement. In CY 2011, based on section 222 of the Public Health Service Act (the PHS Act), which gives discretionary authority to the Secretary to convene advisory councils and committees, the Secretary expanded the panel's scope to include the supervision of hospital outpatient therapeutic services in addition to the APC groups and weights. To reflect this new role of the panel, the Secretary changed the panel's name to the Advisory Panel on Hospital Outpatient Payment (the HOP Panel or the Panel). The HOP Panel is not restricted to using data compiled by CMS, and in conducting its review, it may use data collected or developed by organizations outside the Department.

2. Establishment of the Panel

On November 21, 2000, the Secretary signed the initial charter establishing the Panel, and, at that time, named the APC Panel. This expert panel is composed of appropriate representatives of providers (currently employed full-time, not as consultants, in their respective areas of expertise) who review clinical data and advise CMS about the clinical integrity of the APC groups and their payment weights. Since CY 2012, the Panel also is charged with advising the Secretary on the appropriate level of supervision for individual hospital outpatient therapeutic services. The Panel is technical in nature, and it is governed by the provisions of the Federal Advisory Committee Act (FACA). The current charter specifies, among other requirements, that the Panel--

- May advise on the clinical integrity of Ambulatory Payment Classification (APC) groups and their associated weights;
- May advise on the appropriate supervision level for hospital outpatient services;
- May advise on OPPS APC rates for ASC covered surgical procedures;
- Continues to be technical in nature;
- Is governed by the provisions of the FACA;
- Has a Designated Federal Official (DFO); and
- Is chaired by a Federal Official designated by the Secretary.

The Panel's charter was amended on November 15, 2011, renaming the Panel and expanding the Panel's authority to include supervision of hospital outpatient therapeutic services and to add critical access hospital (CAH) representation to its membership. The Panel's charter was also amended on November 6, 2014 (80 FR 23009), and the number of members was revised from up to 19 to up to 15 members. The Panel's current charter was approved on November 20, 2020, for a 2-year period.

The current Panel membership and other information pertaining to the Panel, including its charter, **Federal Register** notices, membership, meeting dates, agenda topics, and meeting reports, can be viewed on the CMS website at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html>.

3. Panel Meetings and Organizational Structure

The Panel has held many meetings, with the last meeting taking place on August 22, 2021. Prior to each meeting, we publish a notice in the **Federal Register** to announce the meeting, new members, and any other changes of which the public should be aware. Beginning in CY 2017, we have transitioned to one meeting per year (81 FR 31941). In CY 2018, we published a **Federal Register** notice requesting nominations to fill vacancies on

the Panel (83 FR 3715). As published in this notice, CMS is accepting nominations on a continuous basis.

In addition, the Panel has established an administrative structure that, in part, currently includes the use of three subcommittee workgroups to provide preparatory meeting and subject support to the larger panel. The three current subcommittees include the following:

- APC Groups and Status Indicator Assignments Subcommittee, which advises and provides recommendations to the Panel on the appropriate status indicators to be assigned to HCPCS codes, including but not limited to whether a HCPCS code or a category of codes should be packaged or separately paid, as well as the appropriate APC assignment of HCPCS codes regarding services for which separate payment is made;
- Data Subcommittee, which is responsible for studying the data issues confronting the Panel and for recommending options for resolving them; and
- Visits and Observation Subcommittee, which reviews and makes recommendations to the Panel on all technical issues pertaining to observation services and hospital outpatient visits paid under the OPPS.

Each of these workgroup subcommittees was established by a majority vote from the full Panel during a scheduled Panel meeting, and the Panel recommended at the August 23, 2021, meeting that the subcommittees continue. We accepted this recommendation.

For discussions of earlier Panel meetings and recommendations, we refer readers to previously published OPPS/ASC proposed and final rules, the CMS website mentioned earlier in this section, and the FACA database at <http://facadatabase.gov>.

F. Public Comments Received on the CY 2022 OPPS/ASC Final Rule with Comment Period

We received approximately 13 timely pieces of correspondence on the CY 2022 OPPS/ASC final rule with comment period that appeared in the **Federal Register** on November 16, 2021 (86 FR 63458)

II. Proposed Updates Affecting OPPS Payments

A. Proposed Recalibration of APC Relative Payment Weights

1. Database Construction

a. Use of CY 2021 Data in the CY 2023 OPPS Ratesetting

We primarily use two data sources in OPPS ratesetting: claims data and cost report data. Our goal is always to use the best available data overall for ratesetting. Ordinarily, the best available full year of claims data would be the data from the year 2 years prior to the calendar year that is the subject of the rulemaking. As discussed in further detail in section X.C of this proposed rule, unlike CY 2020 claims data, we do not believe there are overwhelming concerns with CY 2021 claims data as a result of the COVID-19 PHE. Therefore, as discussed in further detail in section X.C of this proposed rule, we propose to use CY 2021 claims data and the data components related to it in establishing the CY 2023 OPPS.

b. Database Source and Methodology

Section 1833(t)(9)(A) of the Act requires that the Secretary review not less often than annually and revise the relative payment weights for APCs. In the April 7, 2000 OPPS final rule with comment period (65 FR 18482), we explained in detail how we calculated the relative payment weights that were implemented on August 1, 2000 for each APC group.

For the CY 2023 OPPS, we propose to recalibrate the APC relative payment weights for services furnished on or after January 1, 2023, and before January 1, 2024 (CY 2023), using the same basic methodology that we described in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63466), using CY 2021 claims data. That is, we propose to recalibrate the relative payment weights for each APC based on claims and cost report data for hospital outpatient department (HOPD) services to construct a database for calculating APC group weights.

For the purpose of recalibrating the proposed APC relative payment weights for CY 2023, we began with approximately 180 million final action claims (claims for which all disputes and adjustments have been resolved and payment has been made) for HOPD services furnished on or after January 1, 2021, and before January 1, 2022, before applying our

exclusionary criteria and other methodological adjustments. After the application of those data processing changes, we used approximately 93 million final action claims to develop the proposed CY 2023 OPPS payment weights. For exact numbers of claims used and additional details on the claims accounting process, we refer readers to the claims accounting narrative under supporting documentation for the CY 2023 OPPS/ASC proposed rule on the CMS website at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>.

Addendum N to the CY 2023 OPPS/ASC proposed rule (which is available via the Internet on the CMS website at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html>) includes the proposed list of bypass codes for CY 2023. The proposed list of bypass codes contains codes that are reported on claims for services in CY 2021 and, therefore, includes codes that were in effect in CY 2021 and used for billing. We propose to retain deleted bypass codes on the proposed CY 2023 bypass list because these codes existed in CY 2021 and were covered OPD services in that period, and CY 2021 claims data were used to calculate proposed CY 2023 payment rates. Keeping these deleted bypass codes on the bypass list potentially allows us to create more “pseudo” single procedure claims for ratesetting purposes. “Overlap bypass codes” that are members of the proposed multiple imaging composite APCs are identified by asterisks (*) in the third column of Addendum N to this proposed rule. HCPCS codes that we propose to add for CY 2023 are identified by asterisks (*) in the fourth column of Addendum N.

c. Calculation and Use of Cost-to-Charge Ratios (CCRs)

For CY 2023, we propose to continue to use the hospital-specific overall ancillary and departmental cost-to-charge ratios (CCRs) to convert charges to estimated costs through application of a revenue code-to-cost center crosswalk. However, roughly half of the cost reports we would typically use for CY 2023 ratesetting purposes are from cost reporting periods that overlap with parts of CY 2020. When utilizing this cost report data, more than half of the APC

geometric mean costs increased by more than 10 percent relative to estimates based on prior ratesetting cycles. While some of this increase may be attributable to changes that will continue into CY 2023, other aspects of those changes may be more specific to the COVID-19 PHE. In the CY 2022 OPSS/ASC final rule with comment period (86 FR 63751 through 63754), we described how CY 2020 claims data were too influenced by the COVID-19 PHE to be utilized for setting CY 2022 OPSS payment rates. After reviewing the cost report data from the December 2021 HCRIS data set, we believe cost report data that overlap with CY 2020 are also too influenced by the COVID-19 PHE for purposes of calculating the CY 2023 OPSS payment rates. Therefore, in order to mitigate the impact on our ratesetting process from the COVID-19 PHE effects in the CY 2020 cost report data we would typically use for this CY 2023 OPSS/ASC proposed rule, we propose to use cost report data from the June 2020 HCRIS data set, which only includes cost report data through CY 2019 for CY 2023 OPSS/ASC proposed rule and final rule ratesetting purposes. For additional discussion of the data we propose to use in CY 2023 OPSS ratesetting, please see section X.C of this proposed rule.

To calculate the APC costs on which the CY 2023 APC payment rates are based, we propose to calculate hospital-specific overall ancillary CCRs and hospital-specific departmental CCRs for each hospital for which we had CY 2021 claims data by comparing these claims data to hospital cost reports available for the CY 2022 OPSS/ASC final rule with comment period ratesetting, which, in most cases, are from CY 2019. For the proposed CY 2023 OPSS payment rates, we propose to use CY 2021 claims processed through December 31, 2021. We applied the hospital-specific CCR to the hospital's charges at the most detailed level possible, based on a revenue code-to-cost center crosswalk that contains a hierarchy of CCRs used to estimate costs from charges for each revenue code. To ensure the completeness of the revenue code-to-cost center crosswalk, we reviewed changes to the list of revenue codes for CY 2021 (the year of claims data we used to calculate the proposed CY 2023 OPSS payment rates) and updates to the National Uniform Billing Committee (NUBC) 2020 Data Specifications Manual. That crosswalk

is available for review and continuous comment on the CMS website at:

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>.

In accordance with our longstanding policy, we propose to calculate CCRs for the standard and nonstandard cost centers accepted by the electronic cost report database. In general, the most detailed level at which we calculate CCRs is the hospital-specific departmental level. Additionally, we have historically not included cost report lines for certain nonstandard cost centers in the OPSS ratesetting database construction when hospitals have reported these nonstandard cost centers on cost report lines that do not correspond to the cost center number. We have determined that hospitals are routinely reporting a number of nonstandard cost centers in this way and that including this additional data could significantly reduce certain APC geometric mean costs. In particular, we estimate that the additional cost data from nonstandard cost centers would decrease the geometric mean cost of APC 8004 (Ultrasound Composite) by 20 percent, APC 5863 (Partial Hospitalizations (3 or more services) for hospital-based PHPs) by 12 percent and APC 5573 (Level 3 Imaging with Contrast) by 11 percent. In other instances, we note that there are also potential increases in the geometric mean costs of certain APCs, such as APC 5741 (Level 1 Electronic Analysis of Devices), which would increase by 4 percent, APC 5723 (Level 3 Diagnostic Tests and Related Services), which would increase by 2.6 percent, and APC 5694 (Level 4 Drug Administration), which would increase by 2.3 percent.

While we generally view the use of additional cost data as improving our OPSS ratesetting process, we have historically not included cost report lines for certain nonstandard cost centers in the OPSS ratesetting database construction when hospitals have reported these nonstandard cost centers on cost report lines that do not correspond to the cost center number. Additionally, we are concerned about the significant changes in APC geometric mean costs that our analysis indicates would occur if we were to include such lines. We believe it is important to further investigate the accuracy of these cost report data before including such data in the

ratesetting process. Further, we believe it is appropriate to gather additional information from the public as well before including them in OPSS ratesetting. For CY 2023, we propose not to include the nonstandard cost centers reported in this way in the OPSS ratesetting database construction. We are soliciting comment on whether there exist any specific concerns with regards to the accuracy of the data from these nonstandard cost center lines that we would need to consider before including them in future OPSS ratesetting.

For a discussion of the hospital-specific overall ancillary CCR calculation, we refer readers to the CY 2007 OPSS/ASC final rule with comment period (71 FR 67983 through 67985). The calculation of blood costs is a longstanding exception (since the CY 2005 OPSS) to this general methodology for calculation of CCRs used for converting charges to costs on each claim. This exception is discussed in detail in the CY 2007 OPSS/ASC final rule with comment period and discussed further in section II.A.2.a.(1) of this proposed rule.

2. Proposed Data Development and Calculation of Costs Used for Ratesetting

In this section of this proposed rule, we discuss the use of claims to calculate the OPSS payment rates for CY 2023. The Hospital OPSS page on the CMS website on which the CY 2023 OPSS/ASC proposed rule is posted (<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>) provides an accounting of claims used in the development of the proposed payment rates. That accounting provides additional detail regarding the number of claims derived at each stage of the process. In addition, later in this section we discuss the file of claims that comprises the data set that is available upon payment of an administrative fee under a CMS data use agreement. The CMS website, <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>, includes information about obtaining the “OPSS Limited Data Set,” which now includes the additional variables previously available only in the OPSS Identifiable Data Set, including ICD-10-CM diagnosis codes and revenue code payment

amounts. This file is derived from the CY 2021 claims that are used to calculate the proposed payment rates for this CY 2023 proposed rule.

Previously, the OPSS established the scaled relative weights on which payments are based using APC median costs, a process described in the CY 2012 OPSS/ASC final rule with comment period (76 FR 74188). However, as discussed in more detail in section II.A.2.f of the CY 2013 OPSS/ASC final rule with comment period (77 FR 68259 through 68271), we finalized the use of geometric mean costs to calculate the relative weights on which the CY 2013 OPSS payment rates were based. While this policy changed the cost metric on which the relative payments are based, the data process in general remained the same under the methodologies that we used to obtain appropriate claims data and accurate cost information in determining estimated service cost.

We used the methodology described in sections II.A.2.a through II.A.2.c of this proposed rule to calculate the costs we used to establish the proposed relative payment weights used in calculating the OPSS payment rates for CY 2023 shown in Addenda A and B to this proposed rule (which are available via the Internet on the CMS website at:

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html>). We refer readers to section II.A.4 of this proposed rule for a discussion of the conversion of APC costs to scaled payment weights.

We note that under the OPSS, CY 2019 was the first year in which the claims data used for setting payment rates (CY 2017 data) contained lines with the modifier “PN”, which indicates nonexcepted items and services furnished and billed by off-campus provider-based departments (PBDs) of hospitals. Because nonexcepted items and services are not paid under the OPSS, in the CY 2019 OPSS/ASC final rule with comment period (83 FR 58832), we finalized a policy to remove those claim lines reported with modifier “PN” from the claims data used in

ratesetting for the CY 2019 OPPS and subsequent years. For the CY 2023 OPPS, we would continue to remove claim lines with modifier “PN” from the ratesetting process.

For details of the claims accounting process used in the CY 2023 OPPS/ASC proposed rule, we refer readers to the claims accounting narrative under supporting documentation for the CY 2023 OPPS/ASC proposed rule on the CMS website at:

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>.

a. Calculation of Single Procedure APC Criteria-Based Costs

(1) Blood and Blood Products

Since the implementation of the OPPS in August 2000, we have made separate payments for blood and blood products through APCs rather than packaging payment for them into payments for the procedures with which they are administered. Hospital payments for the costs of blood and blood products, as well as for the costs of collecting, processing, and storing blood and blood products, are made through the OPPS payments for specific blood product APCs.

We propose to continue to establish payment rates for blood and blood products using our blood-specific CCR methodology, which utilizes actual or simulated CCRs from the most recently available hospital cost reports to convert hospital charges for blood and blood products to costs. This methodology has been our standard ratesetting methodology for blood and blood products since CY 2005. It was developed in response to data analysis indicating that there was a significant difference in CCRs for those hospitals with and without blood-specific cost centers, and past public comments indicating that the former OPPS policy of defaulting to the overall hospital CCR for hospitals not reporting a blood-specific cost center often resulted in an underestimation of the true hospital costs for blood and blood products. Specifically, to address the differences in CCRs and to better reflect hospitals’ costs, we propose to continue to simulate blood CCRs for each hospital that does not report a blood cost center by calculating the ratio of the blood-specific CCRs to hospitals’ overall CCRs for those hospitals that do report costs and

charges for blood cost centers. We also propose to apply this mean ratio to the overall CCRs of hospitals not reporting costs and charges for blood cost centers on their cost reports to simulate blood-specific CCRs for those hospitals. We propose to calculate the costs upon which the proposed CY 2023 payment rates for blood and blood products are based using the actual blood-specific CCR for hospitals that reported costs and charges for a blood cost center and a hospital-specific, simulated, blood-specific CCR for hospitals that did not report costs and charges for a blood cost center.

We continue to believe that the hospital-specific, simulated, blood-specific, CCR methodology better responds to the absence of a blood-specific CCR for a hospital than alternative methodologies, such as defaulting to the overall hospital CCR or applying an average blood-specific CCR across hospitals. Because this methodology takes into account the unique charging and cost accounting structure of each hospital, we believe that it yields more accurate estimated costs for these products. We continue to believe that using this methodology in CY 2023 would result in costs for blood and blood products that appropriately reflect the relative estimated costs of these products for hospitals without blood cost centers and, therefore, for these blood products in general.

We note that we defined a comprehensive APC (C-APC) as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. Under this policy, we include the costs of blood and blood products when calculating the overall costs of these C-APCs. We propose to continue to apply the blood-specific CCR methodology described in this section when calculating the costs of the blood and blood products that appear on claims with services assigned to the C-APCs. Because the costs of blood and blood products would be reflected in the overall costs of the C-APCs (and, as a result, in the proposed payment rates of the C-APCs), we propose not to make separate payments for blood and blood products when they appear on the same claims as services assigned to the C-APCs (we refer readers to the CY 2015 OPPI/ASC final rule with comment

period (79 FR 66795 through 66796) for more information about our policy not to make separate payments for blood and blood products when they appear on the same claims as services assigned to a C-APC).

We refer readers to Addendum B to this proposed rule (which is available via the Internet on the CMS website) for the proposed CY 2023 payment rates for blood and blood products (which are generally identified with status indicator “R”). For a more detailed discussion of the blood-specific CCR methodology, we refer readers to the CY 2005 OPSS proposed rule (69 FR 50524 through 50525). For a full history of OPSS payment for blood and blood products, we refer readers to the CY 2008 OPSS/ASC final rule with comment period (72 FR 66807 through 66810).

For CY 2023, we propose to continue to establish payment rates for blood and blood products using our blood-specific CCR methodology.

(2) Brachytherapy Sources

Section 1833(t)(2)(H) of the Act mandates the creation of additional groups of covered OPD services that classify devices of brachytherapy consisting of a seed or seeds (or radioactive source) (“brachytherapy sources”) separately from other services or groups of services. The statute provides certain criteria for the additional groups. For the history of OPSS payment for brachytherapy sources, we refer readers to prior OPSS final rules, such as the CY 2012 OPSS/ASC final rule with comment period (77 FR 68240 through 68241). As we have stated in prior OPSS updates, we believe that adopting the general OPSS prospective payment methodology for brachytherapy sources is appropriate for a number of reasons (77 FR 68240). The general OPSS methodology uses costs based on claims data to set the relative payment weights for hospital outpatient services. This payment methodology results in more consistent, predictable, and equitable payment amounts per source across hospitals by averaging the extremely high and low values, in contrast to payment based on hospitals’ charges adjusted to costs. We believe that the OPSS methodology, as opposed to payment based on hospitals’

charges adjusted to cost, also would provide hospitals with incentives for efficiency in the provision of brachytherapy services to Medicare beneficiaries. Moreover, this approach is consistent with our payment methodology for the vast majority of items and services paid under the OPPS. We refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70323 through 70325) for further discussion of the history of OPPS payment for brachytherapy sources.

For CY 2023, except where otherwise indicated, we propose to use the costs derived from CY 2021 claims data to set the proposed CY 2023 payment rates for brachytherapy sources because CY 2021 is the year of data we propose to use to set the proposed payment rates for most other items and services that would be paid under the CY 2023 OPPS. With the exception of the proposed payment rate for brachytherapy source C2645 (Brachytherapy planar source, palladium-103, per square millimeter) and the proposed payment rates for low-volume brachytherapy APCs discussed in section III.D of this proposed rule, we propose to base the payment rates for brachytherapy sources on the geometric mean unit costs for each source, consistent with the methodology that we propose for other items and services paid under the OPPS, as discussed in section II.A.2. of this proposed rule. We also propose to continue the other payment policies for brachytherapy sources that we finalized and first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537). We propose to pay for the stranded and nonstranded not otherwise specified (NOS) codes, HCPCS codes C2698 (Brachytherapy source, stranded, not otherwise specified, per source) and C2699 (Brachytherapy source, non-stranded, not otherwise specified, per source), at a rate equal to the lowest stranded or nonstranded prospective payment rate for such sources, respectively, on a per-source basis (as opposed to, for example, a per mCi), which is based on the policy we established in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66785). We also propose to continue the policy we first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537) regarding payment for new brachytherapy sources for which we have no claims

data, based on the same reasons we discussed in the CY 2008 OPPTS/ASC final rule with comment period (72 FR 66786; which was delayed until January 1, 2010, by section 142 of Pub. L. 110-275). Specifically, this policy is intended to enable us to assign new HCPCS codes for new brachytherapy sources to their own APCs, with prospective payment rates set based on our consideration of external data and other relevant information regarding the expected costs of the sources to hospitals. The proposed CY 2023 payment rates for brachytherapy sources are included on Addendum B to this proposed rule (which is available via the Internet on the CMS website) and identified with status indicator “U”.

For CY 2018, we assigned status indicator “U” (Brachytherapy Sources, Paid under OPPTS; separate APC payment) to HCPCS code C2645 (Brachytherapy planar source, palladium-103, per square millimeter) in the absence of claims data and established a payment rate using external data (invoice price) at \$4.69 per mm². For CY 2019, in the absence of sufficient claims data, we continued to establish a payment rate for C2645 at \$4.69 per mm². Our CY 2018 claims data available for the CY 2020 OPPTS/ASC final rule with comment period included two claims with a geometric mean cost for HCPCS code C2645 of \$1.02 per mm². In response to comments from stakeholders, we agreed that given the limited claims data available and a new outpatient indication for C2645, a payment rate for HCPCS code C2645 based on the geometric mean cost of \$1.02 per mm² may not adequately reflect the cost of HCPCS code C2645. In the CY 2020 OPPTS/ASC final rule with comment period, we finalized our policy to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act, which states that the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments, to maintain the CY 2019 payment rate of \$4.69 per mm² for HCPCS code C2645 for CY 2020. Similarly, in the absence of sufficient claims data to establish an APC payment rate, in the CY 2021 and CY 2022 OPPTS/ASC final rules (85 FR 85879 through 85880 and 86 FR 63469) with comment period, we finalized our policy to use our equitable adjustment

authority under section 1833(t)(2)(E) of the Act to maintain the CY 2019 payment rate of \$4.69 per mm² for HCPCS code C2645 for CY 2021 and for CY 2022.

We did not receive any CY 2021 claims data for HCPCS code C2645. Therefore, we propose to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to maintain the CY 2019 payment rate of \$4.69 per mm² for HCPCS code C2645 for CY 2023.

Additionally, for CY 2022 and subsequent calendar years, we adopted a Universal Low Volume APC policy for clinical and brachytherapy APCs, discussed in further detail in section III.D of this proposed rule. For these Low Volume APCs, which have fewer than 100 CY 2021 single claims used for ratesetting purposes in this CY 2023 OPPI/ASC proposed rule, we use up to 4 years of claims data to establish a payment rate for each item or service as we historically have done for low volume services assigned to New Technology APCs. Further, we calculate the cost for Low Volume APCs based on the greatest of the arithmetic mean cost, median cost, or geometric mean cost using all claims for the APC for up to 4 years. For CY 2023, we propose to designate 4 brachytherapy APCs as Low Volume APCs for CY 2023 as these APCs meet our criteria to be designated as a Low Volume APC. For more information on the brachytherapy APCs we are designating as Low Volume APCs, see section III.D of this proposed rule.

We invite stakeholders to submit recommendations for new codes to describe new brachytherapy sources. Such recommendations should be directed via email to outpatientpps@cms.hhs.gov or by mail to the Division of Outpatient Care, Mail Stop C4 – 01 – 26, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244. We will continue to add new brachytherapy source codes and descriptors to our systems for payment on a quarterly basis.

b. Comprehensive APCs (C-APCs) for CY 2023

(1) Background

In the CY 2014 OPPI/ASC final rule with comment period (78 FR 74861 through 74910), we finalized a comprehensive payment policy that packages payment for adjunctive and

secondary items, services, and procedures into the most costly primary procedure under the OPPS at the claim level. The policy was finalized in CY 2014 but the effective date was delayed until January 1, 2015, to allow additional time for further analysis, opportunity for public comment, and systems preparation. The comprehensive APC (C-APC) policy was implemented effective January 1, 2015, with modifications and clarifications in response to public comments received regarding specific provisions of the C-APC policy (79 FR 66798 through 66810).

A C-APC is defined as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. We established C-APCs as a category broadly for OPPS payment and implemented 25 C-APCs beginning in CY 2015 (79 FR 66809 through 66810). We have gradually added new C-APCs since the policy was implemented beginning in CY 2015, with the number of C-APCs now totaling 69 (80 FR 70332; 81 FR 79584 through 79585; 83 FR 58844 through 58846; 84 FR 61158 through 61166; 85 FR 85885; and 86 FR 63474).

Under our C-APC policy, we designate a service described by a HCPCS code assigned to a C-APC as the primary service when the service is identified by OPPS status indicator "J1". When such a primary service is reported on a hospital outpatient claim, taking into consideration the few exceptions that are discussed below, we make payment for all other items and services reported on the hospital outpatient claim as being integral, ancillary, supportive, dependent, and adjunctive to the primary service (hereinafter collectively referred to as "adjunctive services") and representing components of a complete comprehensive service (78 FR 74865 and 79 FR 66799). Payments for adjunctive services are packaged into the payments for the primary services. This results in a single prospective payment for each of the primary, comprehensive services based on the costs of all reported services at the claim level.

Services excluded from the C-APC policy under the OPPS include services that are not covered OPD services, services that cannot by statute be paid for under the OPPS, and services that are required by statute to be separately paid. This includes certain mammography and

ambulance services that are not covered OPD services in accordance with section 1833(t)(1)(B)(iv) of the Act; brachytherapy seeds, which also are required by statute to receive separate payment under section 1833(t)(2)(H) of the Act; pass-through payment drugs and devices, which also require separate payment under section 1833(t)(6) of the Act; self-administered drugs (SADs) that are not otherwise packaged as supplies because they are not covered under Medicare Part B under section 1861(s)(2)(B) of the Act; and certain preventive services (78 FR 74865 and 79 FR 66800 through 66801). A list of services excluded from the C-APC policy is included in Addendum J to this proposed rule (which is available via the Internet on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices>). If a service does not appear on this list of excluded services, payment for it will be packaged into the payment for the primary C-APC service when it appears on an outpatient claim with a primary C-APC service.

In the interim final rule with request for comments (IFC) titled, “Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency”, published on November 6, 2020, we stated that, effective for services furnished on or after the effective date of the IFC and until the end of the PHE for COVID-19, there is an exception to the OPPS C-APC policy to ensure separate payment for new COVID-19 treatments that meet certain criteria (85 FR 71158 through 71160). Under this exception, any new COVID-19 treatment that meets the following two criteria will, for the remainder of the PHE for COVID-19, always be separately paid and will not be packaged into a C-APC when it is provided on the same claim as the primary C-APC service. First, the treatment must be a drug or biological product (which could include a blood product) authorized to treat COVID-19, as indicated in section “I. Criteria for Issuance of Authorization” of the FDA letter of authorization for the emergency use of the drug or biological product, or the drug or biological product must be approved by FDA for treating COVID-19. Second, the emergency use authorization (EUA) for the drug or biological

product (which could include a blood product) must authorize the use of the product in the outpatient setting or not limit its use to the inpatient setting, or the product must be approved by FDA to treat COVID-19 disease and not limit its use to the inpatient setting. For further information regarding the exception to the C-APC policy for COVID-19 treatments, please refer to the November 6, 2020 IFC (85 FR 71158 through 71160).

The C-APC policy payment methodology set forth in the CY 2014 OPPS/ASC final rule with comment period and modified and implemented beginning in CY 2015 is summarized as follows (78 FR 74887 and 79 FR 66800):

Basic Methodology. As stated in the CY 2015 OPPS/ASC final rule with comment period, we define the C-APC payment policy as including all covered OPD services on a hospital outpatient claim reporting a primary service that is assigned to status indicator “J1”, excluding services that are not covered OPD services or that cannot by statute be paid for under the OPPS. Services and procedures described by HCPCS codes assigned to status indicator “J1” are assigned to C-APCs based on our usual APC assignment methodology by evaluating the geometric mean costs of the primary service claims to establish resource similarity and the clinical characteristics of each procedure to establish clinical similarity within each APC.

In the CY 2016 OPPS/ASC final rule with comment period, we expanded the C-APC payment methodology to qualifying extended assessment and management encounters through the “Comprehensive Observation Services” C-APC (C-APC 8011). Services within this APC are assigned status indicator “J2”. Specifically, we make a payment through C-APC 8011 for a claim that:

- Does not contain a procedure described by a HCPCS code to which we have assigned status indicator “T”;
- Contains 8 or more units of services described by HCPCS code G0378 (Hospital observation services, per hour);

- Contains services provided on the same date of service or one day before the date of service for HCPCS code G0378 that are described by one of the following codes: HCPCS code G0379 (Direct admission of patient for hospital observation care) on the same date of service as HCPCS code G0378; CPT code 99281 (Emergency department visit for the evaluation and management of a patient (Level 1)); CPT code 99282 (Emergency department visit for the evaluation and management of a patient (Level 2)); CPT code 99283 (Emergency department visit for the evaluation and management of a patient (Level 3)); CPT code 99284 (Emergency department visit for the evaluation and management of a patient (Level 4)); CPT code 99285 (Emergency department visit for the evaluation and management of a patient (Level 5)) or HCPCS code G0380 (Type B emergency department visit (Level 1)); HCPCS code G0381 (Type B emergency department visit (Level 2)); HCPCS code G0382 (Type B emergency department visit (Level 3)); HCPCS code G0383 (Type B emergency department visit (Level 4)); HCPCS code G0384 (Type B emergency department visit (Level 5)); CPT code 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30-74 minutes); or HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient); and

- Does not contain services described by a HCPCS code to which we have assigned status indicator “J1”.

The assignment of status indicator “J2” to a specific set of services performed in combination with each other allows for all other OPPS payable services and items reported on the claim (excluding services that are not covered OPD services or that cannot by statute be paid for under the OPPS) to be deemed adjunctive services representing components of a comprehensive service and resulting in a single prospective payment for the comprehensive service based on the costs of all reported services on the claim (80 FR 70333 through 70336).

Services included under the C-APC payment packaging policy, that is, services that are typically adjunctive to the primary service and provided during the delivery of the

comprehensive service, include diagnostic procedures, laboratory tests, and other diagnostic tests and treatments that assist in the delivery of the primary procedure; visits and evaluations performed in association with the procedure; uncoded services and supplies used during the service; durable medical equipment as well as prosthetic and orthotic items and supplies when provided as part of the outpatient service; and any other components reported by HCPCS codes that represent services that are provided during the complete comprehensive service (78 FR 74865 and 79 FR 66800).

In addition, payment for hospital outpatient department services that are similar to therapy services and delivered either by therapists or nontherapists is included as part of the payment for the packaged complete comprehensive service. These services that are provided during the perioperative period are adjunctive services and are deemed not to be therapy services as described in section 1834(k) of the Act, regardless of whether the services are delivered by therapists or other nontherapist health care workers. We have previously noted that therapy services are those provided by therapists under a plan of care in accordance with section 1835(a)(2)(C) and section 1835(a)(2)(D) of the Act and are paid for under section 1834(k) of the Act, subject to annual therapy caps as applicable (78 FR 74867 and 79 FR 66800). However, certain other services similar to therapy services are considered and paid for as hospital outpatient department services. Payment for these nontherapy outpatient department services that are reported with therapy codes and provided with a comprehensive service is included in the payment for the packaged complete comprehensive service. We note that these services, even though they are reported with therapy codes, are hospital outpatient department services and not therapy services. We refer readers to the July 2016 OPPS Change Request 9658 (Transmittal 3523) for further instructions on reporting these services in the context of a C-APC service.

Items included in the packaged payment provided in conjunction with the primary service also include all drugs, biologicals, and radiopharmaceuticals, regardless of cost, except those

drugs with pass-through payment status and SADs, unless they function as packaged supplies (78 FR 74868 through 74869 and 74909 and 79 FR 66800). We refer readers to Section 50.2M, Chapter 15, of the Medicare Benefit Policy Manual for a description of our policy on SADs treated as hospital outpatient supplies, including lists of SADs that function as supplies and those that do not function as supplies.

We define each hospital outpatient claim reporting a single unit of a single primary service assigned to status indicator “J1” as a single “J1” unit procedure claim (78 FR 74871 and 79 FR 66801). Line item charges for services included on the C-APC claim are converted to line item costs, which are then summed to develop the estimated APC costs. These claims are then assigned one unit of the service with status indicator “J1” and later used to develop the geometric mean costs for the C-APC relative payment weights. (We note that we use the term “comprehensive” to describe the geometric mean cost of a claim reporting “J1” service(s) or the geometric mean cost of a C-APC, inclusive of all of the items and services included in the C-APC service payment bundle.) Charges for services that would otherwise be separately payable are added to the charges for the primary service. This process differs from our traditional cost accounting methodology only in that all such services on the claim are packaged (except certain services as described above). We apply our standard data trims, which exclude claims with extremely high primary units or extreme costs.

The comprehensive geometric mean costs are used to establish resource similarity and, along with clinical similarity, dictate the assignment of the primary services to the C-APCs. We establish a ranking of each primary service (single unit only) to be assigned to status indicator “J1” according to its comprehensive geometric mean costs. For the minority of claims reporting more than one primary service assigned to status indicator “J1” or units thereof, we identify one “J1” service as the primary service for the claim based on our cost-based ranking of primary services. We then assign these multiple “J1” procedure claims to the C-APC to which the service designated as the primary service is assigned. If the reported “J1” services on a claim

map to different C-APCs, we designate the “J1” service assigned to the C-APC with the highest comprehensive geometric mean cost as the primary service for that claim. If the reported multiple “J1” services on a claim map to the same C-APC, we designate the most costly service (at the HCPCS code level) as the primary service for that claim. This process results in initial assignments of claims for the primary services assigned to status indicator “J1” to the most appropriate C-APCs based on both single and multiple procedure claims reporting these services and clinical and resource homogeneity.

Complexity Adjustments. We use complexity adjustments to provide increased payment for certain comprehensive services. We apply a complexity adjustment by promoting qualifying paired “J1” service code combinations or paired code combinations of “J1” services and certain add-on codes (as described further below) from the originating C-APC (the C-APC to which the designated primary service is first assigned) to the next higher paying C-APC in the same clinical family of C-APCs. We apply this type of complexity adjustment when the paired code combination represents a complex, costly form or version of the primary service according to the following criteria:

- Frequency of 25 or more claims reporting the code combination (frequency threshold);
- and
- Violation of the 2 times rule, as stated in section 1833(t)(2) of the Act and section III.B.2. of this final rule with comment period, in the originating C-APC (cost threshold).

These criteria identify paired code combinations that occur commonly and exhibit materially greater resource requirements than the primary service. The CY 2017 OPPI/ASC final rule with comment period (81 FR 79582) included a revision to the complexity adjustment eligibility criteria. Specifically, we finalized a policy to discontinue the requirement that a code combination (that qualifies for a complexity adjustment by satisfying the frequency and cost criteria thresholds described above) also not create a 2 times rule violation in the higher level or receiving APC.

After designating a single primary service for a claim, we evaluate that service in combination with each of the other procedure codes reported on the claim assigned to status indicator “J1” (or certain add-on codes) to determine if there are paired code combinations that meet the complexity adjustment criteria. For a new HCPCS code, we determine initial C-APC assignment and qualification for a complexity adjustment using the best available information, crosswalking the new HCPCS code to a predecessor code(s) when appropriate.

Once we have determined that a particular code combination of “J1” services (or combinations of “J1” services reported in conjunction with certain add-on codes) represents a complex version of the primary service because it is sufficiently costly, frequent, and a subset of the primary comprehensive service overall according to the criteria described above, we promote the claim including the complex version of the primary service as described by the code combination to the next higher cost C-APC within the clinical family, unless the primary service is already assigned to the highest cost APC within the C-APC clinical family or assigned to the only C-APC in a clinical family. We do not create new APCs with a comprehensive geometric mean cost that is higher than the highest geometric mean cost (or only) C-APC in a clinical family just to accommodate potential complexity adjustments. Therefore, the highest payment for any claim including a code combination for services assigned to a C-APC would be the highest paying C-APC in the clinical family (79 FR 66802).

We package payment for all add-on codes into the payment for the C-APC. However, certain primary service add-on combinations may qualify for a complexity adjustment. As noted in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70331), all add-on codes that can be appropriately reported in combination with a base code that describes a primary “J1” service are evaluated for a complexity adjustment.

To determine which combinations of primary service codes reported in conjunction with an add-on code may qualify for a complexity adjustment for CY 2023, we propose to apply the frequency and cost criteria thresholds discussed above, testing claims reporting one unit of a

single primary service assigned to status indicator “J1” and any number of units of a single add-on code for the primary “J1” service. If the frequency and cost criteria thresholds for a complexity adjustment are met and reassignment to the next higher cost APC in the clinical family is appropriate (based on meeting the criteria outlined above), we make a complexity adjustment for the code combination; that is, we reassign the primary service code reported in conjunction with the add-on code to the next higher cost C-APC within the same clinical family of C-APCs. As previously stated, we package payment for add-on codes into the C-APC payment rate. If any add-on code reported in conjunction with the “J1” primary service code does not qualify for a complexity adjustment, payment for the add-on service continues to be packaged into the payment for the primary service and is not reassigned to the next higher cost C-APC. We list the complexity adjustments for “J1” and add-on code combinations for CY 2023, along with all of the other final complexity adjustments, in Addendum J to this proposed rule (which is available via the Internet on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices>).

Addendum J to this proposed rule includes the cost statistics for each code combination that would qualify for a complexity adjustment (including primary code and add-on code combinations). Addendum J to this proposed rule also contains summary cost statistics for each of the paired code combinations that describe a complex code combination that would qualify for a complexity adjustment and are proposed to be reassigned to the next higher cost C-APC within the clinical family. The combined statistics for all proposed reassigned complex code combinations are represented by an alphanumeric code with the first four digits of the designated primary service followed by a letter. For example, the proposed geometric mean cost listed in Addendum J for the code combination described by complexity adjustment assignment 3320R, which is assigned to C-APC 5224 (Level 4 Pacemaker and Similar Procedures), includes all paired code combinations that are proposed to be reassigned to C-APC 5224 when CPT code

33208 is the primary code. Providing the information contained in Addendum J to this proposed rule allows stakeholders the opportunity to better assess the impact associated with the proposed assignment of claims with each of the paired code combinations eligible for a complexity adjustment.

(2) Exclusion of Procedures Assigned to New Technology APCs from the C-APC Policy

Services that are assigned to New Technology APCs are typically new procedures that do not have sufficient claims history to establish an accurate payment for them. Beginning in CY 2002, we retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to an appropriate clinical APC. This policy allows us to move a service from a New Technology APC in less than 2 years if sufficient data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient data upon which to base a decision for reassignment have not been collected (82 FR 59277).

The C-APC payment policy packages payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure under the OPSS at the claim level. Prior to CY 2019, when a procedure assigned to a New Technology APC was included on the claim with a primary procedure, identified by OPSS status indicator “J1”, payment for the new technology service was typically packaged into the payment for the primary procedure. Because the new technology service was not separately paid in this scenario, the overall number of single claims available to determine an appropriate clinical APC for the new service was reduced. This was contrary to the objective of the New Technology APC payment policy, which is to gather sufficient claims data to enable us to assign the service to an appropriate clinical APC.

To address this issue and ensure that there are sufficient claims data for services assigned to New Technology APCs, in the CY 2019 OPSS/ASC final rule with comment period (83 FR 58847), we finalized excluding payment for any procedure that is assigned to a New Technology APC (APCs 1491 through 1599 and APCs 1901 through 1908) from being packaged

when included on a claim with a “J1” service assigned to a C-APC. In the CY 2020 OPPTS/ASC final rule with comment period, we finalized that beginning in CY 2020, payment for services assigned to a New Technology APC would be excluded from being packaged into the payment for comprehensive observation services assigned status indicator “J2” when they are included on a claim with a “J2” service (84 FR 61167). We propose to continue to exclude payment for any procedure that is assigned to a New Technology APC (APCs 1491 through 1599 and APCs 1901 through 1908) from being packaged when included on a claim with a “J1” or “J2” service assigned to a C-APC.

(3) Exclusion of Drugs and Biologicals Described by HCPCS Code C9399 (Unclassified drugs or biologicals) from the C-APC Policy

Section 1833(t)(15) of the Act, as added by section 621(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173), provides for payment under the OPPTS for new drugs and biologicals until HCPCS codes are assigned. Under this provision, we are required to make payment for a covered outpatient drug or biological that is furnished as part of covered outpatient department services but for which a HCPCS code has not yet been assigned in an amount equal to 95 percent of average wholesale price (AWP) for the drug or biological.

In the CY 2005 OPPTS/ASC final rule with comment period (69 FR 65805), we implemented section 1833(t)(15) of the Act by instructing hospitals to bill for a drug or biological that is newly approved by the FDA and that does not yet have a HCPCS code by reporting the National Drug Code (NDC) for the product along with the newly created HCPCS code C9399 (Unclassified drugs or biologicals). We explained that when HCPCS code C9399 appears on a claim, the Outpatient Code Editor (OCE) suspends the claim for manual pricing by the Medicare Administrative Contractor (MAC). The MAC prices the claim at 95 percent of the drug or biological’s AWP, using Red Book or an equivalent recognized compendium, and processes the claim for payment. We emphasized that this approach enables hospitals to bill and

receive payment for a new drug or biological concurrent with its approval by the FDA. The hospital does not have to wait for the next quarterly release or for approval of a product-specific HCPCS code to receive payment for a newly approved drug or biological or to resubmit claims for adjustment. We instructed that hospitals would discontinue billing HCPCS code C9399 and the NDC upon implementation of a product specific HCPCS code, status indicator, and appropriate payment amount with the next quarterly update. We also note that HCPCS code C9399 is paid in a similar manner in the ASC setting, as 42 CFR 416.171(b) outlines that certain drugs and biologicals for which separate payment is allowed under the OPSS are considered covered ancillary services for which the OPSS payment rate, which is 95 percent of AWP for HCPCS code C9399, applies. Since the implementation of the C-APC policy in 2015, payment for drugs and biologicals described by HCPCS code C9399 has been included in the C-APC payment when these products appear on a claim with a primary C-APC service. Packaging payment for these drugs and biologicals that appear on a hospital outpatient claim with a primary C-APC service is consistent with our C-APC packaging policy under which we make payment for all items and services, including all non-pass-through drugs, reported on the hospital outpatient claim as being integral, ancillary, supportive, dependent, and adjunctive to the primary service and representing components of a complete comprehensive service, with certain limited exceptions (78 FR 74869). It has been our position that the total payment for the C-APC with which payment for a drug or biological described by HCPCS code C9399 is packaged includes payment for the drug or biological at 95 percent of its AWP.

However, we have determined that in certain instances, drugs and biologicals described by HCPCS code C9399 are not being paid at 95 percent of their AWP when payment for them is packaged with payment for a primary C-APC service. In order to ensure payment for new drugs, biologicals, and radiopharmaceuticals described by HCPCS code C9399 at 95 percent of their AWP, for CY 2023 and subsequent years, we propose to exclude any drug, biological, or radiopharmaceutical described by HCPCS code C9399 from packaging when the drug,

biological, or radiopharmaceutical is included on a claim with a “J1” service, which is the status indicator assigned to a C-APC, and a claim with a “J2” service, which is the status indicator assigned to comprehensive observation services. Please see OPSS Addendum J for the proposed CY 2023 comprehensive APC payment policy exclusions.

We are also including a corresponding proposal in section XI “Proposed CY 2023 OPSS Payment Status and Comment Indicators”, to add a new definition to status indicator “A” to include unclassified drugs and biologicals that are reportable with HCPCS code C9399. The proposed definition, found in Addendum D1 to this proposed rule, would ensure the MAC prices claims for drugs, biologicals or radiopharmaceuticals billed with HCPCS code C9399 at 95 percent of the drug or biological’s AWP and pays separately for the drug, biological, or radiopharmaceutical under the OPSS when it appears on the same claim as a primary C-APC service.

(4) Additional C-APCs for CY 2023

For CY 2023, we propose to continue to apply the C-APC payment policy methodology. We refer readers to the CY 2017 OPSS/ASC final rule with comment period (81 FR 79583) for a discussion of the C-APC payment policy methodology and revisions.

Each year, in accordance with section 1833(t)(9)(A) of the Act, we review and revise the services within each APC group and the APC assignments under the OPSS. As a result of our annual review of the services and the APC assignments under the OPSS, we propose to add one C-APC under the existing C-APC payment policy in CY 2023: Proposed C-APC 5372 (Level 2 Urology and Related Services). This APC was selected to be included in this proposed rule because, similar to other C-APCs, this APC includes primary, comprehensive services, such as major surgical procedures, that are typically reported with other ancillary and adjunctive services. Also, similar to other clinical APCs that have been converted to C-APCs, there are higher APC levels (Levels 3-8 Urology and Related Services) within the clinical family or related clinical family of this APC that have previously been converted to C-APCs.

Table 1 below lists the proposed C-APCs for CY 2023. All C-APCs are displayed in Addendum J to this proposed rule (which is available via the internet on the CMS website). Addendum J to this proposed rule also contains all of the data related to the C-APC payment policy methodology, including the list of complexity adjustments and other information.

TABLE 1: PROPOSED CY 2023 C-APCs

C-APC	CY 2023 APC Group Title	Clinical Family	New C-APC
5072	Level 2 Excision/Biopsy/Incision and Drainage	EBIDX	
5073	Level 3 Excision/Biopsy/Incision and Drainage	EBIDX	
5091	Level 1 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5092	Level 2 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5093	Level 3 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5094	Level 4 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5112	Level 2 Musculoskeletal Procedures	ORTHO	
5113	Level 3 Musculoskeletal Procedures	ORTHO	
5114	Level 4 Musculoskeletal Procedures	ORTHO	
5115	Level 5 Musculoskeletal Procedures	ORTHO	
5116	Level 6 Musculoskeletal Procedures	ORTHO	
5153	Level 3 Airway Endoscopy	AENDO	
5154	Level 4 Airway Endoscopy	AENDO	
5155	Level 5 Airway Endoscopy	AENDO	
5163	Level 3 ENT Procedures	ENTXX	
5164	Level 4 ENT Procedures	ENTXX	
5165	Level 5 ENT Procedures	ENTXX	
5166	Cochlear Implant Procedure	COCHL	
5182	Level 2 Vascular Procedures	VASCX	
5183	Level 3 Vascular Procedures	VASCX	
5184	Level 4 Vascular Procedures	VASCX	
5191	Level 1 Endovascular Procedures	EVASC	
5192	Level 2 Endovascular Procedures	EVASC	
5193	Level 3 Endovascular Procedures	EVASC	
5194	Level 4 Endovascular Procedures	EVASC	
5200	Implantation Wireless PA Pressure Monitor	WPMXX	
5211	Level 1 Electrophysiologic Procedures	EPHYS	
5212	Level 2 Electrophysiologic Procedures	EPHYS	
5213	Level 3 Electrophysiologic Procedures	EPHYS	
5222	Level 2 Pacemaker and Similar Procedures	AICDP	
5223	Level 3 Pacemaker and Similar Procedures	AICDP	
5224	Level 4 Pacemaker and Similar Procedures	AICDP	
5231	Level 1 ICD and Similar Procedures	AICDP	
5232	Level 2 ICD and Similar Procedures	AICDP	
5244	Level 4 Blood Product Exchange and Related Services	SCTXX	
5302	Level 2 Upper GI Procedures	GIXXX	
5303	Level 3 Upper GI Procedures	GIXXX	
5313	Level 3 Lower GI Procedures	GIXXX	
5331	Complex GI Procedures	GIXXX	

C-APC	CY 2023 APC Group Title	Clinical Family	New C-APC
5341	Abdominal/Peritoneal/Biliary and Related Procedures	GIXXX	
5361	Level 1 Laparoscopy and Related Services	LAPXX	
5362	Level 2 Laparoscopy and Related Services	LAPXX	
5372	Level 2 Urology and Related Services	UROXX	*
5373	Level 3 Urology and Related Services	UROXX	
5374	Level 4 Urology and Related Services	UROXX	
5375	Level 5 Urology and Related Services	UROXX	
5376	Level 6 Urology and Related Services	UROXX	
5377	Level 7 Urology and Related Services	UROXX	
5378	Level 8 Urology and Related Services	UROXX	
5414	Level 4 Gynecologic Procedures	GYNXX	
5415	Level 5 Gynecologic Procedures	GYNXX	
5416	Level 6 Gynecologic Procedures	GYNXX	
5431	Level 1 Nerve Procedures	NERVE	
5432	Level 2 Nerve Procedures	NERVE	
5461	Level 1 Neurostimulator and Related Procedures	NSTIM	
5462	Level 2 Neurostimulator and Related Procedures	NSTIM	
5463	Level 3 Neurostimulator and Related Procedures	NSTIM	
5464	Level 4 Neurostimulator and Related Procedures	NSTIM	
5465	Level 5 Neurostimulator and Related Procedures	NSTIM	
5471	Implantation of Drug Infusion Device	PUMPS	
5491	Level 1 Intraocular Procedures	INEYE	
5492	Level 2 Intraocular Procedures	INEYE	
5493	Level 3 Intraocular Procedures	INEYE	
5494	Level 4 Intraocular Procedures	INEYE	
5495	Level 5 Intraocular Procedures	INEYE	
5503	Level 3 Extraocular, Repair, and Plastic Eye Procedures	EXEYE	
5504	Level 4 Extraocular, Repair, and Plastic Eye Procedures	EXEYE	
5627	Level 7 Radiation Therapy	RADTX	
5881	Ancillary Outpatient Services When Patient Dies	N/A	
8011	Comprehensive Observation Services	N/A	

C-APC Clinical Family Descriptor Key:

AENDO = Airway Endoscopy
 AICDP = Automatic Implantable Cardiac Defibrillators, Pacemakers, and Related Devices.
 BREAS = Breast Surgery
 COCHL = Cochlear Implant
 EBIDX = Excision/ Biopsy/Incision and Drainage
 ENTXX = ENT Procedures
 EPHYS = Cardiac Electrophysiology
 EVASC = Endovascular Procedures
 EXEYE = Extraocular Ophthalmic Surgery
 GIXXX = Gastrointestinal Procedures
 GYNXX = Gynecologic Procedures
 INEYE = Intraocular Surgery
 LAPXX = Laparoscopic Procedures
 NERVE = Nerve Procedures
 NSTIM = Neurostimulators
 ORTHO = Orthopedic Surgery
 PUMPS = Implantable Drug Delivery Systems
 RADTX = Radiation Oncology
 SCTXX = Stem Cell Transplant

UROXX = Urologic Procedures
VASCX = Vascular Procedures
WPMXX = Wireless PA Pressure Monitor

c. Calculation of Composite APC Criteria-Based Costs

As discussed in the CY 2008 OPSS/ASC final rule with comment period (72 FR 66613), we believe it is important that the OPSS enhance incentives for hospitals to provide necessary, high quality care as efficiently as possible. For CY 2008, we developed composite APCs to provide a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service. Combining payment for multiple, independent services into a single OPSS payment in this way enables hospitals to manage their resources with maximum flexibility by monitoring and adjusting the volume and efficiency of services themselves. An additional advantage to the composite APC model is that we can use data from correctly coded multiple procedure claims to calculate payment rates for the specified combinations of services, rather than relying upon single procedure claims which may be low in volume and/or incorrectly coded. Under the OPSS, we currently have composite policies for mental health services and multiple imaging services. We refer readers to the CY 2008 OPSS/ASC final rule with comment period (72 FR 66611 through 66614 and 66650 through 66652) for a full discussion of the development of the composite APC methodology, and the CY 2012 OPSS/ASC final rule with comment period (76 FR 74163) and the CY 2018 OPSS/ASC final rule with comment period (82 FR 59241 through 59242 and 59246 through 52950) for more recent background.

(1) Mental Health Services Composite APC

We propose to continue our longstanding policy of limiting the aggregate payment for specified less resource-intensive mental health services furnished on the same date to the payment for a day of partial hospitalization services provided by a hospital, which we consider to be the most resource-intensive of all outpatient mental health services. We refer readers to the April 7, 2000 OPSS final rule with comment period (65 FR 18452 through 18455) for the initial

discussion of this longstanding policy and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74168) for more recent background.

In the CY 2018 OPPS/ASC proposed rule and final rule with comment period (82 FR 33580 through 33581 and 59246 through 59247, respectively), we proposed and finalized the policy for CY 2018 and subsequent years that, when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on a single date of service, based on the payment rates associated with the APCs for the individual services, exceeds the maximum per diem payment rate for partial hospitalization services provided by a hospital, those specified mental health services will be paid through composite APC 8010 (Mental Health Services Composite). In addition, we set the payment rate for composite APC 8010 for CY 2018 at the same payment rate that will be paid for APC 5863, which is the maximum partial hospitalization per diem payment rate for a hospital, and finalized a policy that the hospital will continue to be paid the payment rate for composite APC 8010. Under this policy, the I/OCE will continue to determine whether to pay for these specified mental health services individually, or to make a single payment at the same payment rate established for APC 5863 for all of the specified mental health services furnished by the hospital on that single date of service. We continue to believe that the costs associated with administering a partial hospitalization program at a hospital represent the most resource intensive of all outpatient mental health services. Therefore, we do not believe that we should pay more for mental health services under the OPPS than the highest partial hospitalization per diem payment rate for hospitals.

We propose that when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on a single date of service, based on the payment rates associated with the APCs for the individual services, exceeds the maximum per diem payment rate for partial hospitalization services provided by a hospital, those specified mental health services would be paid through composite APC 8010 for CY 2023. In addition, we propose to set the payment rate for composite APC 8010 at the same payment rate that we

propose for APC 5863, which is the maximum partial hospitalization per diem payment rate for a hospital, and that the hospital continue to be paid the proposed payment rate for composite APC 8010.

(2) Multiple Imaging Composite APCs (APCs 8004, 8005, 8006, 8007, and 8008)

Effective January 1, 2009, we provide a single payment each time a hospital submits a claim for more than one imaging procedure within an imaging family on the same date of service, to reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session (73 FR 41448 through 41450). We utilize three imaging families based on imaging modality for purposes of this methodology: (1) ultrasound; (2) computed tomography (CT) and computed tomographic angiography (CTA); and (3) magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA). The HCPCS codes subject to the multiple imaging composite policy and their respective families are listed in Table 2 below.

While there are three imaging families, there are five multiple imaging composite APCs due to the statutory requirement under section 1833(t)(2)(G) of the Act that we differentiate payment for OPPS imaging services provided with and without contrast. While the ultrasound procedures included under the policy do not involve contrast, both CT/CTA and MRI/MRA scans can be provided either with or without contrast. The five multiple imaging composite APCs established in CY 2009 are:

- APC 8004 (Ultrasound Composite);
- APC 8005 (CT and CTA without Contrast Composite);
- APC 8006 (CT and CTA with Contrast Composite);
- APC 8007 (MRI and MRA without Contrast Composite); and
- APC 8008 (MRI and MRA with Contrast Composite).

We define the single imaging session for the “with contrast” composite APCs as having at least one or more imaging procedures from the same family performed with contrast on the

same date of service. For example, if the hospital performs an MRI without contrast during the same session as at least one other MRI with contrast, the hospital will receive payment based on the payment rate for APC 8008, the “with contrast” composite APC.

We make a single payment for those imaging procedures that qualify for payment based on the composite APC payment rate, which includes any packaged services furnished on the same date of service. The standard (noncomposite) APC assignments continue to apply for single imaging procedures and multiple imaging procedures performed across families. For a full discussion of the development of the multiple imaging composite APC methodology, we refer readers to the CY 2009 OPPI/ASC final rule with comment period (73 FR 68559 through 68569).

For CY 2023, we propose to continue to pay for all multiple imaging procedures within an imaging family performed on the same date of service using the multiple imaging composite APC payment methodology. We continue to believe that this policy would reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session.

For CY 2023, except where otherwise indicated, we propose to use the costs derived from CY 2021 claims data to set the proposed CY 2023 payment rates. Therefore, for CY 2023, the payment rates for the five multiple imaging composite APCs (APCs 8004, 8005, 8006, 8007, and 8008) are based on proposed geometric mean costs calculated from CY 2021 claims available for this proposed rule that qualify for composite payment under the current policy (that is, those claims reporting more than one procedure within the same family on a single date of service). To calculate the proposed geometric mean costs, we use the same methodology that we use to calculate the geometric mean costs for these composite APCs since CY 2014, as described in the CY 2014 OPPI/ASC final rule with comment period (78 FR 74918). The imaging HCPCS codes referred to as “overlap bypass codes” that we removed from the bypass list for purposes of calculating the proposed multiple imaging composite APC geometric mean costs, in accordance

with our established methodology as stated in the CY 2014 OPPTS/ASC final rule with comment period (78 FR 74918), are identified by asterisks in Addendum N to this proposed rule (which is available via the Internet on the CMS website¹) and are discussed in more detail in section II.A.1.b of this proposed rule,

For CY 2023, we are able to identify approximately 0.95 million “single session” claims out of an estimated 2.0 million potential claims for payment through composite APCs from our ratesetting claims data, which represents approximately 47.5 percent of all eligible claims, to calculate the proposed CY 2023 geometric mean costs for the multiple imaging composite APCs. Table 2 of this proposed rule lists the proposed HCPCS codes that would be subject to the multiple imaging composite APC policy and their respective families and approximate composite APC proposed geometric mean costs for CY 2023.

TABLE 2: OPPTS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS

Family 1 – Ultrasound	
CY 2023 APC 8004 (Ultrasound Composite)	CY 2023 Approximate APC Geometric Mean Cost = \$290.66
76700	Us exam, abdom, complete
76705	Echo exam of abdomen
76770	Us exam abdo back wall, comp
76776	Us exam k transpl w/Doppler
76831	Echo exam, uterus
76856	Us exam, pelvic, complete
76857	Us exam, pelvic, limited
76981	Us parenchyma
76982	Us 1 st target lesion
Family 2 - CT and CTA with and without Contrast	
CY 2023 APC 8005 (CT and CTA without Contrast Composite)*	CY 2023 Approximate APC Geometric Mean Cost = \$218.54
0633T	Ct breast w/3d uni c-
0636T	Ct breast w/3d bi c-

¹ CY 2023 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule (CMS-1772-P); Notice of Proposed Rulemaking. Available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices>

70450	Ct head/brain w/o dye
70480	Ct orbit/ear/fossa w/o dye
70486	Ct maxillofacial w/o dye
70490	Ct soft tissue neck w/o dye
71250	Ct thorax w/o dye
72125	Ct neck spine w/o dye
72128	Ct chest spine w/o dye
72131	Ct lumbar spine w/o dye
72192	Ct pelvis w/o dye
73200	Ct upper extremity w/o dye
73700	Ct lower extremity w/o dye
74150	Ct abdomen w/o dye
74176	Ct angio abd & pelvis
74261	Ct colonography, w/o dye
CY 2023 APC 8006 (CT and CTA with Contrast Composite)	CY 2023 Approximate APC Geometric Mean Cost = \$424.16
0634T	Ct breast w/3d uni c+
0635T	Ct breast w/3d uni c-/c+
0637T	Ct breast w/3d bi c+
0638T	Ct breast w/3d bi c-/c+
70460	Ct head/brain w/dye
70470	Ct head/brain w/o & w/dye
70481	Ct orbit/ear/fossa w/dye
70482	Ct orbit/ear/fossa w/o & w/dye
70487	Ct maxillofacial w/dye
70488	Ct maxillofacial w/o & w/dye
70491	Ct soft tissue neck w/dye
70492	Ct sft tsue nck w/o & w/dye
70496	Ct angiography, head
70498	Ct angiography, neck
71260	Ct thorax w/dye
71270	Ct thorax w/o & w/dye
71275	Ct angiography, chest
72126	Ct neck spine w/dye
72127	Ct neck spine w/o & w/dye
72129	Ct chest spine w/dye
72130	Ct chest spine w/o & w/dye
72132	Ct lumbar spine w/dye
72133	Ct lumbar spine w/o & w/dye
72191	Ct angiograph pelv w/o & w/dye
72193	Ct pelvis w/dye
72194	Ct pelvis w/o & w/dye
73201	Ct upper extremity w/dye
73202	Ct uppr extremity w/o & w/dye

73206	Ct angio upr extrm w/o & w/dye
73701	Ct lower extremity w/dye
73702	Ct lwr extremity w/o & w/dye
73706	Ct angio lwr extr w/o & w/dye
74160	Ct abdomen w/dye
74170	Ct abdomen w/o & w/dye
74175	Ct angio abdom w/o & w/dye
74177	Ct angio abd & pelv w/contrast
74178	Ct angio abd & pelv 1+ regns
74262	Ct colonography, w/dye
75635	Ct angio abdominal arteries
* If a “without contrast” CT or CTA procedure is performed during the same session as a “with contrast” CT or CTA procedure, the I/OCE assigns the procedure to APC 8006 rather than APC 8005.	
Family 3 - MRI and MRA with and without Contrast	
CY 2023 APC 8007 (MRI and MRA without Contrast Composite)*	CY 2023 Approximate APC Geometric Mean Cost = \$509.37
0609T	Mrs disc pain acquisj data
70336	Magnetic image, jaw joint
70540	Mri orbit/face/neck w/o dye
70544	Mr angiography head w/o dye
70547	Mr angiography neck w/o dye
70551	Mri brain w/o dye
70554	Fmri brain by tech
71550	Mri chest w/o dye
72141	Mri neck spine w/o dye
72146	Mri chest spine w/o dye
72148	Mri lumbar spine w/o dye
72195	Mri pelvis w/o dye
73218	Mri upper extremity w/o dye
73221	Mri joint upr extrem w/o dye
73718	Mri lower extremity w/o dye
73721	Mri jnt of lwr extre w/o dye
74181	Mri abdomen w/o dye
75557	Cardiac mri for morph
75559	Cardiac mri w/stress img
76391	Mr elastography
77046	Mri breast c- unilateral
77047	Mri breast c- bilateral
C8901	MRA w/o cont, abd
C8910	MRA w/o cont, chest
C8913	MRA w/o cont, lwr ext
C8919	MRA w/o cont, pelvis
C8932	MRA, w/o dye, spinal canal

C8935	MRA, w/o dye, upper extr
C9762	Cardiac MRI seg dys strain
C9763	Cardiac MRI seg dys stress
CY 2023 APC 8008 (MRI and MRA with Contrast Composite)	CY 2023 Approximate APC Geometric Mean Cost = \$821.63
70542	Mri orbit/face/neck w/dye
70543	Mri orbt/fac/nck w/o & w/dye
70545	Mr angiography head w/dye
70546	Mr angiograph head w/o & w/dye
70547	Mr angiography neck w/o dye
70548	Mr angiography neck w/dye
70549	Mr angiograph neck w/o & w/dye
70552	Mri brain w/dye
70553	Mri brain w/o & w/dye
71551	Mri chest w/dye
71552	Mri chest w/o & w/dye
72142	Mri neck spine w/dye
72147	Mri chest spine w/dye
72149	Mri lumbar spine w/dye
72156	Mri neck spine w/o & w/dye
72157	Mri chest spine w/o & w/dye
72158	Mri lumbar spine w/o & w/dye
72196	Mri pelvis w/dye
72197	Mri pelvis w/o & w/dye
73219	Mri upper extremity w/dye
73220	Mri uppr extremity w/o & w/dye
73222	Mri joint upr extrem w/dye
73223	Mri joint upr extr w/o & w/dye
73719	Mri lower extremity w/dye
73720	Mri lwr extremity w/o & w/dye
73722	Mri joint of lwr extr w/dye
73723	Mri joint lwr extr w/o & w/dye
74182	Mri abdomen w/dye
74183	Mri abdomen w/o & w/dye
75561	Cardiac mri for morph w/dye
75563	Card mri w/stress img & dye
C8900	MRA w/cont, abd
C8902	MRA w/o fol w/cont, abd
C8903	MRI w/cont, breast, uni
C8905	MRI w/o fol w/cont, brst, un
C8906	MRI w/cont, breast, bi
C8908	MRI w/o fol w/cont, breast,
C8909	MRA w/cont, chest
C8911	MRA w/o fol w/cont, chest

C8912	MRA w/cont, lwr ext
C8914	MRA w/o fol w/cont, lwr ext
C8918	MRA w/cont, pelvis
C8920	MRA w/o fol w/cont, pelvis
C8931	MRA, w/dye, spinal canal
C8933	MRA, w/o&w/dye, spinal canal
C8934	MRA, w/dye, upper extremity
C8936	MRA, w/o&w/dye, upper extr
* If a “without contrast” MRI or MRA procedure is performed during the same session as a “with contrast” MRI or MRA procedure, the I/OCE assigns the procedure to APC 8008 rather than APC 8007.	

3. Changes to Packaged Items and Services

a. Background and Rationale for Packaging in the OPSS

Like other prospective payment systems, the OPSS relies on the concept of averaging to establish a payment rate for services. The payment may be more or less than the estimated cost of providing a specific service or a bundle of specific services for a particular beneficiary. The OPSS packages payments for multiple interrelated items and services into a single payment to create incentives for hospitals to furnish services most efficiently and to manage their resources with maximum flexibility. Our packaging policies support our strategic goal of using larger payment bundles in the OPSS to maximize hospitals’ incentives to provide care in the most efficient manner. For example, where there are a variety of devices, drugs, items, and supplies that could be used to furnish a service, some of which are more costly than others, packaging encourages hospitals to use the most cost-efficient item that meets the patient’s needs, rather than to routinely use a more expensive item, which may occur if separate payment is provided for the item.

Packaging also encourages hospitals to effectively negotiate with manufacturers and suppliers to reduce the purchase price of items and services or to explore alternative group purchasing arrangements, thereby encouraging the most economical health care delivery. Similarly, packaging encourages hospitals to establish protocols that ensure that necessary services are furnished, while scrutinizing the services ordered by practitioners to maximize the

efficient use of hospital resources. Packaging payments into larger payment bundles promotes the predictability and accuracy of payment for services over time. Finally, packaging may reduce the importance of refining service-specific payment because packaged payments include costs associated with higher cost cases requiring many ancillary items and services and lower cost cases requiring fewer ancillary items and services. Because packaging encourages efficiency and is an essential component of a prospective payment system, packaging payments for items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service has been a fundamental part of the OPSS since its implementation in August 2000. As we continue to develop larger payment groups that more broadly reflect services provided in an encounter or episode of care, we have expanded the OPSS packaging policies. Most, but not necessarily all, categories of items and services currently packaged in the OPSS are listed in 42 CFR 419.2(b). Our overarching goal is to make payments for all services under the OPSS more consistent with those of a prospective payment system and less like those of a per-service fee schedule, which pays separately for each coded item. As a part of this effort, we have continued to examine the payment for items and services provided under the OPSS to determine which OPSS services can be packaged to further achieve the objective of advancing the OPSS toward a more prospective payment system.

b. Proposal and Comment Solicitation on Packaged Items and Services

For CY 2023, we examined the items and services currently provided under the OPSS, reviewing categories of integral, ancillary, supportive, dependent, or adjunctive items and services for which we believe payment would be appropriately packaged into payment for the primary service that they support. Specifically, we examined the HCPCS code definitions (including CPT code descriptors) and hospital outpatient department billing patterns to determine whether there were categories of codes for which packaging would be appropriate according to existing OPSS packaging policies or a logical expansion of those existing OPSS packaging policies.

For CY 2023, we are not proposing any changes to the overall packaging policy previously discussed. We propose to continue to conditionally package the costs of selected newly identified ancillary services into payment for a primary service where we believe that the packaged item or service is integral, ancillary, supportive, dependent, or adjunctive to the provision of care that was reported by the primary service HCPCS code.

While we are not proposing any changes to the overall packaging policy above, we are soliciting comments on potential modifications to our packaging policy, as described in section XIII.E.5 of this proposed rule. Specifically, we are seeking comments and data regarding whether to expand the current ASC payment system policy for non-opioid pain management drugs and biologicals that function as surgical supplies to the HOPD setting. Details on the current ASC policy can be found in XIII.E.

4. Calculation of OPPS Scaled Payment Weights

We established a policy in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68283) of using geometric mean-based APC costs to calculate relative payment weights under the OPPS. In the CY 2022 OPPS/ASC final rule with comment period (85 FR 63497 through 63498), we applied this policy and calculated the relative payment weights for each APC for CY 2022 that were shown in Addenda A and B of the CY 2022 OPPS/ASC final rule with comment period (which were made available via the internet on the CMS website) using the APC costs discussed in sections II.A.1. and II.A.2. of the CY 2022 OPPS/ASC final rule with comment period. For CY 2023, as we did for CY 2022, we propose to continue to apply the policy established in CY 2013 and calculate relative payment weights for each APC for CY 2023 using geometric mean-based APC costs.

For CY 2012 and CY 2013, outpatient clinic visits were assigned to one of five levels of clinic visit APCs, with APC 0606 representing a mid-level clinic visit. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75036 through 75043), we finalized a policy

that created alphanumeric HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient), representing any and all clinic visits under the OPSS. HCPCS code G0463 was assigned to APC 0634 (Hospital Clinic Visits). We also finalized a policy to use CY 2012 claims data to develop the CY 2014 OPSS payment rates for HCPCS code G0463 based on the total geometric mean cost of the levels one through five CPT E/M codes for clinic visits previously recognized under the OPSS (CPT codes 99201 through 99205 and 99211 through 99215). In addition, we finalized a policy to no longer recognize a distinction between new and established patient clinic visits.

For CY 2016, we deleted APC 0634 and reassigned the outpatient clinic visit HCPCS code G0463 to APC 5012 (Level 2 Examinations and Related Services) (80 FR 70372). For CY 2023, as we did for CY 2022, we proposed to continue to standardize all of the relative payment weights to APC 5012. We believe that standardizing relative payment weights to the geometric mean of the APC to which HCPCS code G0463 is assigned maintains consistency in calculating unscaled weights that represent the cost of some of the most frequently provided OPSS services. For CY 2023, as we did for CY 2022, we proposed to assign APC 5012 a relative payment weight of 1.00 and to divide the geometric mean cost of each APC by the geometric mean cost for APC 5012 to derive the unscaled relative payment weight for each APC. The choice of the APC on which to standardize the relative payment weights does not affect payments made under the OPSS because we scale the weights for budget neutrality.

We note that in the CY 2019 OPSS/ASC final rule with comment period (83 FR 59004 through 59015) and the CY 2020 OPSS/ASC final rule with comment period (84 FR 61365 through 61369), we discuss our policy, implemented beginning on January 1, 2019, to control for unnecessary increases in the volume of covered outpatient department services by paying for clinic visits furnished at excepted off-campus provider-based departments (PBDs) at a reduced rate. While the volume associated with these visits is included in the impact model, and thus used in calculating the weight scalar, the policy has a negligible effect on the scalar. Specifically,

under this policy, there is no change to the relativity of the OPPS payment weights because the adjustment is made at the payment level rather than in the cost modeling. Further, under this policy, the savings that result from the change in payments for these clinic visits are not budget neutral. Therefore, the impact of this policy will generally not be reflected in the budget neutrality adjustments, whether the adjustment is to the OPPS relative weights or to the OPPS conversion factor. For a full discussion of this policy, we refer readers to the CY 2020 OPPS/ASC final rule with comment period (84 FR 61142).

Section 1833(t)(9)(B) of the Act requires that APC reclassification and recalibration changes, wage index changes, and other adjustments be made in a budget neutral manner. Budget neutrality ensures that the estimated aggregate weight under the OPPS for CY 2023 is neither greater than nor less than the estimated aggregate weight that would have been calculated without the changes. To comply with this requirement concerning the APC changes, we propose to compare the estimated aggregate weight using the CY 2022 scaled relative payment weights to the estimated aggregate weight using the proposed CY 2023 unscaled relative payment weights.

For CY 2022, we multiplied the CY 2022 scaled APC relative payment weight applicable to a service paid under the OPPS by the volume of that service from CY 2021 claims to calculate the total relative payment weight for each service. We then added together the total relative payment weight for each of these services in order to calculate an estimated aggregate weight for the year. For CY 2023, we propose to apply the same process using the estimated CY 2023 unscaled relative payment weights rather than scaled relative payment weights. We propose to calculate the weight scalar by dividing the CY 2022 estimated aggregate weight by the unscaled CY 2023 estimated aggregate weight.

For a detailed discussion of the weight scalar calculation, we refer readers to the OPPS claims accounting document available on the CMS website at:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>. Click on the link labeled “CY 2023 OPPS/ASC

Notice of Proposed Rulemaking”, which can be found under the heading “Hospital Outpatient Prospective Payment System Rulemaking” and open the claims accounting document link at the bottom of the page, which is labeled “2023 NPRM OPSS Claims Accounting (PDF)”.

We propose to compare the estimated unscaled relative payment weights in CY 2023 to the estimated total relative payment weights in CY 2022 using CY 2021 claims data, holding all other components of the payment system constant to isolate changes in total weight. Based on this comparison, we propose to adjust the calculated CY 2023 unscaled relative payment weights for purposes of budget neutrality. We propose to adjust the estimated CY 2023 unscaled relative payment weights by multiplying them by a proposed weight scalar of 1.4152 to ensure that the proposed CY 2023 relative payment weights are scaled to be budget neutral. The proposed CY 2023 relative payment weights listed in Addenda A and B to this proposed rule (which are available via the internet on the CMS website) are scaled and incorporate the recalibration adjustments discussed in sections II.A.1 and II.A.2 of this proposed rule.

Section 1833(t)(14) of the Act provides the payment rates for certain specified covered outpatient drugs (SCODs). Section 1833(t)(14)(H) of the Act provides that additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion factor, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9), but shall be taken into account for subsequent years. Therefore, the cost of those SCODs (as discussed in section V.B.2 of this proposed rule) is included in the budget neutrality calculations for the CY 2023 OPSS.

B. Proposed Conversion Factor Update

Section 1833(t)(3)(C)(ii) of the Act requires the Secretary to update the conversion factor used to determine the payment rates under the OPSS on an annual basis by applying the OPD rate increase factor. For purposes of section 1833(t)(3)(C)(iv) of the Act, subject to sections 1833(t)(17) and 1833(t)(3)(F) of the Act, the OPD rate increase factor is equal to the hospital inpatient market basket percentage increase applicable to hospital discharges under

section 1886(b)(3)(B)(iii) of the Act. In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28402), consistent with current law, based on IHS Global, Inc.'s fourth quarter 2021 forecast of the FY 2023 market basket increase, the proposed FY 2023 IPPS market basket update was 3.1 percent. We note that under our regular process for the CY 2023 OPPS/ASC final rule, we will use the market basket update for the FY 2023 IPPS/LTCH PPS final rule, which would be based on IHS Global, Inc.'s second quarter 2022 forecast of the FY 2023 market basket increase. If that forecast is higher than the market basket used for this proposed rule, the CY 2023 OPPS/ASC final rule OPD rate increase factor will reflect that higher market basket estimate.

Specifically, section 1833(t)(3)(F)(i) of the Act requires that, for 2012 and subsequent years, the OPD fee schedule increase factor under subparagraph (C)(iv) be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period) (the "MFP adjustment"). In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692), we finalized our methodology for calculating and applying the MFP adjustment, and then revised this methodology, as discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49509). In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28402), the proposed MFP adjustment for FY 2023 was 0.4 percentage point.

Therefore, we propose that the MFP adjustment for the CY 2023 OPPS will be 0.4 percentage point. We also propose that if more recent data become subsequently available after the publication of the CY 2023 OPPS/ASC proposed rule (for example, a more recent estimate of the market basket increase and/or the MFP adjustment), we would use such updated data, if appropriate, to determine the CY 2023 market basket update and the MFP adjustment, which are

components in calculating the OPD fee schedule increase factor under sections 1833(t)(3)(C)(iv) and 1833(t)(3)(F) of the Act, in the CY 2023 OPPS/ASC final rule.

We note that section 1833(t)(3)(F) of the Act provides that application of this subparagraph may result in the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act being less than 0.0 percent for a year, and may result in OPPS payment rates being less than rates for the preceding year. As described in further detail below, we propose for CY 2023 an OPD fee schedule increase factor of 2.7 percent for the CY 2023 OPPS (which is the proposed estimate of the hospital inpatient market basket percentage increase of 3.1 percent, less the proposed 0.4 percentage point MFP adjustment).

We propose that hospitals that fail to meet the Hospital OQR Program reporting requirements would be subject to an additional reduction of 2.0 percentage points from the OPD fee schedule increase factor adjustment to the conversion factor that would be used to calculate the OPPS payment rates for their services, as required by section 1833(t)(17) of the Act. For further discussion of the Hospital OQR Program, we refer readers to section XIV of this proposed rule.

To set the OPPS conversion factor for 2023, we propose to increase the CY 2022 conversion factor of \$84.177 by 2.7 percent. In accordance with section 1833(t)(9)(B) of the Act, we proposed further to adjust the conversion factor for CY 2023 to ensure that any revisions made to the wage index and rural adjustment are made on a budget neutral basis. We propose to calculate an overall budget neutrality factor of 1.0010 for wage index changes by comparing proposed total estimated payments from our simulation model using the proposed FY 2023 IPPS wage indexes to those payments using the FY 2022 IPPS wage indexes, as adopted on a calendar year basis for the OPPS. We further propose to calculate an additional budget neutrality factor of 0.9995 to account for our proposed policy to cap wage index reductions for hospitals at 5 percent on an annual basis.

For the CY 2023 OPPS, we propose to maintain the current rural adjustment policy, as discussed in section II.E. of this proposed rule. Therefore, the proposed budget neutrality factor for the rural adjustment is 1.0000.

We propose to continue previously established policies for implementing the cancer hospital payment adjustment described in section 1833(t)(18) of the Act, as discussed in section II.F of this proposed rule. We propose to calculate a CY 2023 budget neutrality adjustment factor for the cancer hospital payment adjustment by comparing estimated total CY 2023 payments under section 1833(t) of the Act, including the proposed CY 2023 cancer hospital payment adjustment, to estimated CY 2023 total payments using the CY 2022 final cancer hospital payment adjustment, as required under section 1833(t)(18)(B) of the Act. The proposed CY 2023 estimated payments applying the proposed CY 2023 cancer hospital payment adjustment were the same as estimated payments applying the CY 2022 final cancer hospital payment adjustment. Therefore, we propose to apply a budget neutrality adjustment factor of 1.0000 to the conversion factor for the cancer hospital payment adjustment. In accordance with section 1833(t)(18)(C), as added by section 16002(b) of the 21st Century Cures Act (Pub. L. 114-255), we are applying a budget neutrality factor calculated as if the proposed cancer hospital adjustment target payment-to-cost ratio was 0.90, not the 0.89 target payment-to-cost ratio we applied as stated in section II.F. of this proposed rule.

We estimate that proposed pass-through spending for drugs, biologicals, and devices for CY 2023 would equal approximately \$772.0 million, which represents 0.90 percent of total projected CY 2023 OPPS spending. Therefore, the proposed conversion factor would be adjusted by the difference between the 1.24 percent estimate of pass-through spending for CY 2022 and the 0.90 percent estimate of proposed pass-through spending for CY 2023, resulting in a proposed increase to the conversion factor for CY 2023 of 0.34 percent.

Proposed estimated payments for outliers would remain at 1.0 percent of total OPPS payments for CY 2023. We estimate for the proposed rule that outlier payments would be

approximately 1.29 percent of total OPPS payments in CY 2022; the 1.00 percent for proposed outlier payments in CY 2023 would constitute a 0.29 percent decrease in payment in CY 2023 relative to CY 2022.

We also propose to make an OPPS budget neutrality adjustment of 0.01 percent of the OPPS for the estimated spending of \$8.3 million associated with the proposed payment adjustment under the CY 2023 OPPS for domestic NIOSH-approved surgical N95 respirators, as discussed in section X.H of this proposed rule.

For CY 2023, we also propose that hospitals that fail to meet the reporting requirements of the Hospital OQR Program would continue to be subject to a further reduction of 2.0 percentage points to the OPD fee schedule increase factor. For hospitals that fail to meet the requirements of the Hospital OQR Program, we proposed to make all other adjustments discussed above, but use a reduced OPD fee schedule update factor of 0.7 percent (that is, the proposed OPD fee schedule increase factor of 2.7 percent further reduced by 2.0 percentage points). This would result in a proposed reduced conversion factor for CY 2023 of \$85.093 for hospitals that fail to meet the Hospital OQR Program requirements (a difference of -1.692 in the conversion factor relative to hospitals that met the requirements).

In summary, for 2023, we propose to use a reduced conversion factor of \$85.093 in the calculation of payments for hospitals that fail to meet the Hospital OQR Program requirements (a difference of -1.692 in the conversion factor relative to hospitals that met the requirements).

For 2023, we propose to use a conversion factor of \$86.785 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using geometric mean costs; that is, the proposed OPD fee schedule increase factor of 2.7 percent for CY 2023, the required proposed wage index budget neutrality adjustment of approximately 1.0010, the proposed 5 percent annual cap for individual hospital wage index reductions adjustment of approximately 0.9995, the proposed cancer hospital payment adjustment of 1.0000, the proposed adjustment to account for the 0.01 percentage point of OPPS

spending associated with the payment adjustment for domestic NIOSH-approved surgical N95 respirators, and the proposed adjustment of an increase of 0.34 percentage point of projected OPPS spending for the difference in pass-through spending, which that result in a proposed conversion factor for CY 2023 of \$86.785.

C. Proposed Wage Index Changes

Section 1833(t)(2)(D) of the Act requires the Secretary to determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner (codified at 42 CFR 419.43(a)). This portion of the OPPS payment rate is called the OPPS labor-related share. Budget neutrality is discussed in section II.B of this proposed rule.

The OPPS labor-related share is 60 percent of the national OPPS payment. This labor-related share is based on a regression analysis that determined that, for all hospitals, approximately 60 percent of the costs of services paid under the OPPS were attributable to wage costs. We confirmed that this labor-related share for outpatient services is appropriate during our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553). We propose to continue this policy for the CY 2023 OPPS. We refer readers to section II.H of this proposed rule for a description and an example of how the wage index for a particular hospital is used to determine payment for the hospital.

As discussed in the claims accounting narrative included with the supporting documentation for this proposed rule (which is available via the Internet on the CMS website), for estimating APC costs, we would standardize 60 percent of estimated claims costs for geographic area wage variation using the same FY 2023 pre-reclassified wage index that we use under the IPPS to standardize costs. This standardization process removes the effects of differences in area wage levels from the determination of a national unadjusted OPPS payment rate and copayment amount.

Under 42 CFR 419.41(c)(1) and 419.43(c) (published in the OPPS April 7, 2000 final rule with comment period (65 FR 18495 and 18545)), the OPPS adopted the final fiscal year IPPS post-reclassified wage index as the calendar year wage index for adjusting the OPPS standard payment amounts for labor market differences. Therefore, the wage index that applies to a particular acute care, short-stay hospital under the IPPS also applies to that hospital under the OPPS. As initially explained in the September 8, 1998 OPPS proposed rule (63 FR 47576), we believe that using the IPPS wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall. In accordance with section 1886(d)(3)(E) of the Act, the IPPS wage index is updated annually.

The Affordable Care Act contained several provisions affecting the wage index. These provisions were discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74191). Section 10324 of the Affordable Care Act added section 1886(d)(3)(E)(iii)(II) to the Act, which defines a frontier State and amended section 1833(t) of the Act to add paragraph (19), which requires a frontier State wage index floor of 1.00 in certain cases, and states that the frontier State floor shall not be applied in a budget neutral manner. We codified these requirements at § 419.43(c)(2) and (3) of our regulations. For 2023, we propose to implement this provision in the same manner as we have since CY 2011. Under this policy, the frontier State hospitals would receive a wage index of 1.00 if the otherwise applicable wage index (including reclassification, the rural floor, and rural floor budget neutrality) is less than 1.00. Because the HOPD receives a wage index based on the geographic location of the specific inpatient hospital with which it is associated, the frontier State wage index adjustment applicable for the inpatient hospital also would apply for any associated HOPD. We refer readers to the FY 2011 through FY 2022 IPPS/LTCH PPS final rules for discussions regarding this provision, including our methodology for identifying which areas meet the definition of “frontier States” as provided for in section 1886(d)(3)(E)(iii)(II) of the Act: for FY 2011, 75 FR 50160 through

50161; for FY 2012, 76 FR 51793, 51795, and 51825; for FY 2013, 77 FR 53369 through 53370; for FY 2014, 78 FR 50590 through 50591; for FY 2015, 79 FR 49971; for FY 2016, 80 FR 49498; for FY 2017, 81 FR 56922; for FY 2018, 82 FR 38142; for FY 2019, 83 FR 41380; for FY 2020, 84 FR 42312; for FY 2021, 85 FR 58765; and for FY 2022, 86 FR 45178.

In addition to the changes required by the Affordable Care Act, we note that the proposed FY 2023 IPPS wage indexes continue to reflect a number of adjustments implemented in past years, including, but not limited to, reclassification of hospitals to different geographic areas, the rural floor provisions, the imputed floor wage index adjustment in all-urban states, an adjustment for occupational mix, an adjustment to the wage index based on commuting patterns of employees (the out-migration adjustment), and an adjustment to the wage index for certain low wage index hospitals to help address wage index disparities between low and high wage index hospitals. We refer readers to the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28357 through 28380) for a detailed discussion of all proposed changes to the FY 2023 IPPS wage indexes. We note in particular that in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28377 through 28380), we proposed a permanent approach to smooth year-to-year decreases in hospitals' wage indexes. Specifically, for FY 2023 and subsequent years, we proposed to apply a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY, regardless of the circumstances causing the decline. That is, we proposed that a hospital's wage index for FY 2023 would not be less than 95 percent of its final wage index for FY 2022, and that for subsequent years, a hospital's wage index would not be less than 95 percent of its final wage index for the prior FY. We stated that we believe this policy would increase the predictability of IPPS payments for hospitals and mitigate instability and significant negative impacts to hospitals resulting from changes to the wage index. It would also eliminate the need for temporary and potentially uncertain transition adjustments to the wage index in the future due to specific policy changes or circumstances outside hospitals' control.

CBSAs are made up of one or more constituent counties. Each CBSA and constituent county has its own unique identifying codes. The FY 2018 IPPS/LTCH PPS final rule (82 FR 38130) discussed the two different lists of codes to identify counties: Social Security Administration (SSA) codes and Federal Information Processing Standard (FIPS) codes. Historically, CMS listed and used SSA and FIPS county codes to identify and crosswalk counties to CBSA codes for purposes of the IPPS and OPSS wage indexes. However, the SSA county codes are no longer being maintained and updated, although the FIPS codes continue to be maintained by the U.S. Census Bureau. The Census Bureau's most current statistical area information is derived from ongoing census data received since 2010; the most recent data are from 2015. The Census Bureau maintains a complete list of changes to counties or county equivalent entities on the website at: <https://www.census.gov/geo/reference/county-changes.html> (which, as of May 6, 2019, migrated to: <https://www.census.gov/programs-surveys/geography.html>). In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38130), for purposes of crosswalking counties to CBSAs for the IPPS wage index, we finalized our proposal to discontinue the use of the SSA county codes and begin using only the FIPS county codes. Similarly, for the purposes of crosswalking counties to CBSAs for the OPSS wage index, in the CY 2018 OPSS/ASC final rule with comment period (82 FR 59260), we finalized our proposal to discontinue the use of SSA county codes and begin using only the FIPS county codes. For CY 2023, under the OPSS, we are continuing to use only the FIPS county codes for purposes of crosswalking counties to CBSAs.

We propose to use the FY 2023 IPPS post-reclassified wage index for urban and rural areas as the wage index for the OPSS to determine the wage adjustments for both the OPSS payment rate and the copayment rate for CY 2023. Therefore, any policies and adjustments for the FY 2023 IPPS post-reclassified wage index, including, but not limited to, the 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY described above, would be reflected in the final CY 2023 OPSS wage index beginning on January 1, 2023. We

refer readers to the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28357 through 28380) and the proposed FY 2023 hospital wage index files posted on the CMS website at <https://www.cms.gov/medicare/acute-inpatient-pps/fy-2023-ipp-pps-proposed-rule-home-page>.

With regard to budget neutrality for the CY 2023 OPSS wage index, we refer readers to section II.B of this proposed rule. We continue to believe that using the IPPS post-reclassified wage index as the source of an adjustment factor for the OPSS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall.

Hospitals that are paid under the OPSS, but not under the IPPS, do not have an assigned hospital wage index under the IPPS. Therefore, for non-IPPS hospitals paid under the OPSS, it is our longstanding policy to assign the wage index that would be applicable if the hospital was paid under the IPPS, based on its geographic location and any applicable wage index policies and adjustments. We propose to continue this policy for CY 2023 and are including below a brief summary of the major proposed FY 2023 IPPS wage index policies and adjustments that we propose to apply to these hospitals under the OPSS for CY 2023. We refer readers to the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28357 through 28380) for a detailed discussion of the proposed changes to the FY 2023 IPPS wage indexes.

It has been our longstanding policy to allow non-IPPS hospitals paid under the OPSS to qualify for the out-migration adjustment if they are located in a section 505 out-migration county (section 505 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)). Applying this adjustment is consistent with our policy of adopting IPPS wage index policies for hospitals paid under the OPSS. We note that, because non-IPPS hospitals cannot reclassify, they are eligible for the out-migration wage index adjustment if they are located in a section 505 out-migration county. This is the same out-migration adjustment policy that would apply if the hospital were paid under the IPPS. For CY 2023, we propose to continue our policy of allowing non-IPPS hospitals paid under the OPSS to qualify for the outmigration adjustment if they are located in a section 505 out-migration county (section 505 of the MMA). Furthermore,

we propose that the wage index that would apply for CY 2023 to non-IPPS hospitals paid under the OPSS would continue to include the rural floor adjustment and any policies and adjustments applied to the IPPS wage index to address wage index disparities. In addition, the wage index that would apply to non-IPPS hospitals paid under the OPSS would include the 5 percent cap on wage index decreases that we may finalize for the FY 2023 IPPS wage index as discussed previously.

For CMHCs, for CY 2023, we propose to continue to calculate the wage index by using the post-reclassification IPPS wage index based on the CBSA where the CMHC is located. Furthermore, we propose that the wage index that would apply to a CMHC for CY 2023 would continue to include the rural floor adjustment and any policies and adjustments applied to the IPPS wage index to address wage index disparities. In addition, the wage index that would apply to CMHCs would include the 5 percent cap on wage index decreases that we may finalize for the FY 2023 IPPS wage index as discussed above. Also, we propose that the wage index that would apply to CMHCs would not include the outmigration adjustment because that adjustment only applies to hospitals.

Table 4A associated with the FY 2023 IPPS/LTCH PPS final rule (available via the internet on the CMS website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index>) identifies counties eligible for the out-migration adjustment. Table 2 associated with the FY 2023 IPPS/ LTCH PPS final rule (available for download via the website above) identifies IPPS hospitals that receive the out-migration adjustment for FY 2023. We are including the outmigration adjustment information from Table 2 associated with the FY 2023 IPPS/LTCH PPS proposed rule as Addendum L to this proposed rule, with the addition of non-IPPS hospitals that would receive the section 505 outmigration adjustment under this proposed rule. Addendum L is available via the internet on the CMS website. We refer readers to the CMS website for the OPSS at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index>. At this link, readers will find a link to the proposed

FY 2023 IPPS wage index tables and Addendum L.

D. Proposed Statewide Average Default Cost-to-Charge Ratios (CCRs)

In addition to using CCRs to estimate costs from charges on claims for ratesetting, we use overall hospital-specific CCRs calculated from the hospital's most recent cost report to determine outlier payments, payments for pass-through devices, and monthly interim transitional outpatient payments (TOPs) under the OPSS during the PPS year. For certain hospitals, under the regulations at 42 CFR 419.43(d)(5)(iii), we use the statewide average default CCRs to determine the payments mentioned earlier if it is not possible to determine an accurate CCR for a hospital in certain circumstances. This includes hospitals that are new, hospitals that have not accepted assignment of an existing hospital's provider agreement, and hospitals that have not yet submitted a cost report. We also use the statewide average default CCRs to determine payments for hospitals whose CCR falls outside the predetermined ceiling threshold for a valid CCR or for hospitals in which the most recent cost report reflects an all-inclusive rate status (Medicare Claims Processing Manual (Pub. 100-04), Chapter 4, Section 10.11).

We discussed our policy for using default CCRs, including setting the ceiling threshold for a valid CCR, in the CY 2009 OPSS/ASC final rule with comment period (73 FR 68594 through 68599) in the context of our adoption of an outlier reconciliation policy for cost reports beginning on or after January 1, 2009. For details on our process for calculating the statewide average CCRs, we refer readers to the CY 2023 OPSS proposed rule Claims Accounting document that is posted on our website. Due to concerns with cost report data as a result of the COVID-19 PHE, we propose to calculate the default ratios for CY 2023 using the June 2020 HCRIS cost reports, consistent with the broader proposal regarding CY 2023 OPSS ratesetting discussed in section X of this proposed rule.

We no longer publish a table in the **Federal Register** containing the statewide average CCRs in the annual OPSS proposed rule and final rule with comment period. These CCRs with the upper limit will be available for download with each OPSS CY proposed rule and final rule

on the CMS website. We refer readers to our website at:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service->

[Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html); click on the link on the left of the page titled “Hospital Outpatient Regulations and Notices” and then select the relevant regulation to download the statewide CCRs and upper limit in the Downloads section of the webpage.

E. Proposed Adjustment for Rural Sole Community Hospitals (SCHs) and Essential Access Community Hospitals (EACHs) under Section 1833(t)(13)(B) of the Act for CY 2023

In the CY 2006 OPSS final rule with comment period (70 FR 68556), we finalized a payment increase for rural sole community hospitals (SCHs) of 7.1 percent for all services and procedures paid under the OPSS, excluding drugs, biologicals, brachytherapy sources, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act, as added by section 411 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173). Section 1833(t)(13) of the Act provided the Secretary the authority to make an adjustment to OPSS payments for rural hospitals, effective January 1, 2006, if justified by a study of the difference in costs by APC between hospitals in rural areas and hospitals in urban areas. Our analysis showed a difference in costs for rural SCHs. Therefore, for the CY 2006 OPSS, we finalized a payment adjustment for rural SCHs of 7.1 percent for all services and procedures paid under the OPSS, excluding separately payable drugs and biologicals, brachytherapy sources, items paid at charges reduced to costs, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act.

In the CY 2007 OPSS/ASC final rule with comment period (71 FR 68010 and 68227), for purposes of receiving this rural adjustment, we revised our regulations at § 419.43(g) to clarify that essential access community hospitals (EACHs) are also eligible to receive the rural SCH adjustment, assuming these entities otherwise meet the rural adjustment criteria. Currently, two

hospitals are classified as EACHs, and as of CY 1998, under section 4201(c) of Pub. L. 105-33, a hospital can no longer become newly classified as an EACH.

This adjustment for rural SCHs is budget neutral and applied before calculating outlier payments and copayments. We stated in the CY 2006 OPPS final rule with comment period (70 FR 68560) that we would not reestablish the adjustment amount on an annual basis, but we may review the adjustment in the future and, if appropriate, would revise the adjustment. We provided the same 7.1 percent adjustment to rural SCHs, including EACHs, again in CYs 2008 through 2022.

For CY 2023, we propose to continue the current policy of a 7.1 percent payment adjustment for rural SCHs, including EACHs, for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, items paid at charges reduced to costs, and devices paid under the pass-through payment policy, applied in a budget neutral manner.

F. Proposed Payment Adjustment for Certain Cancer Hospitals for CY 2023

1. Background

Since the inception of the OPPS, which was authorized by the Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33), Medicare has paid the 11 hospitals that meet the criteria for cancer hospitals identified in section 1886(d)(1)(B)(v) of the Act under the OPPS for covered outpatient hospital services. These cancer hospitals are exempted from payment under the IPPS. With the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999 (Pub. L. 106-113), the Congress added section 1833(t)(7), “Transitional Adjustment to Limit Decline in Payment,” to the Act, which requires the Secretary to determine OPPS payments to cancer and children’s hospitals based on their pre-BBA payment amount (these hospitals are often referred to under this policy as “held harmless” and their payments are often referred to as “hold harmless” payments).

As required under section 1833(t)(7)(D)(ii) of the Act, a cancer hospital receives the full amount of the difference between payments for covered outpatient services under the OPSS and a “pre-BBA amount.” That is, cancer hospitals are permanently held harmless to their “pre-BBA amount,” and they receive transitional outpatient payments (TOPs) or hold harmless payments to ensure that they do not receive a payment that is lower in amount under the OPSS than the payment amount they would have received before implementation of the OPSS, as set forth in section 1833(t)(7)(F) of the Act. The “pre-BBA amount” is the product of the hospital’s reasonable costs for covered outpatient services occurring in the current year and the base payment-to-cost ratio (PCR) for the hospital defined in section 1833(t)(7)(F)(ii) of the Act. The “pre-BBA amount” and the determination of the base PCR are defined at § 419.70(f). TOPs are calculated on Worksheet E, Part B, of the Hospital Cost Report or the Hospital Health Care Complex Cost Report (Form CMS–2552–96 or Form CMS–2552–10, respectively), as applicable each year. Section 1833(t)(7)(I) of the Act exempts TOPs from budget neutrality calculations.

Section 3138 of the Affordable Care Act amended section 1833(t) of the Act by adding a new paragraph (18), which instructs the Secretary to conduct a study to determine if, under the OPSS, outpatient costs incurred by cancer hospitals described in section 1886(d)(1)(B)(v) of the Act with respect to APC groups exceed outpatient costs incurred by other hospitals furnishing services under section 1833(t) of the Act, as determined appropriate by the Secretary. Section 1833(t)(18)(A) of the Act requires the Secretary to take into consideration the cost of drugs and biologicals incurred by cancer hospitals and other hospitals. Section 1833(t)(18)(B) of the Act provides that, if the Secretary determines that cancer hospitals’ costs are higher than those of other hospitals, the Secretary shall provide an appropriate adjustment under section 1833(t)(2)(E) of the Act to reflect these higher costs. In 2011, after conducting the study required by section 1833(t)(18)(A) of the Act, we determined that outpatient costs incurred by the 11 specified cancer hospitals were greater than the costs incurred by other OPSS hospitals.

For a complete discussion regarding the cancer hospital cost study, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74200 through 74201).

Based on these findings, we finalized a policy to provide a payment adjustment to the 11 specified cancer hospitals that reflects their higher outpatient costs, as discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74202 through 74206).

Specifically, we adopted a policy to provide additional payments to the cancer hospitals so that each cancer hospital's final PCR for services provided in a given calendar year is equal to the weighted average PCR (which we refer to as the "target PCR") for other hospitals paid under the OPPS. The target PCR is set in advance of the calendar year and is calculated using the most recently submitted or settled cost report data that are available at the time of final rulemaking for the calendar year. The amount of the payment adjustment is made on an aggregate basis at cost report settlement. We note that the changes made by section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs are assessed, as usual, after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period. Table 3 displays the target PCR for purposes of the cancer hospital adjustment for CY 2012 through CY 2022.

TABLE 3: CANCER HOSPITAL ADJUSTMENT TARGET PAYMENT PAYMENT-TO-COST RATIOS (PCRs), CY 2012 THROUGH CY 2022

Calendar Year	Target PCR
2012	0.91
2013	0.91
2014	0.90
2015	0.90
2016	0.92
2017	0.91
2018	0.88
2019	0.88
2020	0.89
2021	0.89
2022	0.89

2. Proposed Policy for CY 2023

Section 16002(b) of the 21st Century Cures Act (Pub. L. 114-255) amended section 1833(t)(18) of the Act by adding subparagraph (C), which requires that in applying § 419.43(i) (that is, the payment adjustment for certain cancer hospitals) for services furnished on or after January 1, 2018, the target PCR adjustment be reduced by 1.0 percentage point less than what would otherwise apply. Section 16002(b) also provides that, in addition to the percentage reduction, the Secretary may consider making an additional percentage point reduction to the target PCR that takes into account payment rates for applicable items and services described under section 1833(t)(21)(C) of the Act for hospitals that are not cancer hospitals described under section 1886(d)(1)(B)(v) of the Act. Further, in making any budget neutrality adjustment under section 1833(t) of the Act, the Secretary shall not take into account the reduced expenditures that result from application of section 1833(t)(18)(C) of the Act.

We propose to provide additional payments to the 11 specified cancer hospitals so that each cancer hospital's proposed PCR is equal to the weighted average PCR (or "target PCR") for the other OPPS hospitals, generally using the most recent submitted or settled cost report data that are available, reduced by 1.0 percentage point, to comply with section 16002(b) of the 21st Century Cures Act. We do not propose an additional reduction beyond the 1.0 percentage point reduction required by section 16002(b) of the 21st Century Cures Act for CY 2023.

Under our established policy, to calculate the proposed CY 2023 target PCR, we would use the same extract of cost report data from HCRIS used to estimate costs for the CY 2023 OPSS which, in most cases, would be the most recently available hospital cost reports. However, as discussed in section II.A.1.c and X.C of this proposed rule, we propose to use cost report data from the June 2020 HCRIS data set, which does not contain cost reports from CY 2020, given our concerns with CY 2020 cost report data as a result of the COVID-19 PHE. We believe a target PCR based on the most recently available cost reports may provide a less accurate estimation of cancer hospital PCRs and non-cancer hospital PCRs than the data used for the CY 2022 rulemaking cycle, which pre-dated the COVID-19 PHE. Therefore, for CY 2023, we propose to continue to use the same target PCR we used for CY 2021 and CY 2022 of 0.89. This proposed CY 2023 target PCR of 0.89 includes the 1.0-percentage point reduction required by section 16002(b) of the 21st Century Cures Act for CY 2023. For a description of the CY 2021 target PCR calculation, on which the proposed CY 2023 target PCR is based, we refer readers to the CY 2021 OPSS/ASC final rule with comment period (84 FR 85912 through 85914).

Table 4 shows the proposed estimated percentage increase in OPSS payments to each cancer hospital for CY 2023, due to the cancer hospital payment adjustment policy. The cost reporting periods for all cancer hospitals in Table 4 overlaps with CY 2020 and the costs and payments associated with each cancer hospital may be impacted by the effects of the COVID-19 PHE. Therefore, the estimates in Table 4 are likely to be less accurate than in other years and may overstate the percentage increase in cancer hospital payments for CY 2023. The actual, final amount of the CY 2023 cancer hospital payment adjustment for each cancer hospital would be determined at cost report settlement and would depend on each hospital's CY 2023 payments and costs from the settled CY 2023 cost report. We note that the requirements contained in section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for

TOPs for cancer hospitals. The TOPs will be assessed, as usual, after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period.

TABLE 4: Estimated CY 2023 Hospital-Specific Payment Adjustment For Cancer Hospitals To Be Provided At Cost Report Settlement

Provider Number	Hospital Name	Estimated Percentage Increase in OPPS Payments for CY 2023 due to Payment Adjustment
050146	City of Hope Comprehensive Cancer Center	45.5%
050660	USC Norris Cancer Hospital	31.7%
100079	Sylvester Comprehensive Cancer Center	24.1%
100271	H. Lee Moffitt Cancer Center & Research Institute	23.1%
220162	Dana-Farber Cancer Institute	42.7%
330154	Memorial Sloan-Kettering Cancer Center	69.2%
330354	Roswell Park Cancer Institute	15.2%
360242	James Cancer Hospital & Solove Research Institute	12.9%
390196	Fox Chase Cancer Center	23.5%
450076	M.D. Anderson Cancer Center	49.4%
500138	Seattle Cancer Care Alliance	46.1%

G. Proposed Hospital Outpatient Outlier Payments

1. Background

The OPSS provides outlier payments to hospitals to help mitigate the financial risk associated with high-cost and complex procedures, where a very costly service could present a hospital with significant financial loss. As explained in the CY 2015 OPSS/ASC final rule with comment period (79 FR 66832 through 66834), we set our projected target for aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPSS for the prospective year. Outlier payments are provided on a service-by-service basis when the cost of a service exceeds the APC payment amount multiplier threshold (the APC payment amount multiplied by a certain amount) as well as the APC payment amount plus a fixed-dollar amount threshold (the APC payment plus a certain dollar amount). In CY 2022, the outlier threshold was

met when the hospital's cost of furnishing a service exceeded 1.75 times (the multiplier threshold) the APC payment amount and exceeded the APC payment amount plus \$6,175 (the fixed-dollar amount threshold) (86 FR 63508 through 63510). If the hospital's cost of furnishing a service exceeds both the multiplier threshold and the fixed-dollar threshold, the outlier payment is calculated as 50 percent of the amount by which the hospital's cost of furnishing the service exceeds 1.75 times the APC payment amount. Beginning with CY 2009 payments, outlier payments are subject to a reconciliation process similar to the IPPS outlier reconciliation process for cost reports, as discussed in the CY 2009 OPSS/ASC final rule with comment period (73 FR 68594 through 68599).

It has been our policy to report the actual amount of outlier payments as a percent of total spending in the claims being used to model the OPSS. Our estimate of total outlier payments as a percent of total CY 2021 OPSS payments, using CY 2021 claims available for this CY 2023 OPSS/ASC proposed rule, is approximately 1.0 percent. Therefore, for CY 2021, we estimated that we paid the outlier target of 1.0 percent of total aggregated OPSS payments. Using an updated claims dataset for this proposed rule, we estimate that we paid approximately 1.01 percent of the total aggregate OPSS payments in outliers for CY 2021.

For this proposed rule, using CY 2021 claims data and CY 2022 payment rates, we estimate that the aggregate outlier payments for CY 2022 would be approximately 1.07 percent of the total CY 2022 OPSS payments. We provide estimated CY 2023 outlier payments for hospitals and CMHCs with claims included in the claims data that we used to model impacts in the Hospital-Specific Impacts - Provider-Specific Data file on the CMS website at:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>.

2. Outlier Calculation for CY 2023

For CY 2023, we propose to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPSS. We propose that a portion of

that 1.0 percent, an amount equal to less than 0.01 percent of outlier payments (or 0.0001 percent of total OPSS payments), would be allocated to CMHCs for PHP outlier payments. This is the amount of estimated outlier payments that would result from the proposed CMHC outlier threshold as a proportion of total estimated OPSS outlier payments. We propose to continue our longstanding policy that if a CMHC's cost for partial hospitalization services, paid under APC 5853 (Partial Hospitalization for CMHCs), exceeds 3.40 times the payment rate for proposed APC 5853, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the proposed APC 5853 payment rate.

For further discussion of CMHC outlier payments, we refer readers to section VIII.C of this proposed rule.

To ensure that the estimated CY 2023 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPSS, we propose that the hospital outlier threshold be set so that outlier payments would be triggered when a hospital's cost of furnishing a service exceeds 1.75 times the APC payment amount and exceeds the APC payment amount plus \$8,350.

We calculate the proposed fixed-dollar threshold of \$8,350 using the standard methodology most recently used for CY 2022 (86 FR 63508 through 63510). For purposes of estimating outlier payments for CY 2023, we use the hospital-specific overall ancillary CCRs available in the April 2022 update to the Outpatient Provider-Specific File (OPSF). The OPSF contains provider-specific data, such as the most current CCRs, which are maintained by the MACs and used by the OPSS Pricer to pay claims. The claims that we generally use to model each OPSS update lag by 2 years.

In order to estimate the CY 2023 hospital outlier payments, we inflate the charges on the CY 2021 claims using the same proposed charge inflation factor of 1.13218 that we used to estimate the IPPS fixed-loss cost threshold for the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28667). We used an inflation factor of 1.06404 to estimate CY 2022 charges from the

CY 2021 charges reported on CY 2021 claims before applying CY 2022 CCRs to estimate the percent of outliers paid in CY 2022. The proposed methodology for determining these charge inflation factors, as well as the solicitation of comments on an alternative approach, is discussed in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28667 through 28678). As we stated in the CY 2005 OPSS final rule with comment period (69 FR 65844 through 65846), we believe that the use of the same charge inflation factors is appropriate for the OPSS because, with the exception of the inpatient routine service cost centers, hospitals use the same ancillary and cost centers to capture costs and charges for inpatient and outpatient services.

As noted in the CY 2007 OPSS/ASC final rule with comment period (71 FR 68011), we are concerned that we could systematically overestimate the OPSS hospital outlier threshold if we did not apply a CCR inflation adjustment factor. Therefore, we propose to apply the same CCR adjustment factor that we proposed to apply for the FY 2023 IPPS outlier calculation to the CCRs used to simulate the proposed CY 2023 OPSS outlier payments to determine the fixed-dollar threshold. Specifically, for CY 2023, we propose to apply an adjustment factor of 0.974495 to the CCRs that were in the April 2022 OPSF to trend them forward from CY 2022 to CY 2023. The methodology for calculating the proposed CCR adjustment factor, as well as the solicitation of comments on an alternative approach, is discussed in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28668). We note that we propose to use the April 2022 OPSF for purposes of estimating costs for the OPSS outlier threshold calculation whereas in section X of this proposed rule we discussed using June 2020 HCRIS data extract for modeling hospital outpatient costs in construction of our CY 2023 OPSS relative weights. For modeling estimated outlier payments, since the April 2022 OPSF contains cost data primarily from CY 2021 and CY 2022 and is the basis for current CY 2022 OPSS outlier payments, we believe the April 2022 OPSF provides a more updated and accurate data source for determining the CCRs that will be applied to CY 2023 hospital outpatient claims. Therefore, we believe the April 2022 OPSF is a more accurate data source for determining the fixed-dollar threshold to ensure that the estimated

CY 2023 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPPS.

To model hospital outlier payments for this CY proposed rule, we apply the overall CCRs from the April 2022 OPSF after adjustment (using the proposed CCR inflation adjustment factor of 0.974495 to approximate CY 2023 CCRs) to charges on CY 2021 claims that were adjusted (using the proposed charge inflation factor of 1.13218 to approximate CY 2023 charges). We simulated aggregated CY 2021 hospital outlier payments using these costs for several different fixed-dollar thresholds, holding the 1.75 multiplier threshold constant and assuming that outlier payments would continue to be made at 50 percent of the amount by which the cost of furnishing the service would exceed 1.75 times the APC payment amount, until the total outlier payments equaled 1.0 percent of aggregated estimated total CY 2023 OPSS payments. We estimated that a proposed fixed-dollar threshold of \$8,350, combined with the proposed multiplier threshold of 1.75 times the APC payment rate, would allocate 1.0 percent of aggregated total OPSS payments to outlier payments. For CMHCs, we propose that, if a CMHC's cost for partial hospitalization services, paid under APC 5853, exceeds 3.40 times the payment rate for APC 5853, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 5853 payment rate.

Section 1833(t)(17)(A) of the Act, which applies to hospitals, as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to report data required for the quality measures selected by the Secretary, in the form and manner required by the Secretary under section 1833(t)(17)(B) of the Act, incur a 2.0 percentage point reduction to their OPD fee schedule increase factor; that is, the annual payment update factor. The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that would apply to certain outpatient items and services furnished by hospitals that are required to report outpatient quality data and that fail to meet the Hospital OQR Program requirements. For hospitals that fail to meet the Hospital OQR Program requirements, we propose to continue the

policy that we implemented in CY 2010 that the hospitals' costs would be compared to the reduced payments for purposes of outlier eligibility and payment calculation. For more information on the Hospital OQR Program, we refer readers to section XIV of this proposed rule.

H. Proposed Calculation of an Adjusted Medicare Payment from the National Unadjusted Medicare Payment

The basic methodology for determining prospective payment rates for HOPD services under the OPPS is set forth in existing regulations at 42 CFR part 419, subparts C and D. For this CY 2023 proposed rule, the proposed payment rate for most services and procedures for which payment is made under the OPPS is the product of the conversion factor calculated in accordance with section II.B of this proposed rule and the relative payment weight described in section II.A. of this proposed rule. Therefore, the national unadjusted payment rate for most APCs contained in Addendum A to this proposed rule (which is available via the Internet on the CMS website) and for most HCPCS codes to which separate payment under the OPPS has been assigned in Addendum B to this proposed rule (which is available via the Internet on the CMS website) is calculated by multiplying the proposed CY 2023 scaled weight for the APC by the CY 2023 conversion factor.

We note that section 1833(t)(17) of the Act, which applies to hospitals, as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to submit data required to be submitted on quality measures selected by the Secretary, in the form and manner and at a time specified by the Secretary, incur a reduction of 2.0 percentage points to their OPD fee schedule increase factor, that is, the annual payment update factor. The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data and that fail to meet the Hospital OQR Program requirements. For further discussion of the payment reduction for hospitals that fail to meet the requirements of the Hospital OQR Program, we refer readers to section XIV. of this proposed rule.

We demonstrate the steps used to determine the APC payments that will be made in a CY under the OPSS to a hospital that fulfills the Hospital OQR Program requirements and to a hospital that fails to meet the Hospital OQR Program requirements for a service that has any of the following status indicator assignments: “J1”, “J2”, “P”, “Q1”, “Q2”, “Q3”, “Q4”, “R”, “S”, “T”, “U”, or “V” (as defined in Addendum D1 to this proposed rule, which is available via the Internet on the CMS website), in a circumstance in which the multiple procedure discount does not apply, the procedure is not bilateral, and conditionally packaged services (status indicator of “Q1” and “Q2”) qualify for separate payment. We note that, although blood and blood products with status indicator “R” and brachytherapy sources with status indicator “U” are not subject to wage adjustment, they are subject to reduced payments when a hospital fails to meet the Hospital OQR Program requirements.

Individual providers interested in calculating the payment amount that they will receive for a specific service from the national unadjusted payment rates presented in Addenda A and B to this proposed rule (which are available via the Internet on the CMS website) should follow the formulas presented in the following steps. For purposes of the payment calculations below, we refer to the national unadjusted payment rate for hospitals that meet the requirements of the Hospital OQR Program as the “full” national unadjusted payment rate. We refer to the national unadjusted payment rate for hospitals that fail to meet the requirements of the Hospital OQR Program as the “reduced” national unadjusted payment rate. The reduced national unadjusted payment rate is calculated by multiplying the reporting ratio of 0.9805 times the “full” national unadjusted payment rate. The national unadjusted payment rate used in the calculations below is either the full national unadjusted payment rate or the reduced national unadjusted payment rate, depending on whether the hospital met its Hospital OQR Program requirements to receive the full CY 2023 OPSS fee schedule increase factor.

Step 1. Calculate 60 percent (the labor-related portion) of the national unadjusted payment rate. Since the initial implementation of the OPSS, we have used 60 percent to

represent our estimate of that portion of costs attributable, on average, to labor. We refer readers to the April 7, 2000 OPPS/ASC final rule with comment period (65 FR 18496 through 18497) for a detailed discussion of how we derived this percentage. During our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553), we confirmed that this labor-related share for hospital outpatient services is appropriate.

The formula below is a mathematical representation of Step 1 and identifies the labor-related portion of a specific payment rate for a specific service.

X is the labor-related portion of the national unadjusted payment rate.

$X = .60 * (\text{national unadjusted payment rate}).$

Step 2. Determine the wage index area in which the hospital is located and identify the wage index level that applies to the specific hospital. The wage index values assigned to each area would reflect the geographic statistical areas (which are based upon OMB standards) to which hospitals are assigned for FY 2023 under the IPPS, reclassifications through the Medicare Geographic Classification Review Board (MGCRB), section 1886(d)(8)(B) “Lugar” hospitals, and reclassifications under section 1886(d)(8)(E) of the Act, as implemented in § 412.103 of the regulations. We propose to continue to apply for the CY 2023 OPPS wage index any adjustments for the FY 2023 IPPS post-reclassified wage index, including, but not limited to, the rural floor adjustment, a wage index floor of 1.00 in frontier states, in accordance with section 10324 of the Affordable Care Act of 2010, and an adjustment to the wage index for certain low wage index hospitals. For further discussion of the wage index we are applying for the CY 2023 OPPS, we refer readers to section II.C of this proposed rule.

Step 3. Adjust the wage index of hospitals located in certain qualifying counties that have a relatively high percentage of hospital employees who reside in the county, but who work in a different county with a higher wage index, in accordance with section 505 of Pub. L. 108-173. Addendum L to this proposed rule (which is available via the Internet on the

CMS website) contains the qualifying counties and the associated wage index increase developed for the proposed FY 2023 IPPS wage index, which are listed in Table 3 associated with the FY 2023 IPPS proposed rule and available via the Internet on the CMS website at:

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service->

[Payment/AcuteInpatientPPS/index.html](http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html). (Click on the link on the left side of the screen titled “FY 2023 IPPS Proposed Rule Home Page” and select “FY 2023 Proposed Rule Tables.”) This step is to be followed only if the hospital is not reclassified or redesignated under section 1886(d)(8) or section 1886(d)(10) of the Act.

Step 4. Multiply the applicable wage index determined under Steps 2 and 3 by the amount determined under Step 1 that represents the labor-related portion of the national unadjusted payment rate.

The formula below is a mathematical representation of Step 4 and adjusts the labor-related portion of the national unadjusted payment rate for the specific service by the wage index.

X_a is the labor-related portion of the national unadjusted payment rate (wage adjusted).

$X_a = .60 * (\text{national unadjusted payment rate}) * \text{applicable wage index}.$

Step 5. Calculate 40 percent (the nonlabor-related portion) of the national unadjusted payment rate and add that amount to the resulting product of Step 4. The result is the wage index adjusted payment rate for the relevant wage index area.

The formula below is a mathematical representation of Step 5 and calculates the remaining portion of the national payment rate, the amount not attributable to labor, and the adjusted payment for the specific service.

Y is the nonlabor-related portion of the national unadjusted payment rate.

$Y = .40 * (\text{national unadjusted payment rate}).$

Adjusted Medicare Payment = $Y + X_a$.

Step 6. If a provider is an SCH, as set forth in the regulations at § 412.92, or an EACH, which is considered to be an SCH under section 1886(d)(5)(D)(iii)(III) of the Act, and located in a rural area, as defined in § 412.64(b), or is treated as being located in a rural area under § 412.103, multiply the wage index adjusted payment rate by 1.071 to calculate the total payment.

The formula below is a mathematical representation of Step 6 and applies the rural adjustment for rural SCHs.

Adjusted Medicare Payment (SCH or EACH) = Adjusted Medicare Payment * 1.071.

We are providing examples below of the calculation of both the full and reduced national unadjusted payment rates that will apply to certain outpatient items and services performed by hospitals that meet and that fail to meet the Hospital OQR Program requirements, using the steps outlined previously. For purposes of this example, we are using a provider that is located in Brooklyn, New York that is assigned to CBSA 35614. This provider bills one service that is assigned to APC 5071 (Level 1 Excision/Biopsy/Incision and Drainage). The CY 2023 full national unadjusted payment rate for APC 5071 is \$659.86. The proposed reduced national adjusted payment rate for APC 5071 for a hospital that fails to meet the Hospital OQR Program requirements is \$646.99. This proposed reduced rate is calculated by multiplying the reporting ratio of 0.9805 by the full unadjusted payment rate for APC 5071.

The FY 2023 wage index for a provider located in CBSA 35614 in New York, which includes the proposed adoption of IPPS 2023 wage index policies, is 1.3296. The labor-related portion of the proposed full national unadjusted payment is approximately \$526.42 (.60 * \$659.86 * 1.3296). The labor-related portion of the proposed reduced national adjusted payment is approximately \$516.14 (.60 * \$646.99 * 1.3296). The nonlabor-related portion of the proposed full national unadjusted payment is approximately \$263.94 (.40 * \$659.86). The nonlabor-related portion of the proposed reduced national adjusted payment is approximately \$258.80 (.40 * \$646.99). The sum of the labor-related and nonlabor-related portions of the

proposed full national unadjusted payment is approximately \$790.36 (\$526.42 + \$263.94). The sum of the portions of the proposed reduced national adjusted payment is approximately \$774.94 (\$516.14 + \$258.80).

I. Proposed Beneficiary Copayments

1. Background

Section 1833(t)(3)(B) of the Act requires the Secretary to set rules for determining the unadjusted copayment amounts to be paid by beneficiaries for covered OPD services.

Section 1833(t)(8)(C)(ii) of the Act specifies that the Secretary must reduce the national unadjusted copayment amount for a covered OPD service (or group of such services) furnished in a year in a manner so that the effective copayment rate (determined on a national unadjusted basis) for that service in the year does not exceed a specified percentage. As specified in section 1833(t)(8)(C)(ii)(V) of the Act, the effective copayment rate for a covered OPD service paid under the OPDS in CY 2006, and in CYs thereafter, shall not exceed 40 percent of the APC payment rate.

Section 1833(t)(3)(B)(ii) of the Act provides that, for a covered OPD service (or group of such services) furnished in a year, the national unadjusted copayment amount cannot be less than 20 percent of the OPD fee schedule amount. However, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure (including items such as drugs and biologicals) performed in a year to the amount of the inpatient hospital deductible for that year.

Section 4104 of the Affordable Care Act eliminated the Medicare Part B coinsurance for preventive services furnished on and after January 1, 2011, that meet certain requirements, including flexible sigmoidoscopies and screening colonoscopies, and waived the Part B deductible for screening colonoscopies that become diagnostic during the procedure. For a discussion of the changes made by the Affordable Care Act with regard to copayments for

preventive services furnished on and after January 1, 2011 we refer readers to section XII.B. of the CY 2011 OPPTS/ASC final rule with comment period (75 FR 72013).

Section 122 of the Consolidated Appropriations Act (CAA) of 2021 (Pub. L. 116-260), Waiving Medicare Coinsurance for Certain Colorectal Cancer Screening Tests, amends section 1833(a) of the Act to offer a special coinsurance rule for screening flexible sigmoidoscopies and screening colonoscopies, regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure, that is furnished in connection with, as a result of, and in the same clinical encounter as the colorectal cancer screening test. We refer readers to section X.B, “Changes to Beneficiary Coinsurance for Certain Colorectal Cancer Screening Tests” of the CY 2022 OPPTS/ASC final rule with comment period for the full discussion of this policy (86 FR 63740 through 63743). Under the regulation at 42 CFR 410.152(l)(5)(i)(B), the Medicare Part B payment percentage for colorectal cancer screening tests described in the regulation at § 410.37(j) that are furnished in CY 2023 through 2026 (and the corresponding reduction in coinsurance) is 85 percent (with beneficiary coinsurance equal to 15 percent).

2. Proposed OPPTS Copayment Policy

For CY 2023, we propose to determine copayment amounts for new and revised APCs using the same methodology that we implemented beginning in CY 2004. (We refer readers to the November 7, 2003 OPPTS final rule with comment period (68 FR 63458).) In addition, we propose to use the same standard rounding principles that we have historically used in instances where the application of our standard copayment methodology would result in a copayment amount that is less than 20 percent and cannot be rounded, under standard rounding principles, to 20 percent. (We refer readers to the CY 2008 OPPTS/ASC final rule with comment period (72 FR 66687) in which we discuss our rationale for applying these rounding principles.) The proposed national unadjusted copayment amounts for services payable under the OPPTS that

would be effective January 1, 2023 are included in Addenda A and B to this proposed rule (which are available via the Internet on the CMS website).

As discussed in section XIV.E of this proposed rule, for CY 2023, the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies will equal the product of the reporting ratio and the national unadjusted copayment, or the product of the reporting ratio and the minimum unadjusted copayment, respectively, for the service.

We note that OPPS copayments may increase or decrease each year based on changes in the calculated APC payment rates, due to updated cost report and claims data, and any changes to the OPPS cost modeling process. However, as described in the CY 2004 OPPS final rule with comment period, the development of the copayment methodology generally moves beneficiary copayments closer to 20 percent of OPPS APC payments (68 FR 63458 through 63459).

In the CY 2004 OPPS final rule with comment period (68 FR 63459), we adopted a new methodology to calculate unadjusted copayment amounts in situations including reorganizing APCs, and we finalized the following rules to determine copayment amounts in CY 2004 and subsequent years.

- When an APC group consists solely of HCPCS codes that were not paid under the OPPS the prior year because they were packaged or excluded or are new codes, the unadjusted copayment amount would be 20 percent of the APC payment rate.
- If a new APC that did not exist during the prior year is created and consists of HCPCS codes previously assigned to other APCs, the copayment amount is calculated as the product of the APC payment rate and the lowest coinsurance percentage of the codes comprising the new APC.
- If no codes are added to or removed from an APC and, after recalibration of its relative payment weight, the new payment rate is equal to or greater than the prior year's rate, the

copayment amount remains constant (unless the resulting coinsurance percentage is less than 20 percent).

- If no codes are added to or removed from an APC and, after recalibration of its relative payment weight, the new payment rate is less than the prior year's rate, the copayment amount is calculated as the product of the new payment rate and the prior year's coinsurance percentage.

- If HCPCS codes are added to or deleted from an APC and, after recalibrating its relative payment weight, holding its unadjusted copayment amount constant results in a decrease in the coinsurance percentage for the reconfigured APC, the copayment amount would not change (unless retaining the copayment amount would result in a coinsurance rate less than 20 percent).

- If HCPCS codes are added to an APC and, after recalibrating its relative payment weight, holding its unadjusted copayment amount constant results in an increase in the coinsurance percentage for the reconfigured APC, the copayment amount would be calculated as the product of the payment rate of the reconfigured APC and the lowest coinsurance percentage of the codes being added to the reconfigured APC.

We noted in the CY 2004 OPSS final rule with comment period that we would seek to lower the copayment percentage for a service in an APC from the prior year if the copayment percentage was greater than 20 percent. We noted that this principle was consistent with section 1833(t)(8)(C)(ii) of the Act, which accelerates the reduction in the national unadjusted coinsurance rate so that beneficiary liability will eventually equal 20 percent of the OPSS payment rate for all OPSS services to which a copayment applies, and with section 1833(t)(3)(B) of the Act, which achieves a 20-percent copayment percentage when fully phased in and gives the Secretary the authority to set rules for determining copayment amounts for new services. We further noted that the use of this methodology would, in general, reduce the beneficiary coinsurance rate and copayment amount for APCs for which the payment rate changes as the result of the reconfiguration of APCs and/or recalibration of relative payment weights

(68 FR 63459).

3. Proposed Calculation of an Adjusted Copayment Amount for an APC Group

Individuals interested in calculating the national copayment liability for a Medicare beneficiary for a given service provided by a hospital that met or failed to meet its Hospital OQR Program requirements should follow the formulas presented in the following steps.

Step 1. Calculate the beneficiary payment percentage for the APC by dividing the APC's national unadjusted copayment by its payment rate. For example, using APC 5071, \$131.98 is approximately 20 percent of the full national unadjusted payment rate of \$659.86. For APCs with only a minimum unadjusted copayment in Addenda A and B to this proposed rule (which are available via the Internet on the CMS website), the beneficiary payment percentage is 20 percent.

The formula below is a mathematical representation of Step 1 and calculates the national copayment as a percentage of national payment for a given service.

B is the beneficiary payment percentage.

$B = \text{National unadjusted copayment for APC} / \text{national unadjusted payment rate for APC}.$

Step 2. Calculate the appropriate wage-adjusted payment rate for the APC for the provider in question, as indicated in Steps 2 through 4 under section II.H. of this proposed rule. Calculate the rural adjustment for eligible providers, as indicated in Step 6 under section II.H. of this proposed rule.

Step 3. Multiply the percentage calculated in Step 1 by the payment rate calculated in Step 2. The result is the wage-adjusted copayment amount for the APC.

The formula below is a mathematical representation of Step 3 and applies the beneficiary payment percentage to the adjusted payment rate for a service calculated under section II.H of this proposed rule, with and without the rural adjustment, to calculate the adjusted beneficiary copayment for a given service.

$\text{Wage-adjusted copayment amount for the APC} = \text{Adjusted Medicare Payment} * B.$

Wage-adjusted copayment amount for the APC (SCH or EACH) = (Adjusted Medicare Payment * 1.071) * B.

Step 4. For a hospital that failed to meet its Hospital OQR Program requirements, multiply the copayment calculated in Step 3 by the reporting ratio of 0.9805.

The unadjusted copayments for services payable under the OPSS that would be effective January 1, 2023 are shown in Addenda A and B to this proposed rule (which are available via the Internet on the CMS website). We note that the proposed national unadjusted payment rates and copayment rates shown in Addenda A and B to this proposed rule reflect the proposed CY 2023 OPD increase factor discussed in section II.B of this proposed rule.

In addition, as noted earlier, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure performed in a year to the amount of the inpatient hospital deductible for that year.

III. Proposed OPSS Ambulatory Payment Classification (APC) Group Policies

A. Proposed OPSS Treatment of New and Revised HCPCS Codes

Payments for OPSS procedures, services, and items are generally based on medical billing codes, specifically, HCPCS codes, that are reported on HOPD claims. HCPCS codes are used to report surgical procedures, medical services, items, and supplies under the hospital OPSS. The HCPCS is divided into two principal subsystems, referred to as Level I and Level II of the HCPCS. Level I is comprised of CPT (Current Procedural Terminology) codes, a numeric and alphanumeric coding system that is established and maintained by the American Medical Association (AMA), and consists of Category I, II, III, MAAA, and PLAA CPT codes. Level II, which is established and maintained by CMS, is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes. Together, Level I and II HCPCS codes are used to report procedures, services, items, and supplies under the OPSS payment system. Specifically, we recognize the following codes on OPSS claims:

- Category I CPT codes, which describe surgical procedures, diagnostic and therapeutic services, and vaccine codes;
- Category III CPT codes, which describe new and emerging technologies, services, and procedures;
- MAAA CPT codes, which describe laboratory multianalyte assays with algorithmic analyses (MAA);
- PLA CPT codes, which describe proprietary laboratory analyses (PLA) services; and
- Level II HCPCS codes (also known as alpha-numeric codes), which are used primarily to identify drugs, devices, supplies, temporary procedures, and services not described by CPT codes.

The codes are updated and changed throughout the year. CPT and Level II HCPCS code changes that affect the OPSS are published through the annual rulemaking cycle and through the OPSS quarterly update Change Requests (CRs). Generally, these code changes are effective January 1, April 1, July 1, or October 1. CPT code changes are released by the AMA (via their website) while Level II HCPCS code changes are released to the public via the CMS HCPCS website. CMS recognizes the release of new CPT and Level II HCPCS codes outside of the formal rulemaking process via OPSS quarterly update CRs. Based on our review, we assign the new codes to interim status indicators (SIs) and APCs. These interim assignments are finalized in the OPSS/ASC final rules. This quarterly process offers hospitals access to codes that more accurately describe the items or services furnished and provides payment for these items or services in a timelier manner than if we waited for the annual rulemaking process. We solicit public comments on the new CPT and Level II HCPCS codes, status indicators, and APC assignments through our annual rulemaking process.

We note that, under the OPSS, the APC assignment determines the payment rate for an item, procedure, or service. The items, procedures, or services not exclusively paid separately under the hospital OPSS are assigned to appropriate status indicators. Certain payment status

indicators provide separate payment while other payment status indicators do not. In section XI of this proposed rule, specifically, the “Proposed CY 2023 Payment Status and Comment Indicators” section, we discuss the various status indicators used under the OPSS. We also provide a complete list of the proposed status indicators and their definitions in Addendum D1 to this proposed rule.

1. April 2022 HCPCS Codes for Which We Are Soliciting Public Comments in This Proposed Rule

For the April 2022 update, 48 new HCPCS codes were established and made effective on April 1, 2022. Through the April 2022 OPSS quarterly update CR (Transmittal 11305, Change Request 12666, dated March 24, 2022), we recognized several new HCPCS codes for separate payment under the OPSS. In this proposed rule, we are soliciting public comments on the proposed APC and status indicator assignments for the codes listed in Table 5 (New HCPCS Codes Effective April 1, 2022). The proposed status indicator, APC assignment, and payment rate for each HCPCS code can be found in Addendum B to this proposed rule. We note that in prior years we included the proposed OPSS status indicators and APC assignments in the coding preamble tables, however, because the same information can be found in Addendum B, we are no longer including them in Table 5. Therefore, readers are advised to refer to the OPSS Addendum B for the OPSS status indicator, APC assignment, and payment rates for all codes reportable under the hospital OPSS. The new codes effective April 1, 2022 are assigned to comment indicator “NP” in Addendum B to this proposed rule to indicate that the codes are assigned to an interim APC assignment and comments will be accepted on their interim APC assignments. The complete list of proposed status indicators and definitions used under the OPSS can be found in Addendum D1 to this proposed rule, while the complete list of proposed comment indicators and definitions can be found in Addendum D2. We note that OPSS Addendum B (OPSS payment file by HCPCS code), Addendum D1 (OPSS Status Indicators),

and Addendum D2 (OPPS Comment Indicators) are available via the Internet on the CMS website.

TABLE 5: NEW HCPCS CODES EFFECTIVE APRIL 1, 2022

CY 2022 HCPCS Code	CY 2022 Long Descriptor
A2011	Supra sdrm, per square centimeter
A2012	Suprathel, per square centimeter
A2013	Innovamatrix fs, per square centimeter
A4100	Skin substitute, fda cleared as a device, not otherwise specified
A4238	Supply allowance for adjunctive continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service
A9291	Prescription digital behavioral therapy, fda cleared, per course of treatment
C9090	Injection, plasminogen, human-tvmh, 1 mg
C9091	Injection, sirolimus protein-bound particles, 1 mg
C9092	Injection, triamcinolone acetonide, suprachoroidal, 1 mg
C9093	Injection, ranibizumab, via intravitreal implant, 0.1 mg
C9782	Blinded procedure for New York Heart Association (NYHA) Class II or III heart failure, or Canadian Cardiovascular Society (CCS) Class III or IV chronic refractory angina; transcatheter intramyocardial transplantation of autologous bone marrow cells (e.g., mononuclear) or placebo control, autologous bone marrow harvesting and preparation for transplantation, left heart catheterization including ventriculography, all laboratory services, and all imaging with or without guidance (e.g., transthoracic echocardiography, ultrasound, fluoroscopy), all device(s), performed in an approved Investigational Device Exemption (IDE) study
C9783	Blinded procedure for transcatheter implantation of coronary sinus reduction device or placebo control, including vascular access and closure, right heart catheterization, venous and coronary sinus angiography, imaging guidance and supervision and interpretation when performed in an approved Investigational Device Exemption (IDE) study
J0219	Injection, avalglucosidase alfa-ngpt, 4 mg
J0491	Injection, anifrolumab-fnia, 1 mg
J0879	Injection, difelikefalin, 0.1 microgram, (for esrd on dialysis)
J9071	Injection, cyclophosphamide, (auromedics), 5 mg
J9273	Injection, tisotumab vedotin-tftv, 1 mg
J9359	Injection, loncastuximab tesirine-lpyl, 0.1 mg
K1028	Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle for the reduction of snoring and obstructive sleep apnea, controlled by phone application
K1029	Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by phone application, 90-day supply

CY 2022 HCPCS Code	CY 2022 Long Descriptor
K1030	External recharging system for battery (internal) for use with implanted cardiac contractility modulation generator, replacement only
K1031	Non-pneumatic compression controller without calibrated gradient pressure
K1032	Non-pneumatic sequential compression garment, full leg
K1033	Non-pneumatic sequential compression garment, half leg
Q4224	Human health factor 10 amniotic patch (hhf10-p), per square centimeter
Q4225	Amniobind, per square centimeter
Q4256	Mlg-complete, per square centimeter
Q4257	Relese, per square centimeter
Q4258	Enverse, per square centimeter
Q5124	Injection, ranibizumab-nuna, biosimilar, (byooviz), 0.1 mg
V2525	Contact lens, hydrophilic, dual focus, per lens
0306U	Oncology (minimal residual disease [mrd]), next-generation targeted sequencing analysis, cell-free dna, initial (baseline) assessment to determine a patient specific panel for future comparisons to evaluate for mrd
0307U	Oncology (minimal residual disease [mrd]), next-generation targeted sequencing analysis of a patient-specific panel, cell-free dna, subsequent assessment with comparison to previously analyzed patient specimens to evaluate for mrd
0308U	Cardiology (coronary artery disease [cad]), analysis of 3 proteins (high sensitivity [hs] troponin, adiponectin, and kidney injury molecule-1 [kim-1]), plasma, algorithm reported as a risk score for obstructive cad
0309U	Cardiology (cardiovascular disease), analysis of 4 proteins (nt-probnp, osteopontin, tissue inhibitor of metalloproteinase-1 [timp-1], and kidney injury molecule-1 [kim-1]), plasma, algorithm reported as a risk score for major adverse cardiac event
0310U	Pediatrics (vasculitis, kawasaki disease [kd]), analysis of 3 biomarkers (nt-probnp, c-reactive protein, and t-uptake), plasma, algorithm reported as a risk score for kd
0311U	Infectious disease (bacterial), quantitative antimicrobial susceptibility reported as phenotypic minimum inhibitory concentration (MIC)-based antimicrobial susceptibility for each organisms identified
0312U	Autoimmune diseases (eg, systemic lupus erythematosus [sle]), analysis of 8 igg autoantibodies and 2 cell-bound complement activation products using enzyme-linked immunosorbent immunoassay (elisa), flow cytometry and indirect immunofluorescence, serum, or plasma and whole blood, individual components reported along with an algorithmic sle-likelihood assessment
0313U	Oncology (pancreas), dna and mrna next-generation sequencing analysis of 74 genes and analysis of cea (ceacam5) gene expression, pancreatic cyst fluid, algorithm reported as a categorical result (ie, negative, low probability of neoplasia or positive, high probability of neoplasia)
0314U	Oncology (cutaneous melanoma), mrna gene expression profiling by rt-pcr of 35 genes (32 content and 3 housekeeping), utilizing formalin-fixed paraffin-embedded (ffpe) tissue, algorithm reported as a categorical result (ie, benign, intermediate, malignant)

CY 2022 HCPCS Code	CY 2022 Long Descriptor
0315U	Oncology (cutaneous squamous cell carcinoma), mrna gene expression profiling by rt-pcr of 40 genes (34 content and 6 housekeeping), utilizing formalin-fixed paraffin-embedded (ffpe) tissue, algorithm reported as a categorical risk result (ie, class 1, class 2a, class 2b)
0316U	Borrelia burgdorferi (Lyme disease), ospa protein evaluation, urine
0317U	Oncology (lung cancer), four-probe fish (3q29, 3p22.1, 10q22.3, 10cen) assay, whole blood, predictive algorithm-generated evaluation reported as decreased or increased risk for lung cancer
0318U	Pediatrics (congenital epigenetic disorders), whole genome methylation analysis by microarray for 50 or more genes, blood
0319U	Nephrology (renal transplant), rna expression by select transcriptome sequencing, using pretransplant peripheral blood, algorithm reported as a risk score for early acute rejection
0320U	Nephrology (renal transplant), rna expression by select transcriptome sequencing, using posttransplant peripheral blood, algorithm reported as a risk score for acute cellular rejection
0321U	Infectious agent detection by nucleic acid (dna or rna), genitourinary pathogens, identification of 20 bacterial and fungal organisms and identification of 16 associated antibiotic-resistance genes, multiplex amplified probe technique
0322U	Neurology (autism spectrum disorder [asd]), quantitative measurements of 14 acyl carnitines and microbiome-derived metabolites, liquid chromatography with tandem mass spectrometry (lc-ms/ms), plasma, results reported as negative or positive for risk of metabolic subtypes associated with asd

2. July 2022 HCPCS Codes for Which We Are Soliciting Public Comments in This Proposed Rule

For the July 2022 update, 63 new codes were established and made effective July 1, 2022. Through the July 2022 OPPS quarterly update CR (Transmittal 11457, Change Request 12761, dated June 15, 2022), we recognized several new codes for separate payment and assigned them to appropriate interim OPPS status indicators and APCs. In this CY 2023 OPPS/ASC proposed rule, we are soliciting public comments on the proposed APC and status indicator assignments for the codes listed in Table 6 (New HCPCS Codes Effective July 1, 2022). The proposed status indicator, APC assignment, and payment rate for each HCPCS code can be found in Addendum B to this proposed rule. We note that in prior years we included the proposed OPPS status indicators and APC assignments in the coding preamble

tables, however, because the same information can be found in Addendum B, we are no longer including them in Table 6. Therefore, readers are advised to refer to the OPPS Addendum B for the OPPS status indicator, APC assignment, and payment rates for all codes reportable under the hospital OPPS. The complete list of proposed status indicators and corresponding definitions used under the OPPS can be found in Addendum D1 to this proposed rule. In addition, the new codes are assigned to comment indicator “NP” in Addendum B to this proposed rule to indicate that the codes are assigned to an interim APC assignment and comments will be accepted on their interim APC assignments. The complete list of proposed comment indicators and definitions used under the OPPS can be found in Addendum D2 to this proposed rule. We note that OPPS Addendum B (OPPS payment file by HCPCS code), Addendum D1 (OPPS Status Indicators), and Addendum D2 (OPPS Comment Indicators) are available via the Internet on the CMS website.

TABLE 6: NEW HCPCS CODES EFFECTIVE JULY 1, 2022

CY 2022 HCPCS Code	CY 2022 Long Descriptor
A9596	Gallium ga-68 gozetotide, diagnostic, (illuccix), 1 millicurie
A9601	Flortaucipir f 18 injection, diagnostic, 1 millicurie
C9094	Inj, sutimlimab-jome, 10 mg
C9095	Inj, tebentafusp-tebn, 1 mcg
C9096	Injection, filgrastim-ayow, biosimilar, (releuko), 1 microgram
C9097	Inj, faricimab-svoa, 0.1 mg
C9098	ciltacabtagene autoleucel, up to 100 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
D1708	Pfizer-BioNTech Covid-19 vaccine administration – third dose
D1709	Pfizer-BioNTech Covid-19 vaccine administration – booster dose
D1710	Moderna Covid-19 vaccine administration – third dose
D1711	Moderna Covid-19 vaccine administration – booster dose
D1712	Janssen Covid-19 vaccine administration - booster dose
D1713	Pfizer-BioNTech Covid-19 vaccine administration tris-sucrose pediatric – first dose

CY 2022 HCPCS Code	CY 2022 Long Descriptor
D1714	Pfizer-BioNTech Covid-19 vaccine administration tris-sucrose pediatric – second dose
G0308	Creation of subcutaneous pocket with insertion of 180 day implantable interstitial glucose sensor, including system activation and patient training
G0309	Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new 180 day implantable sensor, including system activation
J0739	Injection, cabotegravir, 1 mg
J1306	Injection, inclisiran, 1 mg
J1551	Injection, immune globulin (cutaquin), 100 mg
J2356	Injection, tezepelumab-ekko, 1 mg
J2779	Injection, ranibizumab, via intravitreal implant (susvimo), 0.1 mg
J2998	Injection, plasminogen, human-tvmh, 1 mg
J3299	Injection, triamcinolone acetonide (xipere), 1 mg
J9331	Injection, sirolimus protein-bound particles, 1 mg
J9332	Injection, efgartigimod alfa-fcab, 2mg
K1034	Provision of covid-19 test, nonprescription self-administered and self-collected use, fda approved, authorized or cleared, one test count
Q4259	Celera dual layer or celera dual membrane, per square centimeter
Q4260	Signature apatch, per square centimeter
Q4261	Tag, per square centimeter
90584	Dengue vaccine, quadrivalent, live, 2 dose schedule, for subcutaneous use
0714T	Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance
0715T	Percutaneous transluminal coronary lithotripsy (List separately in addition to code for primary procedure)
0716T	Cardiac acoustic waveform recording with automated analysis and generation of coronary artery disease risk score
0717T	Autologous adipose-derived regenerative cell (ADRC) therapy for partial thickness rotator cuff tear; adipose tissue harvesting, isolation and preparation of harvested cells, including incubation with cell dissociation enzymes, filtration, washing and concentration of ADRCs
0718T	Autologous adipose-derived regenerative cell (ADRC) therapy for partial thickness rotator cuff tear; injection into supraspinatus tendon including ultrasound guidance, unilateral
0719T	Posterior vertebral joint replacement, including bilateral facetectomy, laminectomy, and radical discectomy, including imaging guidance, lumbar spine, single segment
0720T	Percutaneous electrical nerve field stimulation, cranial nerves, without implantation

CY 2022 HCPCS Code	CY 2022 Long Descriptor
0721T	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained without concurrent CT examination of any structure contained in previously acquired diagnostic imaging
0722T	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained with concurrent CT examination of any structure contained in the concurrently acquired diagnostic imaging dataset (List separately in addition to code for primary procedure)
0723T	Quantitative magnetic resonance cholangiopancreatography (QMRCB) including data preparation and transmission, interpretation and report, obtained without diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (eg, organ, gland, tissue, target structure) during the same session
0724T	Quantitative magnetic resonance cholangiopancreatography (QMRCB) including data preparation and transmission, interpretation and report, obtained with diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (eg, organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)
0725T	Vestibular device implantation, unilateral
0726T	Removal of implanted vestibular device, unilateral
0727T	Removal and replacement of implanted vestibular device, unilateral
0728T	Diagnostic analysis of vestibular implant, unilateral; with initial programming
0729T	Diagnostic analysis of vestibular implant, unilateral; with subsequent programming
0730T	Trabeculotomy by laser, including optical coherence tomography (OCT) guidance
0731T	Augmentative AI-based facial phenotype analysis with report
0732T	Immunotherapy administration with electroporation, intramuscular
0733T	Remote real-time, motion capture-based neurorehabilitative therapy ordered by a physician or other qualified health care professional; supply and technical support, per 30 days
0734T	Remote body and limb kinematic measurement-based therapy ordered by a physician or other qualified health care professional; treatment management services by a physician or other qualified health care professional, per calendar month
0735T	Preparation of tumor cavity, with placement of a radiation therapy applicator for intraoperative radiation therapy (IORT) concurrent with primary craniotomy (List separately in addition to code for primary procedure)
0736T	Colonic lavage, 35 or more liters of water, gravity-fed, with induced defecation, including insertion of rectal catheter
0737T	Xenograft implantation into the articular surface
0323U	Infectious agent detection by nucleic acid (DNA and RNA), central nervous system pathogen, metagenomic next-generation sequencing, cerebrospinal fluid (CSF), identification of pathogenic bacteria, viruses, parasites, or fungi
0324U	Oncology (ovarian), spheroid cell culture, 4-drug panel (carboplatin, doxorubicin, gemcitabine, paclitaxel), tumor chemotherapy response prediction for each drug

CY 2022 HCPCS Code	CY 2022 Long Descriptor
0325U	Oncology (ovarian), spheroid cell culture, poly (ADP-ribose) polymerase (PARP) inhibitors (niraparib, olaparib, rucaparib, velparib), tumor response prediction for each drug
0326U	Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free circulating DNA analysis of 83 or more genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden
0327U	Fetal aneuploidy (trisomy 13, 18, and 21), DNA sequence analysis of selected regions using maternal plasma, algorithm reported as a risk score for each trisomy, includes sex reporting, if performed
0328U	Drug assay, definitive, 120 or more drugs and metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS), includes specimen validity and algorithmic analysis describing drug or metabolite and presence or absence of risks for a significant patient-adverse event, per date of service
0329U	Oncology (neoplasia), exome and transcriptome sequence analysis for sequence variants, gene copy number amplifications and deletions, gene rearrangements, microsatellite instability and tumor mutational burden utilizing DNA and RNA from tumor with DNA from normal blood or saliva for subtraction, report of clinically significant mutation(s) with therapy associations
0330U	Infectious agent detection by nucleic acid (DNA or RNA), vaginal pathogen panel, identification of 27 organisms, amplified probe technique, vaginal swab
0331U	Oncology (hematolymphoid neoplasia), optical genome mapping for copy number alterations and gene rearrangements utilizing DNA from blood or bone marrow, report of clinically significant alternations

3. October 2022 HCPCS Codes for Which We Will Be Soliciting Public Comments in the CY 2023 OPPI/ASC Final Rule with Comment Period

As has been our practice in the past, we will solicit comments on the new CPT and Level II HCPCS codes that will be effective October 1, 2022, in the CY 2023 OPPI/ASC final rule with comment period, thereby allowing us to finalize the status indicators and APC assignments for the codes in the CY 2024 OPPI/ASC final rule with comment period. The HCPCS codes will be released to the public through the October 2022 OPPI Update CR and the CMS HCPCS website while the CPT codes will be released to the public through the AMA website.

For CY 2023, we propose to continue our established policy of assigning comment indicator “NI” in Addendum B to the CY 2023 OPPI/ASC final rule with comment period to those new HCPCS codes that will be effective October 1, 2022, to indicate that we are assigning

them an interim status indicator, which is subject to public comment. We will be inviting public comments in the CY 2023 OPPS/ASC final rule with comment period on the status indicator and APC assignments, which would then be finalized in the CY 2024 OPPS/ASC final rule with comment period.

4. January 2023 HCPCS Codes

a. New Level II HCPCS Codes for Which We Will Be Soliciting Public Comments in the CY 2023 OPPS/ASC Final Rule with Comment Period

Consistent with past practice, we will solicit comments on the new Level II HCPCS codes that will be effective January 1, 2023, in the CY 2023 OPPS/ASC final rule with comment period, thereby allowing us to finalize the status indicators and APC assignments for the codes in the CY 2024 OPPS/ASC final rule with comment period. Unlike the CPT codes that are effective January 1 and are included in the OPPS/ASC proposed rules, and except for the proposed new C-codes and G-codes listed in Addendum O of this proposed rule, most Level II HCPCS codes are not released until sometime around November to be effective January 1. Because these codes are not available until November, we are unable to include them in the OPPS/ASC proposed rules. Consequently, for CY 2023, we propose to include in Addendum B to the CY 2023 OPPS/ASC final rule with comment period the new Level II HCPCS codes effective January 1, 2023, that would be incorporated in the January 2023 OPPS quarterly update CR. Specifically, for CY 2023, we propose to continue our established policy of assigning comment indicator “NI” in Addendum B to the CY 2023 OPPS/ASC final rule with comment period to the new HCPCS codes that will be effective January 1, 2023, to indicate that we are assigning them an interim status indicator, which is subject to public comment. We will be inviting public comments in the CY 2023 OPPS/ASC final rule with comment period on the status indicator and APC assignments, which would then be finalized in the CY 2024 OPPS/ASC final rule with comment period.

b. CPT Codes for Which We Are Soliciting Public Comments in This Proposed Rule

In the CY 2015 OPPTS/ASC final rule with comment period (79 FR 66841 through 66844), we finalized a revised process of assigning APC and status indicators for new and revised Category I and III CPT codes that would be effective January 1. Specifically, for the new/revised CPT codes that we receive in a timely manner from the AMA's CPT Editorial Panel, we finalized our proposal to include the codes that would be effective January 1 in the OPPTS/ASC proposed rules, along with proposed APC and status indicator assignments for them, and to finalize the APC and status indicator assignments in the OPPTS/ASC final rules beginning with the CY 2016 OPPTS update. For those new/revised CPT codes that were received too late for inclusion in the OPPTS/ASC proposed rule, we finalized our proposal to establish and use HCPCS G-codes that mirror the predecessor CPT codes and retain the current APC and status indicator assignments for a year until we can propose APC and status indicator assignments in the following year's rulemaking cycle. We note that even if we find that we need to create HCPCS G-codes in place of certain CPT codes for the PFS proposed rule, we do not anticipate that these HCPCS G-codes will always be necessary for OPPTS purposes. We will make every effort to include proposed APC and status indicator assignments for all new and revised CPT codes that the AMA makes publicly available in time for us to include them in the proposed rule, and to avoid resorting to use of HCPCS G-codes and the resulting delay in utilization of the most current CPT codes. Also, we finalized our proposal to make interim APC and status indicator assignments for CPT codes that are not available in time for the proposed rule and that describe wholly new services (such as new technologies or new surgical procedures), to solicit public comments in the final rule, and to finalize the specific APC and status indicator assignments for those codes in the following year's final rule.

For the CY 2023 OPPTS update, we received the CPT codes that will be effective January 1, 2023 from the AMA in time to be included in this proposed rule. The new, revised, and deleted CPT codes can be found in Addendum B to this proposed rule (which is available via the Internet on the CMS website). We note that the new and revised CPT codes are assigned to

comment indicator “NP” in Addendum B of this proposed rule to indicate that the code is new for the next calendar year or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to the current calendar year with a proposed APC assignment, and that comments will be accepted on the proposed APC assignment and status indicator.

Further, we note that the CPT code descriptors that appear in Addendum B are short descriptors and do not accurately describe the complete procedure, service, or item described by the CPT code. Therefore, we are including the 5-digit placeholder codes and the long descriptors for the new and revised CY 2023 CPT codes in Addendum O to this proposed rule (which is available via the Internet on the CMS website) so that the public can adequately comment on our proposed APCs and status indicator assignments. The 5-digit placeholder codes can be found in Addendum O, specifically under the column labeled “CY 2023 OPSS/ASC Proposed Rule 5-Digit AMA Placeholder Code”. The final CPT code numbers will be included in the CY 2023 OPSS/ASC final rule with comment period.

In summary, we are soliciting public comments on the proposed CY 2023 status indicators and APC assignments for the new and revised CPT codes that will be effective January 1, 2023. Because the CPT codes listed in Addendum B appear with short descriptors only, we list them again in Addendum O to this proposed rule with long descriptors. In addition, we propose to finalize the status indicator and APC assignments for these codes (with their final CPT code numbers) in the CY 2023 OPSS/ASC final rule with comment period. The proposed status indicator and APC assignments for these codes can be found in Addendum B to this proposed rule. In addition, the complete list of proposed comment indicators and definitions used under the OPSS can be found in Addendum D2 to this proposed rule. We note that OPSS Addendum B (OPSS payment file by HCPCS code), Addendum D1 (OPSS Status Indicators), and Addendum D2 (OPSS Comment Indicators) are available via the Internet on the CMS website.

Finally, in Table 7 (Comment and Finalization Timeframes for New and Revised OPSS-Related HCPCS Codes) below, we summarize our current process for updating codes through our OPSS quarterly update CRs, seeking public comments, and finalizing the treatment of these codes under the OPSS.

TABLE 7: COMMENT AND FINALIZATION TIMEFRAMES FOR NEW AND REVISED OPSS-RELATED HCPCS CODES

OPSS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 2022	HCPCS (CPT and Level II codes)	April 1, 2022	CY 2023 OPSS/ASC proposed rule	CY 2023 OPSS/ASC final rule with comment period
July 2022	HCPCS (CPT and Level II codes)	July 1, 2022	CY 2023 OPSS/ASC proposed rule	CY 2023 OPSS/ASC final rule with comment period
October 2022	HCPCS (CPT and Level II codes)	October 1, 2022	CY 2023 OPSS/ASC final rule with comment period	CY 2024 OPSS/ASC final rule with comment period
January 2023	CPT Codes	January 1, 2023	CY 2023 OPSS/ASC proposed rule	CY 2023 OPSS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2023	CY 2023 OPSS/ASC final rule with comment period	CY 2024 OPSS/ASC final rule with comment period

B. Proposed OPSS Changes—Variations Within APCs

1. Background

Section 1833(t)(2)(A) of the Act requires the Secretary to develop a classification system for covered hospital outpatient department services. Section 1833(t)(2)(B) of the Act provides that the Secretary may establish groups of covered OPD services within this classification system, so that services classified within each group are comparable clinically and with respect to the use of resources. In accordance with these provisions, we developed a grouping classification system, referred to as Ambulatory Payment Classifications (APCs), as set forth in

regulations at 42 CFR 419.31. We use Level I (also known as CPT codes) and Level II HCPCS codes (also known as alphanumeric codes) to identify and group the services within each APC. The APCs are organized such that each group is homogeneous both clinically and in terms of resource use. Using this classification system, we have established distinct groups of similar services. We also have developed separate APC groups for certain medical devices, drugs, biologicals, therapeutic radiopharmaceuticals, and brachytherapy devices that are not packaged into the payment for the procedure.

We have packaged into the payment for each procedure or service within an APC group the costs associated with those items and services that are typically ancillary and supportive to a primary diagnostic or therapeutic modality and, in those cases, are an integral part of the primary service they support. Therefore, we do not make separate payment for these packaged items or services. In general, packaged items and services include, but are not limited to, the items and services listed in regulations at 42 CFR 419.2(b). A further discussion of packaged services is included in section II.A.3 of this proposed rule.

Under the OPSS, we generally pay for covered hospital outpatient services on a rate-per-service basis, where the service may be reported with one or more HCPCS codes. Payment varies according to the APC group to which the independent service or combination of services is assigned. For CY 2023, we propose that each APC relative payment weight represents the hospital cost of the services included in that APC, relative to the hospital cost of the services included in APC 5012 (Clinic Visits and Related Services). The APC relative payment weights are scaled to APC 5012 because it is the hospital clinic visit APC and clinic visits are among the most frequently furnished services in the hospital outpatient setting.

2. Application of the 2 Times Rule

Section 1833(t)(9)(A) of the Act requires the Secretary to review, not less often than annually, and revise the APC groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes

in technology, the addition of new services, new cost data, and other relevant information and factors. Section 1833(t)(9)(A) of the Act also requires the Secretary to consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the APC groups and the relative payment weights. We note that the Advisory Panel on Hospital Outpatient Payment (also known as the HOP Panel or the Panel) recommendations for specific services for the CY 2023 OPSS update will be discussed in the relevant specific sections throughout the CY 2023 OPSS/ASC final rule with comment period.

In addition, section 1833(t)(2) of the Act provides that, subject to certain exceptions, the items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest cost for an item or service in the group is more than 2 times greater than the lowest cost for an item or service within the same group (referred to as the “2 times rule”). The statute authorizes the Secretary to make exceptions to the 2 times rule in unusual cases, such as for low-volume items and services (but the Secretary may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug, and Cosmetic Act). In determining the APCs with a 2 times rule violation, we consider only those HCPCS codes that are significant based on the number of claims. We note that, for purposes of identifying significant procedure codes for examination under the 2 times rule, we consider procedure codes that have more than 1,000 single major claims or procedure codes that both have more than 99 single major claims and contribute at least 2 percent of the single major claims used to establish the APC cost to be significant (75 FR 71832). This longstanding definition of when a procedure code is significant for purposes of the 2 times rule was selected because we believe that a subset of 1,000 or fewer claims is negligible within the set of approximately 100 million single procedure or single session claims we use for establishing costs. Similarly, a procedure code for which there are fewer than 99 single claims and that comprises less than 2 percent of the single major claims

within an APC will have a negligible impact on the APC cost (75 FR 71832). In this section of this proposed rule, for CY 2023, we propose to make exceptions to this limit on the variation of costs within each APC group in unusual cases, such as for certain low-volume items and services.

For the CY 2023 OPSS update, we identified the APCs with violations of the 2 times rule and we propose changes to the procedure codes assigned to these APCs (with the exception of those APCs for which we propose a 2 times rule exception) in Addendum B to this proposed rule. We note that Addendum B does not appear in the printed version of the **Federal Register** as part of this proposed rule. Rather, it is published and made available via the Internet on the CMS website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>. To eliminate a violation of the 2 times rule and improve clinical and resource homogeneity in the APCs for which we are not proposing a 2 times rule exception, we propose to reassign these procedure codes to new APCs that contain services that are similar with regard to both their clinical and resource characteristics. In many cases, the proposed procedure code reassignments and associated APC reconfigurations for CY 2023 included in this proposed rule are related to changes in costs of services that were observed in the CY 2021 claims data available for CY 2023 ratesetting. Addendum B to this CY 2023 OPSS/ASC proposed rule identifies with a comment indicator “CH” those procedure codes for which we propose a change to the APC assignment or status indicator, or both, that were initially assigned in the July 1, 2022 OPSS Addendum B Update (available via the Internet on the CMS website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html>).

3. Proposed APC Exceptions to the 2 Times Rule

Taking into account the APC changes that we propose to make for CY 2023, we reviewed all of the APCs for which we identified 2 times rule violations to determine whether

any of the APCs would qualify for an exception. We used the following criteria to evaluate whether to propose exceptions to the 2 times rule for affected APCs:

- Resource homogeneity;
- Clinical homogeneity;
- Hospital outpatient setting utilization;
- Frequency of service (volume); and
- Opportunity for upcoding and code fragments.

For a detailed discussion of these criteria, we refer readers to the April 7, 2000 final rule (65 FR 18457 through 18458).

Based on the CY 2021 claims data available for this proposed rule, we found 23 APCs with violations of the 2 times rule. We applied the criteria as described above to identify the APCs for which we propose to make exceptions under the 2 times rule for CY 2023 and found that all of the 23 APCs we identified meet the criteria for an exception to the 2 times rule based on the CY 2021 claims data available for this proposed rule. We note that, on an annual basis, based on our analysis of the latest claims data, we identify violations to the 2 times rule and propose changes when appropriate. Those APCs that violate the 2 times rule are identified and appear in Table 8 below. In addition, we did not include in that determination those APCs where a 2 times rule violation was not a relevant concept, such as APC 5401 (Dialysis), which only has two HCPCS codes assigned to it that have similar geometric mean costs and do not create a 2 times rule violation. Therefore, we have only identified those APCs, including those with criteria-based costs, such as device-dependent CPT/HCPCS codes, with violations of the 2 times rule, where a 2 times rule violation is a relevant concept.

Table 8 of this proposed rule lists the 23 APCs for which we propose to make an exception under the 2 times rule for CY 2023 based on the criteria cited above and claims data submitted between January 1, 2021 and December 31, 2021 and processed on or before December 31, 2021, and CCRs, if available. The proposed geometric mean costs for covered

hospital outpatient services for these and all other APCs that were used in the development of this proposed rule can be found on the CMS website at:

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html>.

TABLE 8: PROPOSED CY 2023 APC EXCEPTIONS TO THE 2 TIMES RULE

Proposed CY 2023 APC	Proposed CY 2023 APC Title
5012	Clinic Visits and Related Services
5071	Level 1 Excision/ Biopsy/ Incision and Drainage
5301	Level 1 Upper GI Procedures
5521	Level 1 Imaging without Contrast
5522	Level 2 Imaging without Contrast
5523	Level 3 Imaging without Contrast
5524	Level 4 Imaging without Contrast
5571	Level 1 Imaging with Contrast
5611	Level 1 Therapeutic Radiation Treatment Preparation
5612	Level 2 Therapeutic Radiation Treatment Preparation
5627	Level 7 Radiation Therapy
5673	Level 3 Pathology
5691	Level 1 Drug Administration
5692	Level 2 Drug Administration
5721	Level 1 Diagnostic Tests and Related Services
5731	Level 1 Minor Procedures
5734	Level 4 Minor Procedures
5741	Level 1 Electronic Analysis of Devices
5791	Pulmonary Treatment
5811	Manipulation Therapy
5821	Level 1 Health and Behavior Services
5822	Level 2 Health and Behavior Services
5823	Level 3 Health and Behavior Services

C. Proposed New Technology APCs

1. Background

In the CY 2002 OPSS final rule (66 FR 59903), we finalized changes to the time period in which a service can be eligible for payment under a New Technology APC. Beginning in CY 2002, we retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to an appropriate clinical APC. This policy allows

us to move a service from a New Technology APC in less than 2 years if sufficient data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient data upon which to base a decision for reassignment have not been collected.

We also adopted in the CY 2002 OPSS final rule the following criteria for assigning a complete or comprehensive service to a New Technology APC: 1) the service must be truly new, meaning it cannot be appropriately reported by an existing HCPCS code assigned to a clinical APC and does not appropriately fit within an existing clinical APC; 2) the service is not eligible for transitional pass-through payment (however, a truly new, comprehensive service could qualify for assignment to a new technology APC even if it involves a device or drug that could, on its own, qualify for a pass-through payment); and 3) the service falls within the scope of Medicare benefits under section 1832(a) of the Act and is reasonable and necessary in accordance with section 1862(a)(1)(A) of the Act (66 FR 59898 through 59903). For additional information about our New Technology APC policy, we refer readers to

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service->

[Payment/HospitalOutpatientPPS/passthrough_payment](#) on the CMS Website and then follow the instructions to access the MEARIS™ system for OPSS New Technology APC applications.

In the CY 2004 OPSS final rule with comment period (68 FR 63416), we restructured the New Technology APCs to make the cost intervals more consistent across payment levels and refined the cost bands for these APCs to retain two parallel sets of New Technology APCs: one set with a status indicator of “S” (Significant Procedures, Not Discounted when Multiple. Paid under OPSS; separate APC payment) and the other set with a status indicator of “T” (Significant Procedure, Multiple Reduction Applies. Paid under OPSS; separate APC payment). These current New Technology APC configurations allow us to price new technology services more appropriately and consistently.

For CY 2022, there were 52 New Technology APC levels, ranging from the lowest cost band assigned to APC 1491 (New Technology - Level 1A (\$0-\$10)) to the highest cost band

assigned to APC 1908 (New Technology - Level 52 (\$145,001-\$160,000)). We note that the cost bands for the New Technology APCs, specifically, APCs 1491 through 1599 and 1901 through 1908, vary with increments ranging from \$10 to \$14,999. These cost bands identify the APCs to which new technology procedures and services with estimated service costs that fall within those cost bands are assigned under the OPSS. Payment for each APC is made at the mid-point of the APC's assigned cost band. For example, payment for New Technology APC 1507 (New Technology – Level 7 (\$501 - \$600)) is made at \$550.50.

Under the OPSS, one of our goals is to make payments that are appropriate for the services that are necessary for the treatment of Medicare beneficiaries. The OPSS, like other Medicare payment systems, is budget neutral and increases are limited to the annual hospital market basket increase reduced by the productivity adjustment. We believe that our payment rates reflect the costs that are associated with providing care to Medicare beneficiaries and are adequate to ensure access to services (80 FR 70374). For many emerging technologies, there is a transitional period during which utilization may be low, often because providers are first learning about the technologies and their clinical utility. Quite often, parties request that Medicare make higher payments under the New Technology APCs for new procedures in that transitional phase. These requests, and their accompanying estimates for expected total patient utilization, often reflect very low rates of patient use of expensive equipment, resulting in high per-use costs for which requesters believe Medicare should make full payment. Medicare does not, and we believe should not, assume responsibility for more than its share of the costs of procedures based on projected utilization for Medicare beneficiaries and does not set its payment rates based on initial projections of low utilization for services that require expensive capital equipment. For the OPSS, we rely on hospitals to make informed business decisions regarding the acquisition of high-cost capital equipment, taking into consideration their knowledge about their entire patient base (Medicare beneficiaries included) and an understanding of Medicare's and other payers'

payment policies. We refer readers to the CY 2013 OPPTS/ASC final rule with comment period (77 FR 68314) for further discussion regarding this payment policy.

We note that, in a budget-neutral system, payments may not fully cover hospitals' costs in a particular circumstance, including those for the purchase and maintenance of capital equipment. We rely on hospitals to make their decisions regarding the acquisition of high-cost equipment with the understanding that the Medicare program must be careful to establish its initial payment rates, including those made through New Technology APCs, for new services that lack hospital claims data based on realistic utilization projections for all such services delivered in cost-efficient hospital outpatient settings. As the OPPTS acquires claims data regarding hospital costs associated with new procedures, we regularly examine the claims data and any available new information regarding the clinical aspects of new procedures to confirm that our OPPTS payments remain appropriate for procedures as they transition into mainstream medical practice (77 FR 68314). For CY 2023, we include the proposed payment rates for New Technology APCs 1491 to 1599 and 1901 through 1908 in Addendum A to this proposed rule (which is available via the internet on the CMS website).

2. Establishing Payment Rates for Low-Volume New Technology Services

Services that are assigned to New Technology APCs are typically new services that do not have sufficient claims history to establish an accurate payment for the services. One of the objectives of establishing New Technology APCs is to generate sufficient claims data for a new service so that it can be assigned to an appropriate clinical APC. Some services that are assigned to New Technology APCs have very low annual volume, which we consider to be fewer than 100 claims. We consider services with fewer than 100 claims annually to be low-volume services because there is a higher probability that the payment data for a service may not have a normal statistical distribution, which could affect the quality of our standard cost methodology that is used to assign services to an APC. In addition, services with fewer than 100 claims per year are not generally considered to be significant contributors to the APC ratesetting

calculations and, therefore, are not included in the assessment of the 2 times rule. As we explained in the CY 2019 OPPTS/ASC final rule with comment period (83 FR 58892), we were concerned that the methodology we use to estimate the cost of a service under the OPPTS by calculating the geometric mean for all separately paid claims for a HCPCS service code from the most recent available year of claims data may not generate an accurate estimate of the actual cost of the service for these low-volume services.

In accordance with section 1833(t)(2)(B) of the Act, services classified within each APC must be comparable clinically and with respect to the use of resources. As described earlier, assigning a service to a New Technology APC allows us to gather claims data to price the service and assign it to the APC with services that use similar resources and are clinically comparable. However, where utilization of services assigned to a New Technology APC is low, it can lead to wide variation in payment rates from year to year, resulting in even lower utilization and potential barriers to access to new technologies, which ultimately limits our ability to assign the service to the appropriate clinical APC. To mitigate these issues, we adopted a policy in the CY 2019 OPPTS/ASC final rule with comment period to utilize our equitable adjustment authority at section 1833(t)(2)(E) of the Act to adjust how we determine the costs for low-volume services assigned to New Technology APCs (83 FR 58892 through 58893).

For purposes of this adjustment, we stated in the CY 2019 OPPTS/ASC final rule with comment period that we believed that it was appropriate to use up to 4 years of claims data in calculating the applicable payment rate for the prospective year, rather than using solely the most recent available year of claims data, when a service assigned to a New Technology APC has an annual claims volume of fewer than 100 claims (83 FR 58893). Using multiple years of claims data will potentially allow for more than 100 claims to be used to set the payment rate, which would, in turn, create a more statistically reliable payment rate.

In addition, to better approximate the cost of a low-volume service within a New Technology APC, we also stated that using the median or arithmetic mean rather than the

geometric mean (which “trims” the costs of certain claims out) could be more appropriate in some circumstances, given the extremely low volume of claims. Low claim volumes increase the impact of “outlier” claims; that is, claims with either a very low or very high payment rate as compared to the average claim, which would have a substantial impact on any statistical methodology used to estimate the most appropriate payment rate for a service. Also, having the flexibility to utilize an alternative statistical methodology to calculate the payment rate in the case of low-volume new technology services helps to create a more stable payment rate.

In the CY 2019 OPPTS/ASC final rule (83 FR 58893), we implemented a policy that we would seek public comments on which statistical methodology should be used to determine the payment rate for each low-volume service assigned to a New Technology APC. In the preamble of each annual rulemaking, we stated that we would present the result of each statistical methodology and solicit public comment on which methodology should be used to establish the payment rate for a low-volume new technology service. In addition, we explained that we would use our assessment of the resources used to perform a service and guidance from the developer or manufacturer of the service, as well as other interested parties, to determine the most appropriate payment rate. Once we identified the most appropriate payment rate for a service, we would assign the service to the New Technology APC with the cost band that includes its payment rate.

In the CY 2022 OPPTS/ASC final rule with comment period, we adopted a policy to continue to utilize our equitable adjustment authority under section 1833(t)(2)(E) of the Act to calculate the geometric mean, arithmetic mean, and median using up to four years of claims data to select the appropriate payment rate for purposes of assigning services with fewer than 100 claims per year to a New Technology APC (86 FR 63529). However, we replaced our specific low-volume New Technology APC policy with the universal low volume APC policy that we adopted beginning in CY 2022. Our universal low volume APC policy is similar to our past New Technology APC low volume policy except that the universal low volume APC policy applies to

clinical APCs and brachytherapy APCs as well as low volume procedures assigned to New Technology APCs, and uses the highest of the geometric mean, arithmetic mean, or median based on up to 4 years of claims data to assign a procedure with fewer than 100 claims per year to an appropriate New Technology APC. For this proposed rule, we propose to designate three procedures assigned to New Technology APCs as low volume procedures and use the highest of the geometric mean, arithmetic mean, or median based on up to 4 years of claims data to assign such procedures to the appropriate New Technology APCs.

3. Procedures Assigned to New Technology APC Groups for CY 2023

As we described in the CY 2002 OPPS final rule (66 FR 59902), we generally retain a procedure in the New Technology APC to which it is initially assigned until we have obtained sufficient claims data to justify reassignment of the procedure to a clinically appropriate APC. In addition, in cases where we find that our initial New Technology APC assignment was based on inaccurate or inadequate information (although it was the best information available at the time), where we obtain new information that was not available at the time of our initial New Technology APC assignment, or where the New Technology APCs are restructured, we may, based on more recent resource utilization information (including claims data) or the availability of refined New Technology APC cost bands, reassign the procedure or service to a different New Technology APC that more appropriately reflects its cost (66 FR 59903).

Consistent with our current policy, for CY 2023, we propose to retain services within New Technology APC groups until we obtain sufficient claims data to justify reassignment of the service to an appropriate clinical APC. The flexibility associated with this policy allows us to reassign a service from a New Technology APC in less than 2 years if we have obtained sufficient claims data. It also allows us to retain a service in a New Technology APC for more than 2 years if we have not obtained sufficient claims data upon which to base a reassignment decision (66 FR 59902).

a. Retinal Prosthesis Implant Procedure

CPT code 0100T (Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy) describes the implantation of a retinal prosthesis, specifically, a procedure involving the use of the Argus® II Retinal Prosthesis System. This first retinal prosthesis was approved by FDA in 2013 for adult patients diagnosed with severe to profound retinitis pigmentosa. For information on the utilization and payment history of the Argus® II procedure and the Argus® II device through CY 2022, please refer to the CY 2022 OPSS final rule (86 FR 63529 through 63530).

Early in 2022, we learned that the manufacturer of the Argus® II device discontinued manufacturing the device in 2020. We also contacted the consultant who represented the manufacturer in presentations with CMS, and he confirmed that the Argus® II device is no longer being implanted. A review of OPSS claims data found that there were no claims billed for CPT code 0100T in either CY 2020 or CY 2021. Based on this information, we have determined that the Argus® II device is no longer available in the marketplace and that outpatient hospital providers are no longer performing the Argus® II implantation procedure. Therefore, we propose to make changes to the OPSS status indicators for HCPCS and CPT codes that are related to the Argus® II device and the Argus® II implantation procedure to indicate that Medicare payment is no longer available for the device and the implementation procedure as the Argus® II device is no longer on the market and therefore, is not being implanted. These coding changes would mean that providers could no longer receive payment for performing the Argus® II device or the device implantation procedure. These changes are described in Table 9.

TABLE 9: CY 2023 PROPOSED OPSS STATUS INDICATOR AND APC ASSIGNMENTS FOR THE ARGUS® II DEVICE AND THE ARGUS® II IMPLANTATION PROCEDURE

CPT Code	Long Descriptor	Final CY 2022 OPSS SI	Final CY 2022 OPSS APC	Proposed CY 2023 OPSS SI	Proposed CY 2023 OPSS APC
0100T	Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intraocular retinal electrode array, with vitrectomy	T	1908	E2	N/A

C1841	Retinal prosthesis, includes all internal and external components	N	N/A	D	N/A
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b. Administration of Subretinal Therapies Requiring Vitrectomy (APC 1562)

Effective January 1, 2021, CMS established HCPCS code C9770 (Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent) and assigned it to a New Technology APC based on the geometric mean cost of HCPCS code 67036 (*Vitrectomy, mechanical, pars plana approach*) due to similar resource utilization. For CY 2021, HCPCS code C9770 was assigned to APC 1561 (New Technology – Level 24 (\$3001-\$3500)). This code may be used to describe the administration of CPT code J3398 (Injection, voretigene neparvovec-rzyl, 1 billion vector genomes). This procedure was previously discussed in depth in the CY 2021 OPSS/ASC final rule with comment period (85 FR 85939 through 85940). For CY 2022, we maintained the APC assignment of APC 1561 (New Technology – Level 24 (\$3001-\$3500)) for HCPCS code C9770 (86 FR 63531 through 63532).

CPT code J3398 (Injection, voretigene neparvovec-rzyl, 1 billion vector genomes) is for a gene therapy product indicated for a rare mutation-associated retinal dystrophy. Voretigene neparvovec-rzyl (Luxturna[®]) was approved by FDA in December of 2017 and is an adeno-associated virus vector-based gene therapy indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy.² This therapy is administered through a subretinal injection, which interested parties describe as an extremely delicate and sensitive surgical procedure. The FDA package insert describes one of the steps for administering Luxturna as, “after completing a vitrectomy, identify the intended site of administration. The subretinal injection can be introduced via pars plana.”

Interested parties, including the manufacturer of Luxturna[®], recommended HCPCS code 67036 (Vitrectomy, mechanical, pars plana approach) for the administration of the gene therapy.³

² Luxturna. FDA Package Insert. Available: <https://www.fda.gov/media/109906/download>

³ LUXTURNA REIMBURSEMENT GUIDE FOR TREATMENT CENTERS.

https://mysparkgeneration.com/pdf/Reimbursement_Guide_for_Treatment_Centers_Interactive_010418_FINAL.pdf

However, the manufacturer previously contended the administration was not accurately described by any existing codes as HCPCS code 67036 (Vitreotomy, mechanical, pars plana approach) does not account for the administration itself.

CMS recognized the need to accurately describe the unique procedure that is required to administer the therapy described by HCPCS code J3398. Therefore, in the CY 2021 OPPI/ASC proposed rule (85 FR 48832), we proposed to establish a new HCPCS code, C97X1 (Vitreotomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent) to describe this process. We stated that we believed that this new HCPCS code accurately described the unique service associated with intraocular administration of HCPCS code J3398. We recognized that HCPCS code 67036 represents a clinically similar procedure and process that approximates similar resource utilization to C97X1. However, we also recognized that it is not prudent for the code that describes the administration of this unique gene therapy, C97X1, to be assigned to the same C-APC to which HCPCS code 67036 is assigned, as this would package the primary therapy, HCPCS code J3398, into the code that represents the process to administer the gene therapy.

Therefore, for CY 2021, we proposed to assign the services described by C97X1 to a New Technology APC with a cost band that contains the geometric mean cost for HCPCS code 67036. The placeholder code C97X1 was replaced by C9770. For CY 2021, we finalized our proposal to create C9770 (Vitreotomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent), and we assigned this code to APC 1561 (New Technology – Level 24 (\$3001-\$3500)) using the geometric mean cost of HCPCS code 67036. For CY 2022, we continued to assign HCPCS code C9770 to APC 1561 (New Technology – Level 24 (\$3001-\$3500)) using the geometric mean cost of HCPCS code 67036.

For CY 2023, there are 11 single claims available for ratesetting for HCPCS code C9770. Because this is the first year we have claims data for HCPCS code C9770, we propose to base the payment rate of HCPCS code C9770 on claims data for that code rather than on the

geometric mean cost of HCPCS code 67036. Given the low number of claims for this procedure, we propose to designate HCPCS C9770 as a low volume procedure under our universal low volume APC policy and use the greater of the geometric mean, arithmetic mean, or median cost calculated based on the available claims data to calculate an appropriate payment rate for purposes of assigning C9770 to a New Technology APC.

Using CY 2021 claims, which are the only claims available in our 4-year look back period, we found the geometric mean cost for the service to be approximately \$3,326, the arithmetic mean cost to be approximately \$3,466, and the median cost to be approximately \$3,775. The median was the statistical methodology that estimated the highest cost for the service. The payment rate calculated using this methodology falls within the cost band for New Technology APC 1562 (New Technology—Level 25 (\$3501–\$4000)). Therefore, we propose to assign HCPCS code C9770 to APC 1562 for CY 2023.

Please refer to Table 10 below for the proposed OPSS New Technology APC and status indicator assignments for HCPCS code C9770 for CY 2023. The proposed CY 2023 payment rates can be found in Addendum B to this proposed rule.

TABLE 10: FINAL CY 2022 & PROPOSED CY 2023 OPSS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR HCPCS CODE C9770

HCPCS Code	Long Descriptor	Final CY 2022 OPSS SI	Final CY 2022 OPSS APC	Proposed CY 2023 OPSS SI	Proposed CY 2023 OPSS APC
C9770	Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent	T	1561	T	1562

c. Bronchoscopy with Transbronchial Ablation of Lesion(s) by Microwave Energy (APC 1562)

Effective January 1, 2019, CMS established HCPCS code C9751 (Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3-D rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (EBUS) guided

transtracheal and/or transbronchial sampling (for example, aspiration[s]/biopsy[ies]) and all mediastinal and/or hilar lymph node stations or structures and therapeutic intervention(s)). This microwave ablation procedure utilizes a flexible catheter to access the lung tumor via a working channel and may be used as an alternative procedure to a percutaneous microwave approach. Based on our review of the New Technology APC application for this service and the service's clinical similarity to existing services paid under the OPPTS, we estimated the likely cost of the procedure would be between \$8,001 and \$8,500.

In claims data available for CY 2019 for the CY 2021 OPPTS/ASC final rule with comment period, there were four claims reported for bronchoscopy with transbronchial ablation of lesions by microwave energy. Given the low volume of claims for the service, we proposed for CY 2021 to apply the policy we adopted in CY 2019, under which we utilize our equitable adjustment authority under section 1833(t)(2)(E) of the Act to calculate the geometric mean, arithmetic mean, and median costs to calculate an appropriate payment rate for purposes of assigning bronchoscopy with transbronchial ablation of lesions by microwave energy to a New Technology APC. We found the geometric mean cost for the service to be approximately \$2,693, the arithmetic mean cost to be approximately \$3,086, and the median cost to be approximately \$3,708. The median was the statistical methodology that estimated the highest cost for the service. The payment rate calculated using this methodology fell within the cost band for New Technology APC 1562 (New Technology—Level 25 (\$3501–\$4000)). Therefore, we assigned HCPCS code C9751 to APC 1562 for CY 2021.

In CY 2022, we used again the claims data from CY 2019 for HCPCS code C9751. Since the claims data was unchanged from when it was used in CY 2021, the values for the geometric mean cost (\$2,693), the arithmetic mean cost (\$3,086), and the median cost (\$3,708) for the service described by HCPCS code C9751 remained the same. The highest cost metric using these methodologies was again the median and within the cost band for New Technology APC 1562 (New Technology—Level 25 (\$3,501–\$4,000)). Therefore, we continued to assign HCPCS code

C9751 to APC 1562 (New Technology—Level 25 (\$3,501– \$4,000)), with a payment rate of \$3,750.50 for CY 2022.

There were no claims reported in CY 2020 or CY 2021 for HCPCS code C9751. Thus, for CY 2023, the only available claims for HCPCS code C9751 continue to be from CY 2019, and the reported claims are the same claims used to calculate the payment rate for the service in the CY 2021 and CY 2022 OPPS/ASC final rules with comment period. Therefore, given the low number of claims for this procedure, we propose to designate this procedure as low volume under our universal low volume policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign the procedure to the appropriate New Technology APCs. Because our proposal uses the same claims as we used for CY 2021 and CY 2022, we found the same values for the geometric mean cost, arithmetic mean cost, and the median cost for CY 2023. Once again, the median (\$3,708) was the statistical methodology that estimated the highest cost for the service. The payment rate calculated using this methodology continues to fall within the cost band for New Technology APC 1562 (New Technology—Level 25 (\$3501–\$4000)). Therefore, we propose to continue to assign HCPCS code C9751 to APC 1562 (New Technology—Level 25 (\$3501–\$4000)), with a proposed payment rate of \$3,750.50 for CY 2023. Details regarding HCPCS code C9751 are included in Table 11.

TABLE 11: FINAL CY 2022 AND PROPOSED CY 2023 OPPTS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR HCPCS CODE C9751

HCPCS Code	Long Descriptor	Final CY 2022 OPPTS SI	Final CY 2022 OPPTS APC	Proposed CY 2023 OPPTS SI	Proposed CY 2023 OPPTS APC
C9751	Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3-D rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (eg, aspiration[s]/biopsy[ies])	T	1562	T	1562

d. Cardiac Positron Emission Tomography (PET)/Computed Tomography (CT) Studies (APCs 1522 and 1523)

Effective January 1, 2020, we assigned three CPT codes (78431, 78432, and 78433) that describe the services associated with cardiac PET/CT studies to New Technology APCs. CPT code 78431 was assigned to APC 1522 (New Technology—Level 22 (\$2001–\$2500)) with a payment rate of \$2,250.50. CPT codes 78432 and 78433 were assigned to APC 1523 (New Technology—Level 23 (\$2501–\$3000)) with a payment rate of \$2,750.50. We did not receive any claims data for these services for either of the CY 2021 or CY 2022 OPPTS proposed or final rules. Therefore, we continued to assign CPT code 78431 to APC 1522 (New Technology—Level 22 (\$2001–\$2500)) with a payment rate of \$2,250.50 in CY 2021 and CY 2022. Likewise, we continued to assign CPT codes 78432 and 78433 to APC 1523 (New Technology—Level 23 (\$2501–\$3000)) with a payment rate of \$2,750.50.

For CY 2023, we propose to use CY 2021 claims data to determine the payment rates for CPT codes 78431, 78432, and 78433. CPT code 78431 had over 18,000 single frequency claims in CY 2021, which are used to calculate estimated costs for individual services. The geometric

mean for CPT code 78431 was approximately \$2,509, which is an amount that is above the cost band for APC 1522 (New Technology—Level 22 (\$2001–\$2500)), where the procedure is currently assigned. We propose, for CY 2023, that CPT code 78431 be reassigned to APC 1523 (New Technology—Level 23 (\$2501–\$3000)) with a payment rate of \$2,750.50. Please refer to Table 12 for the proposed New Technology APC and status indicator assignments for CPT code 78431.

There were only 5 single frequency claims in CY 2021 for CPT code 78432. As this is below the threshold of 100 claims for a service within a year, we propose to apply our universal low volume APC policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign CPT code 78432 to the appropriate New Technology APC. Although we use up to four years of claims data to calculate the appropriate New Technology APC assignment for low volume procedures, for CPT code 78432, the only available claims data are from CY 2021. Our analysis of the data found the geometric mean cost of the service is approximately \$1,747, the arithmetic mean cost of the service is approximately \$1,899, and the median cost of the service is approximately \$1,481. The arithmetic mean was the statistical methodology that estimated the highest cost for the service. Therefore, we propose, for CY 2023, to assign CPT code 78432 to APC 1520 (New Technology - Level 20 (\$1801-\$1900)) with a payment rate of \$1,850.50. Please refer to Table 12 for the proposed on New Technology APC and status indicator assignments for CPT code 78432.

There were 954 single frequency claims reporting CPT code 78433 in CY 2021. The geometric mean for CPT code 78433 was approximately \$1,999, which is an amount that is below the cost band for APC 1523 (New Technology—Level 23 (\$2501–\$3000)), where the procedure is currently assigned. We propose, for CY 2023, that CPT code 78433 be reassigned to APC 1521 (New Technology - Level 21 (\$1901-\$2000)) with a payment rate of \$1,950.50. Please refer to Table 12 for the proposed New Technology APC and status indicator assignments for CPT code 78433.

**TABLE 12: FINAL CY 2022 AND PROPOSED CY 2023 OPPS NEW
TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODES
78431, 78432, AND 78433**

CPT Code	Long Descriptor	Final CY 2022 OPPS SI	Final CY 2022 OPPS APC	Proposed CY 2023 OPPS SI	Proposed OPPS CY 2023 APC
78431	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan	S	1522	S	1523
78432	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (eg, myocardial viability);	S	1523	S	1520
78433	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (eg, myocardial viability); with concurrently acquired computed tomography transmission scan	S	1523	S	1521

e. V-Wave Medical Interatrial Shunt Procedure (APC 1590)

A randomized, double-blinded, controlled IDE study is currently in progress for the V-Wave interatrial shunt. The V-Wave interatrial shunt is for patients with severe symptomatic heart failure and is designed to regulate left atrial pressure in the heart. All participants who passed initial screening for the study receive a right heart catheterization procedure described by CPT code 93451 (Right heart catheterization including measurement(s) of oxygen saturation and cardiac output, when performed). Participants assigned to the experimental group also receive the V-Wave interatrial shunt procedure while participants assigned to the control group only receive right heart catheterization. The developer of V-Wave was concerned that the current

coding of these services by Medicare would reveal to the study participants whether they had received the interatrial shunt because an additional procedure code, CPT code 93799 (Unlisted cardiovascular service or procedure), would be included on the claims for participants receiving the interatrial shunt. Therefore, for CY 2020, we created a temporary HCPCS code to describe the V-wave interatrial shunt procedure for both the experimental group and the control group in the study. Specifically, we established HCPCS code C9758 (Blinded procedure for NYHA class III/IV heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization, trans-esophageal echocardiography (TEE)/intracardiac echocardiography (ICE), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved investigational device exemption (IDE) study) to describe the service, and we assigned the service to New Technology APC 1589 (New Technology - Level 38 (\$10,001-\$15,000)).

In the CY 2021 OPSS/ASC final rule with comment period (85 FR 85946), we stated that we believe similar resources and device costs are involved with the V-Wave interatrial shunt procedure and the Corvia Medical interatrial shunt procedure (HCPCS code C9760), except that payment for HCPCS codes C9758 and C9760 differs based on how often the interatrial shunt is implanted when each code is billed. An interatrial shunt is implanted one-half of the time HCPCS code C9758 is billed, whereas an interatrial shunt is implanted every time HCPCS code C9760 is billed. Accordingly, for CY 2021, we reassigned HCPCS code C9758 to New Technology APC 1590, which reflects the cost of having surgery every time and receiving the interatrial shunt one-half of the time the procedure is performed.

For CY 2022, we used the same claims data from CY 2019 that we did for CY 2021 OPSS final rule. Because there were no claims reporting HCPCS code C9758, we continued to assign HCPCS code C9758 to New Technology APC 1590 with a payment rate of \$17,500.50 for CY 2022.

For CY 2023, there were no claims from CY 2021 billed with HCPCS code C9758.

Because there are no claims reporting HCPCS code C9758, we propose to continue to assign HCPCS code C9758 to New Technology APC 1590 with a payment rate of \$17,500.50 for CY 2023. The proposed New Technology APC and status indicator assignments for HCPCS codes C9758 are shown in Table 13.

TABLE 13: FINAL CY 2022 AND PROPOSED CY 2023 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR BLINDED INTRATRIAL SHUNT PROCEDURE

HCPCS Code	Long Descriptor	Final CY 2022 OPPS SI	Final CY 2022 OPPS SI	Proposed 2023 OPPS SI	Proposed 2023 OPPS SI
C9758	Blinded procedure for NYHA class III/IV heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization, trans-esophageal echocardiography (TEE)/intracardiac echocardiography (ICE), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved investigational device exemption (IDE) study	T	1590	T	1590

f. Corvia Medical Interatrial Shunt Procedure (APC 1592)

Corvia Medical is currently conducting its pivotal trial for its interatrial shunt procedure. The trial started in Quarter 1 of CY 2017 and continued through Quarter 3 of CY 2021.⁴ On July 1, 2020, we established HCPCS code C9760 (Non-randomized, non-blinded procedure for nyha

⁴ <https://clinicaltrials.gov/ct2/show/NCT03088033?term=NCT03088033&rank=1>

class ii, iii, iv heart failure; transcatheter implantation of interatrial shunt or placebo control, including right and left heart catheterization, transeptal puncture, trans-esophageal echocardiography (tee)/intracardiac echocardiography (ice), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved investigational device exemption (ide) study) to facilitate the implantation of the Corvia Medical interatrial shunt.

As we stated in the CY 2021 OPSS final rule with comment period (85 FR 85947), we believe that similar resources and device costs are involved with the Corvia Medical interatrial shunt procedure and the V-Wave interatrial shunt procedure. Unlike the V-Wave interatrial shunt, which is implanted half the time the associated interatrial shunt procedure described by HCPCS code C9758 is billed, the Corvia Medical interatrial shunt is implanted every time the associated interatrial shunt procedure (HCPCS code C9760) is billed. Therefore, for CY 2021, we assigned HCPCS code C9760 to New Technology APC 1592 (New Technology - Level 41 (\$25,001-\$30,000)) with a payment rate of \$27,500.50. We also modified the code descriptor for HCPCS code C9760 to remove the phrase “or placebo control,” from the descriptor. In CY 2022, we used the same claims data as was used in the CY 2021 OPSS final rule to determine the payment rate for HCPCS code C9760 because there were no claims for this service in CY 2019, the year used for ratesetting for CY 2022. Accordingly, we continued to assign HCPCS code C9760 to New Technology APC 1592 in CY 2022.

For CY 2023, we propose to use the claims data from CY 2021 to establish payment rates for services. However, there are no claims with HCPCS code C9760 in the CY 2021 claims data available for ratesetting. Therefore, we propose to continue to assign HCPCS code C9760 to New Technology APC 1592. The proposed New Technology APC and status indicator assignments for HCPCS code C9760 are shown in Table 14.

TABLE 14: FINAL CY 2022 AND PROPOSED CY 2023 OPSS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR NON-RANDOMIZED, NON-BLINDED INTERATRIAL SHUNT PROCEDURE

HCPCS Code	Long Descriptor	Final CY 2022 OPPS SI	Final CY 2022 OPPS APC	Proposed 2023 OPPS SI	Proposed 2023 OPPS APC
C9760	Non-randomized, non-blinded procedure for nyha class ii, iii, iv heart failure; transcatheter implantation of interatrial shunt including right and left heart catheterization, transeptal puncture, trans-esophageal echocardiography (tee)/intracardiac echocardiography (ice), and all imaging with or without guidance (eg, ultrasound, fluoroscopy), performed in an approved investigational device exemption (ide) study	T	1592	T	1592

g. Supervised Visits for Esketamine Self-Administration (APCs 1512 and 1516)

On March 5, 2019, FDA approved Spravato™ (esketamine) nasal spray, used in conjunction with an oral antidepressant, for treatment of depression in adults who have tried other antidepressant medicines but have not benefited from them (treatment-resistant depression (TRD)). Because of the risk of serious adverse outcomes resulting from sedation and dissociation caused by Spravato administration, and the potential for misuse of the product, it is only available through a restricted distribution system under a Risk Evaluation and Mitigation Strategy (REMS). A REMS is a drug safety program that FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks.

A treatment session of esketamine consists of instructed nasal self-administration by the patient followed by a period of post-administration observation of the patient under direct supervision of a health care professional. Esketamine is a noncompetitive N-methyl D-aspartate (NMDA) receptor antagonist. It is a nasal spray supplied as an aqueous solution of esketamine hydrochloride in a vial with a nasal spray device. This is the first FDA approval of esketamine for any use. Each device delivers two sprays containing a total of 28 mg of esketamine. Patients

would require either two devices (for a 56 mg dose) or three devices (for an 84 mg dose) per treatment.

Because of the risk of serious adverse outcomes resulting from sedation and dissociation caused by Spravato administration, and the potential for misuse of the product, Spravato is only available through a restricted distribution system under a REMS, patients must be monitored by a health care provider for at least two hours after receiving their Spravato dose, the prescriber and patient must both sign a Patient Enrollment Form, and the product must only be administered in a certified medical office where the health care provider can monitor the patient. Please refer to the CY 2020 PFS final rule and interim final rule for more information about supervised visits for esketamine self-administration (84 FR 63102 through 63105).

To facilitate prompt beneficiary access to the new, potentially life-saving treatment for TRD using esketamine, we created two new HCPCS G codes, G2082 and G2083, effective January 1, 2020. HCPCS code G2082 is for an outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of up to 56 mg of esketamine through nasal self-administration and includes two hours of post-administration observation. HCPCS code G2082 was assigned to New Technology APC 1508 (New Technology - Level 8 (\$601 - \$700)) with a payment rate of \$650.50. HCPCS code G2083 describes a similar service to HCPCS code G2082 but involves the administration of more than 56 mg of esketamine. HCPCS code G2083 was assigned to New Technology APC 1511 (New Technology - Level 11 (\$901 - \$1000)) with a payment rate of \$950.50.

For CY 2023, we propose to use CY 2021 claims data to determine the payment rates for HCPCS codes G2082 and G2083. Therefore, for CY 2023, we propose to assign these two HCPCS codes to New Technology APCs based on the codes' geometric mean costs. Specifically, we propose to assign HCPCS code G2082 to New Technology APC 1511 (New Technology - Level 11 (\$901 - \$1000)) based on its geometric mean cost of \$995.47. We also

propose to assign HCPCS code G2083 to New Technology APC 1516 (New Technology - Level 16 (\$1401 - \$1500)) based on its geometric mean cost of \$1,489.93.

Details about the proposed New Technology APC and status indicator assignments for these HCPCS codes are shown in Table 15. The proposed CY 2023 payment rates for these HCPCS codes can be found in Addendum B to this proposed rule.

TABLE 15: FINAL CY 2022 & PROPOSED CY 2023 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR HCPCS CODES G2082 AND G2083

HCPCS Code	Long Descriptor	Final CY 2022 OPPS SI	Final CY 2022 OPPS APC	Proposed CY 2023 OPPS SI	Proposed CY 2023 OPPS APC
G2082	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of up to 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation	S	1508	S	1511
G2083	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of greater than 56 mg esketamine nasal self-administration, includes 2 hours post-administration observation	S	1511	S	1516

h. DARI Motion Procedure (APC 1505)

CPT code 0693T (Comprehensive full body computer-based markerless 3D kinematic and kinetic motion analysis and report) was effective January 1, 2022. The technology consists of eight cameras that surround a patient. The cameras send live video to a computer workstation that analyzes the video to create a 3D reconstruction of the patient without the need for special clothing, markers, or devices attached to the patient’s clothing or skin. The technology is intended to guide health care providers on pre- and post-operative surgical intervention and on the best course of physical therapy and rehabilitation for patients. In CY 2022, we assigned CPT

code 0693T to New Technology APC 1505 (New Technology – Level 5 (\$301 - \$400)), for CY 2022.

This service became effective in the OPSS in CY 2022. Therefore, there are no claims for this service in the CY 2021 OPSS claims data. Accordingly, for CY 2023 we propose to continue assigning CPT code 0693T to New Technology APC 1505. The proposed New Technology APC and status indicator assignments for CPT code 0693T are found in Table 16.

TABLE 16: FINAL CY 2022 AND PROPOSED CY 2023 OPSS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE DARI MOTION PROCEDURE

CPT Code	Long Descriptor	Final CY 2022 OPSS SI	Final CY 2022 OPSS APC	Proposed CY 2023 OPSS SI	Proposed CY 2023 OPSS APC
0693T	Comprehensive full body computer-based markerless 3D kinematic and kinetic motion analysis and report	S	1505	S	1505

i. Histotripsy Service (APC 1575)

CPT code 0686T (Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance) was effective July 1, 2021.

Histotripsy is a non-invasive, non-thermal, mechanical process that uses a focused beam of sonic energy to destroy cancerous liver tumors. We note that the device that is used in the histotripsy procedure is currently under a Category A IDE clinical study (NCT04573881). The clinical trial is a non-randomized, prospective trial to evaluate the efficacy and safety of the device for the treatment of primary or metastatic tumors located in the liver.⁵ We note that devices from Category A IDE studies are excluded from Medicare payment. Therefore, payment for CPT code 0686T reflects only the service that is performed each time it is reported on a claim. For

⁵ ClinicalTrials.gov. “The HistoSonics System for Treatment of Primary and Metastatic Liver Tumors Using Histotripsy (#HOPE4LIVER) (#HOPE4LIVER).” Accessed May 10, 2022. <https://clinicaltrials.gov/ct2/show/study/NCT04573881>

CY 2022, we assigned CPT code 0686T to New Technology APC 1575 (New Technology – Level 38 (\$10,000 - \$15,000) with a payment rate of \$12,500.

Since the service became effective in the OPSS in July 2021, there are no claims for this service in the CY 2021 OPSS claims data. Therefore, for CY 2023, we propose to continue assigning CPT code 0686T to New Technology APC 1575. The proposed New Technology APC and status indicator assignments for CPT code 0686T are found in Table17.

TABLE 17: FINAL CY 2022 AND PROPOSED CY 2023 OPSS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE HISTOTRIPTY SERVICE

CPT Code	Long Descriptor	Final CY 2022 OPSS SI	Final CY 2022 OPSS APC	Proposed CY 2023 OPSS SI	Proposed CY 2023 OPSS APC
0686T	Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance	S	1575	S	1575

j. Liver Multiscan Service (APC 1511)

CPT code 0648T (Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic mri examination of the same anatomy (eg, organ, gland, tissue, target structure) during the same session; single organ) was effective July 1, 2021. LiverMultiScan is a Software as a medical Service (SaaS) that is intended to aid the diagnosis and management of chronic liver disease, the most prevalent of which is Non-Alcoholic Fatty Liver Disease (NAFLD). It provides standardized, quantitative imaging biomarkers for the characterization and assessment of inflammation, hepatocyte ballooning, and fibrosis, as well as steatosis, and iron accumulation. The SaaS receives MR images acquired from patients’ providers and analyzes the images using their proprietary Artificial Intelligence

(AI) algorithms. The SaaS then sends the providers a quantitative metric report of the patient’s liver fibrosis and inflammation. For CY 2022, we assigned CPT code 0648T to New Technology APC 1511 (New Technology – Level 11 (\$901 - \$1,000) with a payment rate of \$950.50.

Since HCPCS code 0648T became effective in the OPSS in July 2021, there has been only one claim from the CY 2021 claims data; but its payment rate appears to be an outlier based on the service invoice we received from the software developer. Accordingly, for CY 2023, we propose to continue assigning CPT code 0648T to New Technology APC 1511. The proposed New Technology APC and status indicator assignment for CPT code 0648T are found in Table 18.

TABLE 18: FINAL CY 2022 AND PROPOSED CY 2023 OPSS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE LIVER MULTISCAN SERVICE

CPT Code	Long Descriptor	Final CY 2022 OPSS SI	Final CY 2022 OPSS APC	Proposed CY 2023 OPSS SI	Proposed CY 2023 OPSS APC
0648T	Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic mri examination of the same anatomy (eg, organ, gland, tissue, target structure) during the same session; single organ	S	1511	S	1511

k. Minimally Invasive Glaucoma Surgery (MIGS) (APC 1526)

Prior to CY 2022, extracapsular cataract removal with insertion of intraocular lens was reported using CPT codes describing cataract removal alongside a CPT code for device insertion. Specifically, the procedure was described using CPT codes 66982 (Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (for example, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (for example, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; without endoscopic cyclophotocoagulation) or 66984 (Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (for example, irrigation and aspiration or phacoemulsification); without endoscopic cyclophotocoagulation) and 0191T (Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the trabecular meshwork; initial insertion).

For CY 2022, the AMA's CPT Editorial Panel created two new Category I CPT codes describing extracapsular cataract removal with insertion of intraocular lens prosthesis, specifically, CPT codes 66989 and 66991; deleted a Category III CPT code, specifically, CPT code 0191T, describing insertion of anterior segment aqueous drainage device; and created a new Category III CPT code, specifically, CPT code 0671T, describing interior segment aqueous drainage device without concomitant cataract removal.

For CY 2022, we finalized the assignment of CPT codes 66989 and 66991 to New Technology APC 1526 (New Technology – Level 26 (\$4001–\$4500)). We stated that we believed that the change in coding for MIGS is significant in that it changes longstanding billing for the service from reporting two separate CPT codes to reporting a single bundled code. Without claims data, and given the magnitude of the coding change, we explained that we did not believe we had the necessary information on the costs associated with CPT codes 66989 and 66991 to assign them to a clinical APC at that time.

We note that for this proposed rule, the proposed payment rates are based on claims data submitted between January 1, 2021, and December 31, 2021, and processed on or before December 31, 2021, and CCRs, if available. Because CPT codes 66989 and 66991 were effective January 1, 2022, and we have no claims data for CY 2022, we propose to continue assigning CPT codes 66989 and 66991 to New Technology APC 1526 for CY 2023. The proposed New Technology APC and status indicator assignments for CPT codes 66989 and 66991 are found in Table 19.

Table 19: CY 2022 FINAL AND CY 2023 PROPOSED OPPTS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODES 66989 AND 66991

CPT Code	Long Descriptor	Final CY 2022 OPPTS SI	Final CY 2022 OPPTS APC	Proposed CY 2023 OPPTS SI	Proposed OPPTS CY 2023 APC
66989	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more	S	1526	S	1526
66991	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); with insertion of intraocular (eg,	S	1526	S	1526

	trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more				
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1. Scalp Cooling (APC 1520)

CPT code 0662T (Scalp cooling, mechanical; initial measurement and calibration of cap) became effective on July 1, 2021 to describe initial measurement and calibration of a scalp cooling device for use during chemotherapy administration to prevent hair loss. According to Medicare’s National Coverage Determination (NCD) policy, specifically, NCD 110.6 (Scalp Hypothermia During Chemotherapy to Prevent Hair Loss), the scalp cooling cap itself is classified as an incident to supply to a physician service, and would not be paid under the OPSS; however, interested parties have indicated that there are substantial resource costs of around \$1,900 to \$2,400 associated with calibration and fitting of the cap. CPT guidance states that CPT code 0662T should be billed once per chemotherapy session, which we interpret to mean once per course of chemotherapy. Therefore, if a course of chemotherapy involves 6 or 18 sessions, HOPDs should report CPT 0662T only once for that 6 or 18 therapy sessions. For CY 2022, we assigned CPT code 0662T to APC New Technology 1520 (New Technology - Level 20 (\$1801-\$1900)) with a payment rate of \$1,850.50.

This service became effective in the OPSS in CY 2022. Therefore, there are no claims for this service in the CY 2021 OPSS claims data. Accordingly, for CY 2023, we propose to continue assigning CPT code 0662T to New Technology APC 1520. The proposed New Technology APC and status indicator assignments for CPT code 0662T are found in Table 20.

TABLE 20: FINAL CY 2022 AND PROPOSED CY 2023 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE SCALP COOLING PROCEDURE

CPT Code	Long Descriptor	Final CY 2022 OPPS SI	Final CY 2022 OPPS APC	Proposed CY 2023 OPPS SI	Proposed CY 2023 OPPS APC
0662T	Scalp cooling, mechanical; initial measurement and calibration of cap	S	1520	S	1520

m. Optellem Lung Cancer Prediction (LCP) (APC 1508)

CPT code 0721T (Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained without concurrent CT examination of any structure contained in previously acquired diagnostic imaging) became effective July 1, 2022. The Optellum LCP applies an algorithm to a patient’s CT scan to produce a raw risk score for a patient’s pulmonary nodule. The risk score is used by the physician to quantify the risk of lung cancer and to help determine whether to refer the patient to a pulmonologist. For CY 2022, we assigned CPT code 0721T to APC New Technology 1508 (New Technology - Level 8 (\$601-\$700)).

This service became effective in the OPSS in CY 2022. Therefore, there are no claims for this service in the CY 2021 OPSS claims data for use in CY 2023 ratesetting. Accordingly, for CY 2023, we propose to continue to assign CPT code 0721T to New Technology APC 1508 with a status indication of “S”. The proposed New Technology APC and status indicator assignments for CPT code 0721T are found in Table 21.

TABLE 21: FINAL CY 2022 AND PROPOSED CY 2023 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE OPTELLEM LCP PROCEDURE

CPT Code	Long Descriptor	Final CY 2022 OPSS SI	Final CY 2022 OPSS APC	Proposed CY 2023 OPSS SI	Proposed CY 2023 OPSS APC
0721T	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained without concurrent CT examination of any structure contained in previously acquired diagnostic imaging	S	1508	S	1508

n. Quantitative Magnetic Resonance Cholangiopancreatography (QMRCP) (APC 1511)

CPT code 0723T (Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained without diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (e.g., organ, gland, tissue, target structure) during the same session) became effective July 1, 2022. The QMRCP is a Software as a medical Service (SaaS) that performs quantitative assessment of the biliary tree and gallbladder. It uses a proprietary algorithm that produces a three-dimensional reconstruction of the biliary tree and pancreatic duct and also provides precise quantitative information of biliary tree volume and duct metrics. For CY 2022, we assigned CPT code 0723T to APC New Technology 1511 (New Technology - Level 11(\$900-\$1,000)).

This service became effective in the OPSS in CY 2022. Therefore, there are no claims for this service in the CY 2021 OPSS claims data. Accordingly, for CY 2023, we propose to continue to assign CPT code 0723T to New Technology APC 1511 with a status indicator of “S”. The proposed New Technology APC and status indicator assignments for CPT code 0723T are found in Table 22.

TABLE 22: FINAL CY 2022 AND PROPOSED CY 2023 OPSS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE QMRCP PROCEDURE

CPT Code	Long Descriptor	Final CY 2022 OPPS SI	Final CY 2022 OPPS APC	Proposed CY 2023 OPPS SI	Proposed CY 2023 OPPS APC
0723T	Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained without diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (eg, organ, gland, tissue, target structure) during the same session	S	1511	S	1511

o. CardiAMP (APC 1574)

The CardiAMP cell therapy IDE studies are two randomized, double-blinded, controlled IDE studies: the CardiAMP Cell Therapy Chronic Myocardial Ischemia Trial⁶ and the CardiAMP Cell Therapy Heart Failure Trial⁷. The two trials are designed to investigate the safety and efficacy of autologous bone marrow mononuclear cells treatment for the following: 1) patients with medically refractory and symptomatic ischemic cardiomyopathy; and 2) patients with refractory angina pectoris and chronic myocardial ischemia. On April 1, 2022, we established HCPCS code C9782 to describe the CardiAMP cell therapy IDE studies and assigned HCPCS code C9782 to APC 1574 (New Technology - Level 37 (\$9,501-\$10,000)) with the status indicator “T”. We subsequently revised the descriptor for HCPCS code C9782 to:

⁶ ClinicalTrials.gov. “Randomized Controlled Pivotal Trial of Autologous Bone Marrow Cells Using the CardiAMP Cell Therapy System in Patients With Refractory Angina Pectoris and Chronic Myocardial Ischemia.” Accessed May 10, 2022. <https://clinicaltrials.gov/ct2/show/NCT03455725?term=NCT03455725&rank=1>

⁷ ClinicalTrials.gov. “Randomized Controlled Pivotal Trial of Autologous Bone Marrow Mononuclear Cells Using the CardiAMP Cell Therapy System in Patients With Post Myocardial Infarction Heart Failure.” Accessed May 10, 2022. <https://clinicaltrials.gov/ct2/show/NCT02438306>

(Blinded procedure for New York Heart Association (NYHA) Class II or III heart failure, or Canadian Cardiovascular Society (CCS) Class III or IV chronic refractory angina; transcatheter intramyocardial transplantation of autologous bone marrow cells (e.g., mononuclear) or placebo control, autologous bone marrow harvesting and preparation for transplantation, left heart catheterization including ventriculography, all laboratory services, and all imaging with or without guidance (e.g., transthoracic echocardiography, ultrasound, fluoroscopy), all device(s), performed in an approved Investigational Device Exemption (IDE) study) to clarify the inclusion of the Helix transendocardial injection catheter device in the descriptor. Additionally, we determined that APC 1590 (New Technology - Level 39 (\$15,001-\$20,000)) most accurately accounts for the resources associated with furnishing the procedure described by HCPCS code C9782. We note that a transitional device pass-through application was submitted for the Helix transendocardial injection catheter device for CY 2023. We direct readers to section IV.A of this proposed rule for a more detailed discussion of the transitional device pass-through applications.

This service became effective in the OPSS in CY 2022. Therefore, there are no claims for this service in the CY 2021 OPSS claims data for use in CY 2023 ratesetting. Accordingly, for CY 2023, we propose to assign HCPCS code C9782 to New Technology APC 1590 with a status indication of “T”. The proposed New Technology APC and status indicator assignments for HCPCS code C9782 are found in Table 23.

TABLE 23: FINAL CY 2022 AND PROPOSED CY 2023 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE OPTELLUM LCP PROCEDURE

HCPCS Code	Long Descriptor	Final CY 2022 OPSS SI	Final CY 2022 OPSS APC	Proposed CY 2023 OPSS SI	Proposed CY 2023 OPSS APC
C9782	Blinded procedure for New York Heart Association (NYHA) Class II or III heart failure, or Canadian Cardiovascular Society (CCS) Class III or IV chronic refractory	T	1590	T	1590

HCPCS Code	Long Descriptor	Final CY 2022 OPPTS SI	Final CY 2022 OPPTS APC	Proposed CY 2023 OPPTS SI	Proposed CY 2023 OPPTS APC
	angina; transcatheter intramyocardial transplantation of autologous bone marrow cells (e.g., mononuclear) or placebo control, autologous bone marrow harvesting and preparation for transplantation, left heart catheterization including ventriculography, all laboratory services, and all imaging with or without guidance (e.g., transthoracic echocardiography, ultrasound, fluoroscopy), all device(s), performed in an approved Investigational Device Exemption (IDE) study				

D. Universal Low Volume APC Policy for Clinical and Brachytherapy APCs

In the CY 2022 OPPTS/ASC final rule with comment period (86 FR 63743 through 63747) we finalized our proposal to designate clinical and brachytherapy APCs as low volume APCs if they have fewer than 100 single claims that can be used for ratesetting purposes in the claims year used for ratesetting for the prospective year. For this proposed rule, CY 2021 claims are generally the claims used for ratesetting and clinical and brachytherapy APCs with fewer than 100 single claims from CY 2021 that can be used for ratesetting would be low volume APCs subject to our universal low volume APC policy. As we stated in the CY 2022 OPPTS/ASC final rule with comment period, we adopted this policy to reduce the volatility in the payment rate for

those APCs with fewer than 100 single claims. Where a clinical or brachytherapy APC has fewer than 100 single claims that can be used for ratesetting, under our low volume APC payment adjustment policy we determine the APC cost as the greatest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data. We excluded APC 5853 (Partial Hospitalization for CMHCs) and APC 5863 (Partial Hospitalization for Hospital-based PHPs) from our universal low volume APC policy given the different nature of policies that affect the partial hospitalization program. We also excluded APC 2698 (Brachytx, stranded, nos) and APC 2699 (Brachytx, non-stranded, nos) as our current methodology for determining payment rates for non-specified brachytherapy sources is appropriate.

Based on claims data available for this proposed rule, we propose to designate four brachytherapy APCs and four clinical APCs as low volume APCs under the OPPS. The four brachytherapy APCs and 4 clinical APCs meet our criteria of having fewer than 100 single claims in the claims year used for ratesetting (CY 2021 for this CY 2023 OPPS/ASC proposed rule) and therefore, we propose that they would be subject to our low volume APC policy. These eight APCs were designated as low volume APCs in CY 2022; a ninth APC -- APC 2647 (Brachytherapy, non-stranded, Gold-198) -- was designated as a low volume APC for CY 2022 but did not meet our claims threshold for this proposed rule.

Table 24 includes the APC geometric mean cost without the low volume APC designation, that is, if we calculated the geometric mean cost based on CY 2021 claims data available for ratesetting; the median, arithmetic mean, and geometric mean cost using up to four years of claims data based on the APCs' designation as a low volume APC; and the statistical methodology we propose to use to determine the APC's cost for ratesetting purposes for CY 2023. As discussed in our CY 2022 OPPS/ASC final rule with comment period (86 FR 63751 through 63754), given our concerns with CY 2020 claims data as a result of the PHE, the 4 years of claims data we proposed to use to calculate the costs for these APCs are CYs 2017, 2018, 2019, and 2021.

**TABLE 24: COST STATISTICS FOR PROPOSED LOW VOLUME APCS
USING COMPREHENSIVE (OPPS) RATESETTING METHODOLOGY FOR CY 2023**

APC	APC Description	CY 2021 Claims Available for Ratesetting	Geometric Mean Cost without Low Volume APC Designation	Proposed Median Cost	Proposed Arithmetic Mean Cost	Proposed Geometric Mean Cost	Proposed CY 2023 APC Cost
2632	Iodine I-125 sodium iodide	9	\$141.23	\$31.74	\$44.35	\$37.26	\$44.35
2635	Brachytx, non-str, HA, P-103	26	\$125.24	\$34.04	\$51.09	\$42.77	\$51.09
2636	Brachy linear, non-str, P-103	0	---*	\$49.65	\$53.38	\$38.80	\$53.38
2647	Brachytx, NS, Non-HDRIr-192	14	\$144.37	\$184.49	\$377.65	\$141.18	\$377.65
5244	Level 4 Blood Product Exchanges and Related Services	61	\$44,995.52	\$40,050.40	\$42,322.34	\$37,808.63	\$42,322.34
5494	Level 4 Intraocular Procedures	52	\$10,716.07	\$16,498.85	\$15,812.91	\$12,394.87	\$16,498.85
5495	Level 5 Intraocular Procedures	12	\$11,280.14	\$16,711.80	\$15,595.47	\$12,577.08	\$16,711.80
5881	Ancillary Outpatient Services When Patient Dies	71	\$7,882.93	\$6,955.70	\$12,301.75	\$7,217.15	\$12,301.75

* For this proposed rule, there are no CY 2021 claims that contain the HCPCS code assigned to APC 2636 (HCPCS code C2636) that are available for CY 2023 OPPS/ASC ratesetting.

E. OPPS APC-Specific Policies

1. Fractional Flow Reserve Derived from Computed Tomography (FFRCT) (APC 5724)

Fractional Flow Reserve Derived from Computed Tomography (FFRCT), also known by the trade name HeartFlow, is a noninvasive diagnostic service that allows physicians to measure coronary artery disease in a patient through the use of coronary CT scans. The HeartFlow procedure is intended for clinically stable symptomatic patients with coronary artery disease,

and, in many cases, may avoid the need for an invasive coronary angiogram procedure.

HeartFlow uses a proprietary data analysis process performed at a central facility to develop a three-dimensional image of a patient's coronary arteries, which allows physicians to identify the fractional flow reserve to assess whether patients should undergo further invasive testing (that is, a coronary angiogram).

For many services paid under the OPPS, payment for analytics that are performed after the main diagnostic/image procedure are packaged into the payment for the primary service. However, in CY 2018, we determined that we should pay separately for HeartFlow because the service is performed by a separate entity (that is, a HeartFlow technician who conducts computer analysis offsite) rather than the provider performing the CT scan. We assigned CPT code 0503T, which describes the analytics performed, to New Technology APC 1516 (New Technology - Level 16 (\$1,401 - \$1,500)), with a payment rate of \$1,450.50 based on pricing information provided by the developer of the procedure that indicated the price of the procedure was approximately \$1,500. We did not have Medicare claims data in CY 2019 for CPT code 0503T, and we continued to assign the service to New Technology APC 1516 (New Technology - Level 16 (\$1,401 - \$1,500)), with a payment rate of \$1,450.50.

CY 2020 was the first year for which we had Medicare claims data to calculate the cost of HCPCS code 0503T. For the CY 2020 OPPS/ASC final rule with comment period, there were 957 claims with CPT code 0503T, of which 101 were single frequency claims that were used to calculate the geometric mean of the procedure. We planned to use the geometric mean to determine the cost of HeartFlow for purposes of determining the appropriate APC assignment for the procedure. However, the number of single claims for CPT code 0503T was below the New Technology APC low-volume payment policy threshold for the proposed rule, and this number of single claims was only two claims above the threshold for the New Technology APC low-volume policy for the final rule. Therefore, we used our equitable adjustment authority under section 1833(t)(2)(E) of the Act to calculate the geometric mean, arithmetic mean, and

median using the CY 2018 claims data to determine an appropriate payment rate for HeartFlow using our New Technology APC low-volume payment policy. While the number of single frequency claims was just above our threshold to use the low-volume payment policy, we still had concerns about the normal cost distribution of the claims used to calculate the payment rate for HeartFlow, and we decided the low-volume payment policy would be the best approach to address those concerns.

Our analysis found that the geometric mean cost for CPT code 0503T was \$768.26, the arithmetic mean cost for CPT code 0503T was \$960.12, and the median cost for CPT code 0503T was \$900.28. Of the three cost methods, the highest amount was for the arithmetic mean, which fell within the cost band for New Technology APC 1511 (New Technology—Level 11 (\$901–\$1000)) with a payment rate of \$950.50. The arithmetic mean also helped to account for some of the higher costs of CPT code 0503T identified by the developer and other stakeholders that may not have been reflected by either the median or the geometric mean.

For CY 2021, we observed a significant increase in the number of claims billed with CPT code 0503T. Specifically, using CY 2019 data, we identified 3,188 claims billed with CPT code 0503T including 465 single frequency claims. These totals were well above the threshold of 100 claims for a procedure to be evaluated using the New Technology APC low-volume policy. Therefore, we used our standard methodology rather than the low-volume methodology we previously used to determine the cost of CPT code 0503T. Our analysis found that the geometric mean for CPT code 0503T was \$804.35, and the geometric mean cost for the service fell within the cost band for New Technology APC 1510 (New Technology—Level 10 (\$801–\$900)). However, providers and other stakeholders noted that the FFRCT service costs \$1,100 and that there are additional staff costs related to the submission of coronary CT image data for processing by HeartFlow.

We noted that HeartFlow was one of the first procedures utilizing artificial intelligence to be separately payable in the OPPS, and providers were learning how to accurately report their

charges to Medicare when billing for artificial intelligence services (85 FR 85943). This especially appeared to be the case for allocating the cost of staff resources between the HeartFlow procedure and the coronary CT imaging services. Therefore, we decided it would be appropriate to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to assign CPT code 0503T to the same New Technology APC in CY 2021 as in CY 2020 in order to provide payment stability and equitable payment for providers as they continued to become familiar with the proper cost reporting for HeartFlow and other artificial intelligence services. Accordingly, we assigned CPT code 0503T to New Technology APC 1511 (New Technology—Level 11 (\$901–\$1000)) with a payment rate of \$950.50 for CY 2020, and we continued to assign CPT code 0503T to New Technology APC 1511 for CY 2021.

For CY 2022, we used claims data from CY 2019 to estimate the cost of the HeartFlow service. Because we were using the same claims data as in CY 2021, these data continued to reflect that providers were learning how to accurately report their charges to Medicare when billing for artificial intelligence services. Therefore, we continued to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to assign CPT code 0503T to the same New Technology APC in CY 2022 as in CY 2020 and CY 2021: New Technology APC 1511 (New Technology—Level 11 (\$901–\$1000)), with a payment rate of \$950.50 for CY 2022, which was the same payment rate for the service as in CY 2020 and CY 2021.

For CY 2023, we have three years of claims data from CY 2018, CY 2019, and CY 2021 for CPT code 0503T to review to determine whether there is an appropriate clinical APC to assign the HeartFlow service. First, we have sufficient single frequency claims from these three years to have a reliable estimate of the cost of the service. There were 101 single frequency claims in CY 2018, 465 single frequency claims in CY 2019, and 1,681 single frequency claims in CY 2021. The estimated cost of 0503T has been reasonably consistent over the same three years as well. The estimated cost of HeartFlow was around \$768 in CY 2018, around \$808 in CY 2019, and around \$827 in CY 2021. Since the cost data have been stable for HeartFlow, we

can assign it to a clinical APC using our regular process of using the most recent year of claims data for a procedure. HeartFlow is a diagnostic service, and the OPSS has a clinical APC series for diagnostic tests and related services, with the cost of 0503T based on claims data falling between Level 3, with a payment rate of around \$498, and Level 4, with a payment rate of around \$961. Since the geometric mean cost of HCPCS code 0503T is \$827, and \$827 is closer to \$961 than \$498, the best APC assignment for the HeartFlow procedure appears to be APC 5724 (Level 4 Diagnostic Tests and Related Services).

Therefore, we propose for CY 2023 to assign CPT code 0503T to clinical APC 5724 (Level 4 Diagnostic Tests and Related Services). Table 25 shows the current and proposed status indicator and APC assignment for 0503T. We refer readers to Addendum B of this proposed rule for the payment rates for all codes reportable under the OPSS. Addendum B is available via the internet on the CMS website.

TABLE 25: FINAL CY 2022 AND PROPOSED CY 2023 OPSS APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODE 0503T

CPT Code	Long Descriptor	Final CY 2022 OPSS SI	Final CY 2022 OPSS APC	Proposed CY 2023 OPSS SI	Proposed CY 2023 OPSS APC
0503T	Noninvasive estimated coronary fractional flow reserve (ffr) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; analysis of fluid dynamics and simulated maximal coronary hyperemia, and generation of estimated ffr model	S	1511	S	5724

2. Neurostimulator and Related Procedures (APCs 5461 Through 5465)

In the CY 2015 OPSS/ASC final rule with comment period (79 FR 66807 through 66808), we finalized a restructuring of what were previously several neurostimulator

procedure-related APCs into a four-level series. Since CY 2015, the four-level APC structure for the series has remained unchanged. In addition to that restructuring, in the CY 2015 OPSS/ASC final rule with comment period, we also made the Levels 2 through 4 APCs comprehensive APCs (79 FR 66807 through 66808). Later, in the CY 2020 OPSS/ASC final rule with comment period, we also made the Level 1 Neurostimulator and Related Procedure APC (APC 5461) a comprehensive APC (84 FR 61162 through 61166).

In reviewing the claims data available for the CY 2021 OPSS/ASC proposed rule, we believed that it was appropriate to create an additional Neurostimulator and Related Procedures level, between what were then the Levels 2 and 3 APCs. Creating this APC allowed for a smoother distribution of the costs between the different levels based on their resource costs and clinical characteristics. Therefore, for the CY 2021 OPSS, we finalized a five-level APC structure for the Neurostimulator and Related Procedures series (85 FR 85968 through 85970). In addition to creating the new level, we also assigned CPT code 0398T (Magnetic resonance image guided high intensity focused ultrasound (mrgfus), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed) to the new Level 3 APC (85 FR 85970).

Some commenters have requested that we create a Level 6 Neurostimulator and Related Procedures APC, due to their concerns around clinical and resource cost similarity in the Level 5 Neurostimulator and Related Procedures APC. Based on our review of the data available for this CY 2023 OPSS/ASC proposed rule, we believe that the five-level structure for the Neurostimulator and Related Procedures APC series remains appropriate. The proposed geometric mean cost for the Level 5 Neurostimulator and Related Procedures is \$30,198.36 with the geometric means of cost significant codes in Level 5 ranging from approximately \$28,000 to \$36,000, which is well within the range of the 2 times rule. In addition, a review of the clinical characteristics of the services in the APC suggests that the current structure is appropriate. Finally, as discussed in the CY 2021 OPSS/ASC final rule with comment period, we reiterate

that the OPSS is a prospective payment system. We group procedures with similar clinical characteristics and resource costs into APCs and establish a payment rate that reflects the geometric mean of all services in the group even though the cost of each service within the APC may be higher or lower than the APC's geometric mean. As a result, in the OPSS any individual procedure may potentially be overpaid or underpaid because the payment rate is based on the geometric mean of the entire group of services in the APC. However, the impact of these payment differences should be mitigated when distributed across a large number of APCs. (85 FR 85968).

While we are not proposing any changes in the CY 2023 OPSS to the 5-level structure of the Neurostimulator and Related Procedures APC series in this proposed rule, we recognize the commenters' concerns regarding the granularity of the current APC levels and their request to create an additional level to address such concerns. Accordingly, we are soliciting comments on the potential creation of a new Level 6 APC from the current Level 5 within the Neurostimulator and Related Procedures APC series, which would include the following codes:

- 0266T: Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)
- 0268T: Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)
- 0424T: Insertion or replacement of neurostimulator system for treatment of central sleep apnea; complete system (transvenous placement of right or left stimulation lead, sensing lead, implantable pulse generator)
- 0431T: Removal and replacement of neurostimulator system for treatment of central sleep apnea, pulse generator only

- 64568: Open implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator

In summary, for the CY 2023, we propose to maintain the current 5-level structure for the Neurostimulator and Related Procedure APC series. However, we are also soliciting comment from stakeholders on the creation of an additional Level 6 APC in the series from the current Level 5 APC. See Table 26 below for the proposed CY 2023 for the Neurostimulator and Related Procedures APCs.

TABLE 26: PROPOSED CY 2023 NEUROSTIMULATOR AND RELATED PROCEDURES APCS

APC	Group Title	SI	Proposed CY 2023 Proposed APC Geometric Mean Cost	6-Level Alternative APC Geometric Mean Cost
5461	Level 1 Neurostimulator and Related Procedures	J1	\$3,491.49	\$3,491.49
5462	Level 2 Neurostimulator and Related Procedures	J1	\$6,808.24	\$6,808.24
5463	Level 3 Neurostimulator and Related Procedures	J1	\$12,980.43	\$12,980.43
5464	Level 4 Neurostimulator and Related Procedures	J1	\$22,059.02	\$22,059.02
5465	Level 5 Neurostimulator and Related Procedures	J1	\$30,198.36	\$29,434.26
5466	Level 6 Neurostimulator and Related Procedures	J1	N/A	\$33,947.12

3. Urology and Related Services (APCs 5371 through 5378)

In the CY 2021 OP/AS final rule with comment period (85 FR 85984 through 85986), we finalized a reorganization of the Urology and Related Services APCs from what was previously a seven-level series of related APCs into an eight-level series. In addition to creating the Urology and Related Services APC 5378 (Level 8 Urology and Related Services), and finalizing the reassignment of several urology procedures, we also revised the APC assignment for CPT 53440 (Male sling procedure) and CPT 0548T (Transperineal periurethral balloon continence device; bilateral placement, including cystoscopy and fluoroscopy) from APC 5376 to APC 5377. We believed the CY 2021 reorganization appropriately addressed the resource

costs for the procedures whose geometric mean costs were between APC 5376 and APC 5377.

Since CY 2021, the eight-level APC structure for the series has remained unchanged.

In our annual review of the CY 2021 claims submitted between January 1, 2021 through December 31, 2021 and processed on or before December 31, 2021, we examined the procedures assigned to the Urology Procedures APCs. In the CY 2022 final rule with comment period (86 FR 63565), we received comments requesting that CPT code 55880 be reassigned from APC 5375 (Level 5 Urology and Related Services) to APC 5376 (Level 6 Urology and Related Services). We remind readers that, for the CY 2022 ratesetting, we used the CY 2019 claims data due to the PHE. For CY 2022, we did not finalize any APC reassignment because our data analysis using the CY 2019 claims did not support the impact on the urology APCs' geometric means. For the CY 2023 ratesetting, we propose to use CY 2021 claims data. Using the CY 2021 claims data, we identified eight procedures (listed below) from APC 5375 whose geometric mean ranged between the geometric means for APC 5375 and APC 5376. The geometric means of these services are closer to the geometric mean of APC 5376, which is \$8,788.53, than the geometric mean of APC 5375, which is \$4,826.23. This reassignment to APC 5476 improves the resource cost and clinical homogeneity for the procedures within APC 5375 and APC 5376. Below is a list of the procedures and their geometric mean costs that we propose to reassign from APC 5375 to APC 5376 for CY 2023.

- CPT 50576: Renal endoscopy through nephrotomy or pyelotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with fulguration and/or incision, with or without biopsy (Geometric mean cost: \$11,137.98)
- HCPCS C9769: Cystourethroscopy, with insertion of temporary prostatic implant/stent with fixation/anchor and incisional struts (Geometric mean cost: \$7,742.45)
- CPT 51860: Cystorrhaphy, suture of bladder wound, injury or rupture; simple (Geometric mean cost: \$7,548.83)

- CPT 0549T: Transperineal periurethral balloon continence device; unilateral placement, including cystoscopy and fluoroscopy (Geometric mean cost: \$7,337.54)
- CPT 53449: Repair of inflatable urethral/bladder neck sphincter, including pump, reservoir, and cuff (Geometric mean cost: \$7,109.79)
- CPT 54344: Repair of hypospadias complication(s) (ie, fistula, stricture, diverticula); requiring mobilization of skin flaps and urethroplasty with flap or patch graft (Geometric mean cost: \$7,005.64)
- CPT 54316: Urethroplasty for second stage hypospadias repair (including urinary diversion) with free skin graft obtained from site other than genitalia (Geometric mean cost: \$7,069.06)
- CPT 55880: Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (hifu), including ultrasound guidance (Geometric mean cost: \$7,015.62)

In summary, for the CY 2023, we propose to reassign eight procedures from APC 5375 to APC 5376 for the Urology and Related Procedure APC series. Table 27 below shows the proposed geometric mean cost for each APC with reassignment of the eight procedures.

TABLE 27: PROPOSED CY 2023 UROLOGY AND RELATED SERVICES APCs

APC	Group Title	SI	Proposed CY 2023 Proposed APC Geometric Mean Cost With Reassignment
5371	Level 1 Urology and Related Services	J1	\$226.14
5372	Level 2 Urology and Related Services	J1	\$643.47
5373	Level 3 Urology and Related Services	J1	\$1,906.74
5374	Level 4 Urology and Related Services	J1	\$3,289.11
5375	Level 5 Urology and Related Services	J1	\$4,826.23
5376	Level 6 Urology and Related Services	J1	\$8,788.53

APC	Group Title	SI	Proposed CY 2023 Proposed APC Geometric Mean Cost With Reassignment
5377	Level 7 Urology and Related Services	J1	\$12,357.80
5378	Level 8 Urology and Related Services	J1	\$19,806.45

4. Unlisted Dental Procedure/Service (APC 5871)

For CY 2022, CPT code 41899 (Unlisted procedure, dentoalveolar structures) is assigned to APC 5161 (Level 1 ENT Procedures). Unlisted codes, like CPT 41899, do not describe any specific procedure or service, so they lack the specificity needed to describe the resources used. As a reminder, the fact that a drug, device, procedure, or service is assigned a HCPCS code and a payment rate under the OPSS does not imply coverage by the Medicare program, but indicates only how the product, procedure, or service may be paid if covered by the program. Medicare Administrative Contractors (MACs) determine whether a drug, device, procedure, or other service meets all program requirements for coverage. For example, MACs determine that the drug, device, procedure, or service is reasonable and necessary to treat the beneficiary's condition and whether it is excluded from payment. Unlisted codes provide a way for providers to report services for which there is no HCPCS code that specifically describes the service furnished. Because of the lack of specificity, unlisted codes are generally assigned to the lowest level APC within the most appropriate clinically related APC group under the OPSS. However, we believe that APC 5161 (Level 1 ENT Procedures) is not the most clinically appropriate APC series for this code. While APC 5161 includes some dental services, we believe that CPT code 41899 is more closely aligned clinically to the dental services in APC 5871 (Dental Procedures), which is the sole APC where dental procedures described by the Current Dental Terminology (CDT) reside. Therefore, for CY 2023, we propose to reassign HCPCS code 41899 to clinical APC 5871, which is the only, and therefore lowest, APC group that specifically describes dental procedures.

While we do not consider costs for services described by unlisted codes for rate setting purposes, based on both our established policy of generally assigning these codes to the lowest level APC within the most appropriate, clinically related APC group, and our inability to determine the specific services the unlisted code describes, we would note that the geometric mean cost for CPT code 41899 is more closely aligned with the geometric mean cost of other dental procedures in APC 5871 than with its current APC assignment. Specifically, in our annual review of the CY 2021 claims submitted between January 1, 2021 through December 31, 2021 and processed on or before December 31, 2021, the geometric mean cost for CPT code 41899 was \$2,310.47, while the geometric mean cost of the code’s current APC assignment, APC 5161, was \$203.64. In contrast, the geometric mean cost of APC 5871 (Dental Procedures) was \$1,958.92.

Table 28 below shows the current and proposed status indicator and APC assignment for CPT code 41899. We refer readers to Addendum B of this proposed rule for the payment rates for all codes reportable under the OPSS. Addendum B is available via the internet on the CMS website.

TABLE 28: CY 2023 PROPOSED OPSS APC AND STATUS INDICATOR FOR CPT CODE 41899

CPT Code	Long Descriptor	CY 2022 OPSS SI	CY 2022 OPSS APC	Proposed CY 2023 OPSS SI	Proposed CY 2023 OPSS APC
41899	Unlisted procedure, dentoalveolar structures	T	5161	S	5871

5. COVID-19 Vaccine and Monoclonal Antibody Administration Services

a. Statutory and Regulatory Background

Section 3713 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L 116-136, March 27, 2020) provides for coverage of the COVID-19 vaccine under Part B

of the Medicare program without any beneficiary cost sharing. Specifically, section 3713 added the COVID-19 vaccine and its administration to section 1861(s)(10)(A) of the Act in the same subparagraph as the influenza and pneumococcal vaccines and their administration. Additionally, section 3713(e) of the CARES Act authorizes CMS to implement the amendments made by section 3713 “through program instruction or otherwise.” The changes to section 1861(s)(10)(A) of the Act were effective on the date of enactment, that is, March 27, 2020, and apply to a COVID-19 vaccine beginning on the date that such vaccine is licensed under section 351 of the PHS Act (42 U.S.C. 262).

We discussed our implementation of section 3713 in the interim final rule with comment period titled, “Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency,” published in the November 6, 2020 **Federal Register** (85 FR 71145 through 71150). In that rule, we stated that, while section 3713(e) of the CARES Act authorizes us to implement the amendments made by that section through program instruction or otherwise, we believed it was important to clarify our interpretation of section 3713 and announce our plans to ensure timely Medicare Part B coverage and payment for the COVID-19 vaccine and its administration. We anticipated that payment rates for the administration of other Part B preventive vaccines and related services, such as the flu and pneumococcal vaccines, would inform the payment rates for administration of COVID-19 vaccines. In the same interim final rule, we stated that, as soon as practicable after the authorization or licensure of each COVID-19 vaccine product by FDA, we would announce the interim coding and a payment rate for its administration (or, in the case of the OPSS, an APC assignment for each vaccine product's administration code), taking into consideration any product-specific costs or considerations involved in furnishing the service. We further stated that the codes and payment rates would be announced through technical direction to the Medicare Administrative Contractors (MACs) and posted publicly on the CMS website.

In December 2020, we publicly posted the applicable CPT codes for the Pfizer-BioNTech and Moderna COVID-19 vaccines and initial Medicare payment rates for administration of these vaccines upon FDA's authorization of them. We announced an initial Medicare payment rate for COVID-19 vaccine administration of \$28.39 to administer single-dose vaccines. For a COVID-19 vaccine requiring a series of two or more doses—for example, for both the Pfizer-BioNTech and Moderna products—we announced a payment rate for administration of the initial dose(s) of \$16.94, which was based on the Medicare payment rate for administering the other preventive vaccines under section 1861(s)(10) of the Act. We also announced a payment rate for administering the second dose of \$28.39.⁸ CMS continues to establish product-specific HCPCS codes for each COVID-19 vaccine product on a rolling basis as they are authorized by the FDA. On March 15, 2021, we announced an increase in the payment rate for administering a COVID-19 vaccine to \$40 per dose, effective for doses administered on or after March 15, 2021. For additional information, on timing and payment rates for COVID-19 vaccine administration, please see the CMS website: <https://www.cms.gov/medicare/preventive-services/covid-19-services-billing-coverage/covid-19/medicare-covid-19-vaccine-shot-payment>.

b. Payment for COVID-19 Vaccine Administration Services Under the OPPS

Under the OPPS, separate payment is made for the COVID-19 vaccine product and its administration. Except when the provider receives the COVID-19 vaccine for free (as has been the case to date), providers are paid for COVID-19 vaccine products at reasonable cost, as is the case with influenza and pneumococcal vaccines.⁹ The HCPCS codes associated with the vaccine products are assigned OPPS status indicator "L" to indicate that they are paid at reasonable cost and are exempt from coinsurance and deductible payments under sections 1833(a)(3) and 1833(b) of the Act.

⁸ Medicare COVID-19 Vaccine Shot Payment. CMS Website. <https://www.cms.gov/medicare/preventive-services/covid-19-services-billing-coverage/covid-19/medicare-covid-19-vaccine-shot-payment#:~:text=%2416.94%20for%20the%20initial%20dose,final%20dose%20in%20the%20series>

⁹ COVID-19 Vaccines and Monoclonal Antibodies. CMS Website. <https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-mono-clonal-antibodies>.

While COVID-19 and other preventive vaccine products are paid based on reasonable cost under the OPPTS, the payment rates for the COVID-19 vaccine administration HCPCS codes are based on the APCs to which the codes are assigned. Because COVID-19 vaccination can involve more than one dose, we established APCs 9397 (COVID-19 Vaccine Admin Dose 1 of 2) and 9398 (COVID-19 Vaccine Admin Dose 2 of 2, Single Dose Product or Additional Dose) to appropriately identify and pay for the administration of the COVID-19 vaccines. In CY 2021, we announced the establishment of APCs 9397 and 9398 for the COVID-19 vaccine administration codes through the April 2021 OPPTS Update CR (Transmittal 10666, Change Request 12175 dated March 8, 2021). Prior to March 15, 2021, APC 9397 for the first dose of the COVID-19 vaccine was assigned a payment rate of \$16.94; and APC 9398 for the second dose was assigned a payment rate of \$28.39. As described above, we changed the payment rate to \$40 per dose for the first, second, and booster dose(s) of the COVID-19 vaccine effective March 15, 2021.

For CYs 2021 and 2022, we maintained the payment rate of \$40 for the APCs to which the COVID-19 vaccine administration services are assigned. For further information please see Addendum B on the CY 2021 and 2022 OPPTS websites.

As of July 1, 2022, there are approximately 18 COVID-19 vaccine administration HCPCS codes. These codes are listed in Table 29 below. We note that the latest list of HCPCS codes for COVID-19 vaccine products and vaccine administration, along with their effective dates and payment rates, is available on the CMS COVID-19 Vaccines and Monoclonal Antibodies website at <https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies>.

Based on our review of CY 2021 claims data associated with the COVID-19 vaccine administration HCPCS codes, the geometric mean cost for APC 9397 is \$25.86 and the geometric mean cost for APC 9398 is \$36.80. We note that CY 2021 utilization of the COVID-19 vaccine administration codes in the outpatient hospital setting was very high, with nearly

7 million claims for these codes in that year and may not be reflective of future year utilization. Since we do not know if demand for COVID-19 vaccine administration in the outpatient hospital setting will be significantly different in CY 2023 than CY 2021 because CY 2021 was the first complete year for which we had COVID-19 vaccine administration claims data, and because we do not know if the PHE for COVID-19 will be in effect in CY 2023, we believe that we should maintain the \$40 per dose payment rate for the COVID-19 administration HCPCS codes in CY 2023 until we have an additional year of claims data on which to base the payment rate. Therefore, for CY 2023 we propose to use the equitable adjustment authority at 1833(t)(2)(E) to maintain the payment rate of \$40 for each of the COVID-19 vaccine administration APCs 9397 and 9398. We believe maintaining the current, site neutral, payment rate is necessary to ensure equitable payments during the continuing PHE and at least through the end of CY 2023. We refer readers to Table 29 below for the proposed payment rates for the COVID-19 vaccine administration HCPCS codes.

We also note that this policy does not pertain to OPPS payment for monoclonal antibody products used for COVID-19 and their administration. The OPPS payment rates for administration of COVID-19 monoclonal antibody products under the Part B preventive vaccine benefit are set at the midpoint of the cost bands for the New Technology APCs to which the monoclonal antibody administration services are assigned under the OPPS. We assigned COVID-19 monoclonal antibody administration services to New Technology APCs based on estimated costs for these services.

c. Use of Alternative Site-Neutral Methodology to Update Payment Rates for COVID-19 Vaccine Administration Services for CY 2023

Under current policy, the payment rates for COVID-19 vaccine administration services are site-neutral across most outpatient and ambulatory settings. We request comment on whether we should continue a site-neutral payment policy for COVID-19 vaccine administration for CY 2023, and what alternative approaches (including under our equitable adjustment authority at

1833(t)(2)(E)) may be appropriate to update the OPPS payment rates for the COVID-19 vaccine administration HCPCS codes (including the in-home add-on HCPCS code M0201) while continuing to ensure site-neutral payment for these services. For example, in the CY 2023 PFS proposed rule that will be included in the July 29, 2022 **Federal Register**, we are proposing to update the payment rate for the administration of preventive vaccines (other than for COVID-19 and other than for services paid under other payment systems such as the OPPS) using the annual increase to the Medicare Economic Index (MEI). We request public comments on whether, as an alternative to our proposal to maintain current OPPS payment rates for COVID-19 vaccine administration using our equitable adjustment authority at section 1833(t)(2)(E), we should instead use the rate finalized through PFS rulemaking that generally applies under the preventive vaccine benefit, or an alternative method commenters suggest, to determine the appropriate payment rates for preventive vaccine administration under the OPPS, which would likely also require use of our equitable adjustment authority.

For more information on the payment rates for the administration of preventive vaccines, including the proposal to update the payment rate by the annual increase to the MEI, we refer readers to the CY 2023 PFS proposed rule that will be included in the July 29, 2022 **Federal Register**.

We are also seeking comment on whether to use the rate finalized through PFS rulemaking generally as it applies under the preventive vaccine benefit, or an alternative method commenters suggest, to set the CY 2023 payment rate for HCPCS code M0201 (*COVID-19 vaccine administration inside a patient's home; reported only once per individual home per date of service when only COVID-19 vaccine administration is performed at the patient's home*).

In summary, for CY 2023, we are proposing to continue to pay \$40 per dose for the administration of the COVID-19 vaccines provided in the HOPD setting, and an additional \$35.50 for the administration of the COVID-19 vaccines when provided under certain circumstances in the patient's home, in CY 2023. Additionally, we request comments on

whether, as an alternative to maintaining the CY 2022 OPPS payment rates for COVID-19 vaccine administration services in CY 2023, we should use a different approach, including relying on our equitable adjustment authority in section 1833(t)(2)(E) to base the payment rate for COVID-19 vaccine administration under the OPPS in CY 2023 on the payment rate for the COVID-19 vaccine administration under the preventive vaccine benefit under Part B as finalized in PFS rulemaking, or employing another alternate methodology to set CY 2023 payment rates for these services.

TABLE 29: PROPOSED CY 2023 SI, APCS, AND PAYMENT RATES FOR COVID-19 ADMINISTRATION SERVICES

HCPCS Code	Short Descriptor	CY 2022 OPPS SI	CY 2022 OPPS APC	CY 2022 OPPS Payment	Proposed CY 2023 OPPS SI	Proposed CY 2023 OPPS APC	Proposed CY 2023 OPPS Payment
M0201	Covid-19 vaccine home admin	S	1494	\$35.50	S	1494	\$35.50
0001A	Adm sarscov2 30mcg/0.3ml 1st	S	9397	\$40.00	S	9397	\$40.00
0002A	Adm sarscov2 30mcg/0.3ml 2 nd	S	9398	\$40.00	S	9398	\$40.00
0003A	Adm sarscov2 30mcg/0.3ml 3 rd	S	9398	\$40.00	S	9398	\$40.00
0004A	Adm sarscov2 30mcg/0.3ml bst	S	9398	\$40.00	S	9398	\$40.00
0011A	Adm sarscov2 100mcg/0.5ml 1st	S	9397	\$40.00	S	9397	\$40.00
0012A	Adm sarscov2 100mcg/0.5ml 2 nd	S	9398	\$40.00	S	9398	\$40.00
0013A	Adm sarscov2 100mcg/0.5ml 3 rd	S	9398	\$40.00	S	9398	\$40.00
0031A	Adm sarscov2 vac ad26 .5ml	S	9398	\$40.00	S	9398	\$40.00
0034A	Adm sarscov2 vac ad26 .5ml b	S	9398	\$40.00	S	9398	\$40.00
0051A	Adm sarscv2 30mcg trs-sucr 1	S	9397	\$40.00	S	9397	\$40.00
0052A	Adm sarscv2 30mcg trs-sucr 2	S	9398	\$40.00	S	9398	\$40.00
0053A	Adm sarscv2 30mcg trs-sucr 3	S	9398	\$40.00	S	9398	\$40.00
0054A	Adm sarscv2 30mcg trs-sucr b	S	9398	\$40.00	S	9398	\$40.00
0064A	Adm sarscov2 50mcg/0.25mlbst	S	9398	\$40.00	S	9398	\$40.00

HCPCS Code	Short Descriptor	CY 2022 OPSS SI	CY 2022 OPSS APC	CY 2022 OPSS Payment	Proposed CY 2023 OPSS SI	Proposed CY 2023 OPSS APC	Proposed CY 2023 OPSS Payment
0071A	Adm sarscv2 10mcg trs-sucr 1	S	9397	\$40.00	S	9397	\$40.00
0072A	Adm sarscv2 10mcg trs-sucr 2	S	9398	\$40.00	S	9398	\$40.00
0073A	Adm sarscv2 10mcg trs-sucr 3	S	9398	\$40.00	S	9398	\$40.00
0094A	Adm sarscov2 50 mcg/.5 mlbst	S	9398	\$40.00	S	9398	\$40.00

d. Comment Solicitation on the Appropriate Payment Methodology for Administration of Preventive Vaccines Post PHE

Currently, under the OPSS, the codes describing the administration of the influenza, pneumococcal, and hepatitis b vaccines are assigned to APC 5691 (Level 1 Drug Administration), with a payment rate of about \$40. However, given that the statutory benefit for Medicare Part B preventive vaccines and their administration is based on 1861(s)(10) of the Act, we are seeking comments on whether we should adopt a different methodology to make payment when these services are furnished by a HOPD other than the one for covered OPD services under section 1833(t) of the Act. Therefore, in this proposed rule, we are seeking comments on the appropriate payment methodology for the administration of Part B preventive vaccines, including the COVID-19 vaccine post PHE.

e. COVID-19 Monoclonal Antibody Products and Their Administration Services Under OPSS

Subsequent to the November 6, 2020 IFC and as discussed in the CY 2022 PFS final rule (86 FR 65190 through 65194), when monoclonal antibody products for COVID-19 treatment were granted EUAs during the PHE for COVID-19, we made the determination to cover and pay for them under the Part B vaccine benefit in section 1861(s)(10) of the Act

Regarding availability of COVID-19 monoclonal antibody products, there are no monoclonal antibody products approved for the treatment or prevention of COVID-19. There are five authorized monoclonal antibody COVID-19 products; four are authorized for the

treatment or post-exposure prophylaxis for prevention of COVID-19 and one is authorized as pre-exposure prophylaxis for prevention of COVID-19.¹⁰ We note that none of the four monoclonal antibody products for treatment or post-exposure prevention of COVID-19 that have been granted an EUA are authorized for use in geographic regions where infection was likely caused by a non-susceptible variant. Due to data indicating decreased activity for three of these treatments against Omicron variants currently in wide circulation, only one of these treatments is currently authorized in any U.S. region until further notice by FDA.

Consistent with how we pay for COVID-19 vaccine products and their administration, under the OPSS, we pay separately for COVID-19 monoclonal antibodies and their administration. Except when the provider receives the COVID-19 monoclonal antibody product for free, providers are paid for these products at reasonable cost.¹¹ The HCPCS codes associated with the COVID-19 monoclonal antibody products are assigned OPSS status indicator "L" to indicate that they are paid at reasonable cost and are exempt from coinsurance and deductible payments under sections 1833(a)(3) and 1833(b) of the Act.

While the COVID-19 monoclonal antibody products are paid based on reasonable cost under the OPSS, the payment rates for the COVID-19 monoclonal antibody product administration depends on the route of administration and whether the product is furnished in a healthcare setting or in the beneficiary's home. As discussed in more detail in the CMS COVID-19 Monoclonal Toolkit,¹² payment for administration of monoclonal antibodies can range from \$150.50 to \$750.00. The HCPCS codes associated with the COVID-19 monoclonal antibody product administration are assigned to New Technology APCs 1503, 1504, 1505, 1506, 1507, and 1509 with an OPSS status indicator "S" (Procedure or Service, Not Discounted When

¹⁰ Viewed 5/6/2022. <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

¹¹ COVID-19 Vaccines and Monoclonal Antibodies. CMS Website. <https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-mono-clonal-antibodies>.

¹² <https://www.cms.gov/monoclonal>

Multiple, separate APC assignment) to indicate that the administration of monoclonal antibodies is paid separately under the OPPS.

For CYs 2021 and 2022, we maintained the payment rates for the COVID-19 monoclonal antibody product administration services by maintaining their New Technology APCs assignments. For further information, please see Addendum B on the CY 2021 and 2022 OPPS websites. For CY 2023, we propose to use the equitable adjustment authority at 1833(t)(2)(E) to maintain the CY 2022 New Technology APC assignments (specifically, New Technology APCs 1503, 1504, 1505, 1506, 1507, or 1509) and corresponding payment rates for each of the COVID-19 monoclonal antibody product administration HCPCS codes for as long as these products are considered to be covered and paid under the Medicare Part B vaccine benefit so that, if the PHE ends, the benefit category and corresponding payment methodology under the OPPS will remain site neutral.

We note that, once these products are no longer considered to be covered and paid under the Medicare Part B vaccine benefit, we would expect the COVID-19 monoclonal antibody product administration services to be paid similar to monoclonal antibody products used in the treatment of other health conditions – to be “biologicals”. For more background on Medicare Part B payment for COVID-19 monoclonal antibody products and their administration, and for current proposals regarding such payment, we refer readers to the CY 2023 PFS proposed rule that will be included in the July 29, 2022 **Federal Register**. In particular, the CY 2023 PFS proposed rule proposes to clarify that the COVID-19 monoclonal antibody products would be covered and paid for under the Medicare Part B vaccine benefit until the end of the calendar year in which the March 27, 2020 EUA declaration for drugs and biologics is terminated.

Additionally, we are proposing to continue the existing policy to pay for monoclonal antibody COVID-19 pre-exposure prophylaxis products and their administration under the Part B vaccine benefit even after the EUA declaration for drugs and biological products is terminated, so long as after the EUA declaration is terminated, such products have market authorization.

IV. Proposed OPSS Payment for Devices

A. Proposed Pass-Through Payment for Devices

1. Beginning Eligibility Date for Device Pass-Through Status and Quarterly Expiration of Device Pass-Through Payments

a. Background

The intent of transitional device pass-through payment, as implemented at § 419.66, is to facilitate access for beneficiaries to the advantages of new and truly innovative devices by allowing for adequate payment for these new devices while the necessary cost data is collected to incorporate the costs for these devices into the procedure APC rate (66 FR 55861). Under section 1833(t)(6)(B)(iii) of the Act, the period for which a device category eligible for transitional pass-through payments under the OPSS can be in effect is at least 2 years but not more than 3 years. Prior to CY 2017, our regulation at § 419.66(g) provided that this pass-through payment eligibility period began on the date CMS established a particular transitional pass-through category of devices, and we based the pass-through status expiration date for a device category on the date on which pass-through payment was effective for the category. In the CY 2017 OPSS/ASC final rule with comment period (81 FR 79654), in accordance with section 1833(t)(6)(B)(iii)(II) of the Act, we amended § 419.66(g) to provide that the pass-through eligibility period for a device category begins on the first date on which pass-through payment is made under the OPSS for any medical device described by such category.

In addition, prior to CY 2017, our policy was to propose and finalize the dates for expiration of pass-through status for device categories as part of the OPSS annual update. This means that device pass-through status would expire at the end of a calendar year when at least 2 years of pass-through payments had been made, regardless of the quarter in which the device was approved. In the CY 2017 OPSS/ASC final rule with comment period (81 FR 79655), we changed our policy to allow for quarterly expiration of pass-through payment status for devices, beginning with pass-through devices approved in CY 2017 and subsequent calendar years, to

afford a pass-through payment period that is as close to a full 3 years as possible for all pass-through payment devices. We also have an established policy to package the costs of the devices that are no longer eligible for pass-through payments into the costs of the procedures with which the devices are reported in the claims data used to set the payment rates (67 FR 66763).

We refer readers to the CY 2017 OPPTS/ASC final rule with comment period (81 FR 79648 through 79661) for a full discussion of the current device pass-through payment policy.¹³

b. Expiration of Transitional Pass-Through Payments for Certain Devices

As stated earlier, section 1833(t)(6)(B)(iii) of the Act requires that, under the OPPTS, a category of devices be eligible for transitional pass-through payments for at least 2 years, but not more than 3 years. Currently, there are 11 device categories eligible for pass-through payment. These devices are listed in Table 30 where we detail the expiration dates of pass-through payment status for each of the 11 devices currently receiving device pass-through payment.

In the CY 2022 OPPTS/ASC final rule with comment period we used CY 2019 claims data, rather than CY 2020 claims data, to inform CY 2022 ratesetting (86 FR 63755). As a result, we utilized our equitable adjustment authority at section 1833(t)(2)(E) of the Act to provide up to four quarters of separate payment for 27 drugs and biologicals and one device category whose pass-through payment status expired between December 31, 2021 and September 30, 2022 to mimic continued pass-through payment, promote adequate access to innovative therapies for Medicare beneficiaries, and gather sufficient data for purposes of assigning these devices to clinical APCs (86 FR 63755). A full discussion of this finalized policy is included in section X.F

¹³ To apply for OPPTS transitional device pass-through status, applicants complete an application that is subject to the Paperwork Reduction Act (PRA). This collection (CMS-10052) has an OMB control number of 0938-0857 and an expiration date of 11/30/2022. The application is currently undergoing the PRA reapproval process, which has notice and comment periods separate from this proposed rule. The 60-day notice was published in the **Federal Register** on April 29, 2022 (87 FR 25488).

of the CY 2022 OPPTS/ASC final rule with comment (86 FR 63755). In section X.B of this proposed rule, we propose to resume the regular update process of using claims from the year 2 years prior to the year for which we are setting rates, specifically CY 2021 outpatient claims for CY 2023 OPPTS ratesetting. Based on CMS’s policy proposal in section X.B we are not proposing to provide any additional quarters of separate payments for any device category whose pass-through payment status will expire between December 31, 2022 and September 30, 2023. We seek comment on how the circumstances for CY 2023 are similar to those in CY 2022, when we adopted the equitable adjustment to mimic continued pass-through status for drugs, biologicals, and a device category with pass-through status that expired between December 31, 2021, and September 30, 2023.

We utilized our equitable adjustment authority at section 1833(t)(2)(E) of the Act to provide separate payment for C1823 for four quarters in CY 2022 for C1823, as its pass-through payment status expired on December 31, 2021 (86 FR 63570). Separate payment for HCPCS code C1823 under our equitable adjustment authority will end on December 31, 2022. Table 30 includes this date for the device described by HCPCS code C1823 and includes the specific expiration dates for devices with pass-through status expiring at the end of the fourth quarter of 2022, in 2023, or in 2024.

TABLE 30: DEVICES WITH PASS-THROUGH STATUS (OR ADJUSTED SEPARATE PAYMENT) EXPIRING AT THE END OF THE FOURTH QUARTER OF 2022, IN 2023, OR IN 2024

HCPCS Code	Long Descriptor	Effective Date	Pass-Through Expiration Date
C1823	Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads	1/1/2019	12/31/2022*
C1824	Generator, cardiac contractility modulation (implantable)	1/1/2020	12/31/2022
C1982	Catheter, pressure-generating, one-way valve, intermittently occlusive	1/1/2020	12/31/2022
C1839	Iris prosthesis	1/1/2020	12/31/2022

HCPCS Code	Long Descriptor	Effective Date	Pass-Through Expiration Date
C1734	Orthopedic/device/drug matrix for opposing bone-to-bone or soft tissue-to bone (implantable)	1/1/2020	12/31/2022
C2596	Probe, image-guided, robotic, waterjet ablation	1/1/2020	12/31/2022
C1748	Endoscope, single-use (that is, disposable), Upper GI, imaging/illumination device (insertable)	7/1/2020	6/30/2023
C1052	Hemostatic agent, gastrointestinal, topical	1/1/2021	12/31/2023
C1062	Intravertebral body fracture augmentation with implant (e.g., metal, polymer)	1/1/2021	12/31/2023
C1825	Generator, neurostimulator (implantable), nonrechargeable with carotid sinus baroreceptor stimulation lead(s)	1/1/2021	12/31/2023
C1761	Catheter, transluminal intravascular lithotripsy, coronary	7/1/2021	6/30/2024

* We utilized our equitable adjustment authority at section 1833(t)(2)(E) of the Act to provide separate payment for C1823 for four quarters of CY 2022 for C1823 whose pass-through payment status expired on December 31, 2021. Adjusted separate payment for HCPCS code C1823 will end on December 31, 2022.

2. New Device Pass-Through Applications for CY 2023

a. Background

Section 1833(t)(6) of the Act provides for pass-through payments for devices, and section 1833(t)(6)(B) of the Act requires CMS to use categories in determining the eligibility of devices for pass-through payments. As part of implementing the statute through regulations, we have continued to believe that it is important for hospitals to receive pass-through payments for devices that offer substantial clinical improvement in the treatment of Medicare beneficiaries to facilitate access by beneficiaries to the advantages of the new technology. Conversely, we have noted that the need for additional payments for devices that offer little or no clinical improvement over previously existing devices is less apparent. In such cases, these devices can still be used by hospitals, and hospitals will be paid for them through appropriate APC payment. Moreover, a goal is to target pass-through payments for those devices where cost considerations are most likely to interfere with patient access (66 FR 55852; 67 FR 66782; and 70 FR 68629).

As specified in regulations at § 419.66(b)(1) through (3), to be eligible for transitional pass-through payment under the OPPS, a device must meet the following criteria:

- If required by FDA, the device must have received FDA marketing authorization (except for a device that has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by FDA), or meet another appropriate FDA exemption; and the pass-through payment application must be submitted within 3 years from the date of the initial FDA marketing authorization, if required, unless there is a documented, verifiable delay in U.S. market availability after FDA marketing authorization is granted, in which case CMS will consider the pass-through payment application if it is submitted within 3 years from the date of market availability;

- The device is determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part, as required by section 1862(a)(1)(A) of the Act; and

- The device is an integral part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted (either permanently or temporarily), or applied in or on a wound or other skin lesion.

In addition, according to § 419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15-1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker).

Separately, we use the following criteria, as set forth under § 419.66(c), to determine whether a new category of pass-through payment devices should be established. The device to be included in the new category must—

- Not be appropriately described by an existing category or by any category previously in effect established for transitional pass-through payments, and was not being paid for as an outpatient service as of December 31, 1996;

- Have an average cost that is not “insignificant” relative to the payment amount for the procedure or service with which the device is associated as determined under § 419.66(d) by demonstrating: (1) the estimated average reasonable cost of devices in the category exceeds 25 percent of the applicable APC payment amount for the service related to the category of devices; (2) the estimated average reasonable cost of the devices in the category exceeds the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent; and (3) the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device exceeds 10 percent of the APC payment amount for the related service (with the exception of brachytherapy and temperature-monitored cryoablation, which are exempt from the cost requirements as specified at § 419.66(c)(3) and (e)); and

- Demonstrate a substantial clinical improvement, that is, substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment, or, for devices for which pass-through payment status will begin on or after January 1, 2020, as an alternative pathway to demonstrating substantial clinical improvement, a device is part of the FDA’s Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Device designation.

Beginning in CY 2016, we changed our device pass-through evaluation and determination process. Device pass-through applications are still submitted to CMS through the quarterly subregulatory process, but the applications will be subject to notice and comment rulemaking in the next applicable OPPS annual rulemaking cycle. Under this process, all applications that are preliminarily approved upon quarterly review will automatically be included

in the next applicable OPPS annual rulemaking cycle, while submitters of applications that are not approved upon quarterly review will have the option of being included in the next applicable OPPS annual rulemaking cycle or withdrawing their application from consideration. Under this notice-and-comment process, applicants may submit new evidence, such as clinical trial results published in a peer-reviewed journal or other materials for consideration during the public comment process for the proposed rule. This process allows those applications that we are able to determine meet all of the criteria for device pass-through payment under the quarterly review process to receive timely pass-through payment status, while still allowing for a transparent, public review process for all applications (80 FR 70417 through 70418).

In the CY 2020 annual rulemaking process, we finalized an alternative pathway for devices that are granted a Breakthrough Device designation (84 FR 61295) and receive FDA marketing authorization. Under this alternative pathway, devices that are granted an FDA Breakthrough Device designation are not evaluated in terms of the current substantial clinical improvement criterion at § 419.66(c)(2) for the purposes of determining device pass-through payment status, but do need to meet the other requirements for pass-through payment status in our regulation at § 419.66. Devices that are part of the Breakthrough Devices Program, have received FDA marketing authorization for the indication covered by the Breakthrough Devices designation, and meet the other criteria in the regulation can be approved through the quarterly process and announced through that process (81 FR 79655). Proposals regarding these devices and whether pass-through payment status should continue to apply are included in the next applicable OPPS rulemaking cycle. This process promotes timely pass-through payment status for innovative devices, while also recognizing that such devices may not have a sufficient evidence base to demonstrate substantial clinical improvement at the time of FDA marketing authorization.

More details on the requirements for device pass-through payment applications are included on the CMS website in the application form itself at:

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service->

[Payment/HospitalOutpatientPPS/passthrough_payment.html](http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html), in the “Downloads” section. In

addition, CMS is amenable to meeting with applicants or potential applicants to discuss research trial design in advance of any device pass-through application or to discuss application criteria, including the substantial clinical improvement criterion.

b. Applications Received for Device Pass-Through Status for CY 2023

We received nine complete applications by the March 1, 2022 quarterly deadline, which was the last quarterly deadline for applications to be received in time to be included in the CY 2023 OPPTS/ASC proposed rule. We received one of the applications in the second quarter of 2021, one of the applications in the third quarter of 2021, two of the applications in the fourth quarter of 2021, and five of the applications in the first quarter of 2022. One of the applications was approved for device pass-through status during the quarterly review process: the aprevo™ Intervertebral Body Fusion, which received quarterly approval under the alternative pathway effective October 1, 2021. As previously stated, all applications that are preliminarily approved upon quarterly review will automatically be included in the next applicable OPPTS annual rulemaking cycle. Therefore, aprevo™ Intervertebral Body Fusion is discussed in section IV.2.b.1 of this proposed rule.

Applications received for the later deadlines for the remaining 2022 quarters (the quarters beginning June 1, September 1, and December 1 of 2022), if any, will be discussed in the CY 2024 OPPTS/ASC proposed rule. We note that the quarterly application process and requirements have not changed because of the addition of rulemaking review. Detailed instructions on submission of a quarterly device pass-through payment application are included on the CMS website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/catapp.pdf>.

Discussions of the applications we received by the March 1, 2022 deadline are included below.

1. Alternative Pathway Device Pass-through Applications

We received two device pass-through applications by the March 2022 quarterly application deadline for devices that have received Breakthrough Device designation from FDA and FDA marketing authorization for the indication for which they have a Breakthrough Device designation, and therefore are eligible to apply under the alternative pathway.

(1) aprevo™ Intervertebral Body Fusion Device

Carlsmed, Inc. submitted an application for a new device category for transitional pass-through payment status for aprevo™ Intervertebral Fusion Device (aprevo™) for CY 2023. Per the applicant, the device is an interbody fusion implant that stabilizes the lumbar spinal column and facilitates fusion during lumbar fusion procedures indicated for the treatment of spinal deformity. The applicant stated that the implant device is custom made for patient-specific features using patient computed tomography (CT) scans to create 3D virtual models of the deformity to be used during anterior lumbar interbody fusion, lateral lumbar interbody fusion, and transforaminal lumbar interbody fusion procedures. The aprevo™ device is additively manufactured and made from Titanium Alloy (Ti-6Al-4V) per ASTM F3001, and has a cavity intended for the packing of bone graft. In addition, the applicant explained that aprevo™ is used with supplemental fixation devices and bone graft packing. Per the applicant, the device was formerly known as “Corra™.”

According to the applicant, the surgical correction plan for adult patients with spinal deformity is significantly more complex than performing a spine fusion for a degenerative spinal condition. The applicant further described that these deformity correction plans require numerous complex measurements and calculations that consider a multitude of relationships between each area of the spine (cervical, thoracic, lumbar), the 33 individual levels of the spine, the pelvis, hips, and other reference points in relation to normal values based on the patient’s age. The applicant stated that achieving the proper balance between these factors has been shown to directly contribute to improved clinical outcomes and increased patient satisfaction. Despite the

use of sophisticated planning tools, surgeons are frequently unable to obtain the planned correction, and this is often because stock devices, which are not patient-specific, do not match the specific geometry that is required to realign each level of the individual patient's spine. The applicant claims that aprevo™ devices provide the precise geometry to match the planned surgical correction for a spinal deformity patient, and they maintain this precise position while the bones fuse together in their new alignment.

According to the applicant, aprevo™ devices are surgically placed between two vertebral levels of the spine. The approach may be from the front, side, or back of the patient. The surgeon will gently clear away the disc material (which is often degenerated) before placing the device. Bone graft is placed inside a central opening of the interbody device. This allows the patient's bone to integrate with the graft material and form a bony bridge.

The applicant asserted that there are no other devices in the market like aprevo™. Per the applicant, other stock devices do not match the anatomy of each patient precisely. The applicant stated, in contrast, aprevo™ utilizes 3D generated reconstructions of each level of the patient's lumbar spine that match the anatomy of the patient. Per the applicant, the device's upper and lower surfaces match the topography of the patient's bone as this is important because the surfaces of the vertebral endplates can be extremely bumpy or wavy and sometimes thin and fragile. Per the applicant, by having a fit that matches these contours, the high loads that result from body weight are more evenly distributed across the surface. The applicant stated that this contributes to faster healing of the bone and lessens the risk of having high stress points that could result in a stock interbody device breaking through the thin endplate.

Aprevo™ is indicated for use as an adjunct to fusion at one or more levels of the lumbar spine in patients having an ODI >40 and diagnosed with severe symptomatic adult spinal deformity (ASD) conditions. These patients should have had 6 months of non-operative treatment. The devices are intended to be used with autograft and/or allogenic bone graft comprised of cancellous and/or cortico-cancellous bone graft. These implants may be implanted

via a variety of open or minimally invasive approaches. These approaches may include anterior lumbar interbody fusion or lateral lumbar interbody fusion.

With respect to the newness criterion at § 419.66(b)(1), aprevo™ received FDA Breakthrough Device designation under the name “Corra” on July 1, 2020 for the Corra Anterior, Corra Transforaminal, and Corra Lateral Lumbar Fusion System interbody device which is intended for use in anterior lumbar interbody fusion, lateral lumbar interbody fusion, and transforaminal lumbar interbody fusion under this designation. The applicant received 510(k) clearance from FDA for the Intervertebral Body Fusion Device (anterior lumbar interbody fusion and aprevo™ lateral lumbar interbody fusion devices) on December 3, 2020. The applicant also received 510(k) clearance from FDA for the Transforaminal Intervertebral Body Fusion (IBF) device on June 30, 2021. We received the application for a new device category for transitional pass-through payment status for aprevo™ on May 27, 2021, which is within 3 years of the date of the initial FDA marketing authorization of both indications. We are inviting public comment on whether aprevo™ meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, aprevo™ is integral to the service provided, is used for one patient only, comes in contact with human tissue and is surgically inserted in a patient until the procedure is completed. The applicant also claimed that aprevo™ meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. We are inviting public comments on whether aprevo™ meets the eligibility criteria at § 419.66(b).

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of

December 31, 1996. The applicant describes aprevo™ as an interbody fusion implant that stabilizes the lumbar spinal column and facilitates fusion during lumbar fusion procedures indicated for the treatment of spinal deformity. Per the applicant, no previous device categories for pass-through payment have encompassed the device. In addition, per the applicant, the possible existing pass-through codes: C1821 (Interspinous process distraction device (implantable)), C1776 (Joint device (implantable)), C1734 (Orthopedic/device/drug matrix for opposing bone-to- bone or soft tissue-to-bone), and C1062 (Intravertebral body fracture augmentation with implant (e.g., metal, polymer)) do not appropriately describe aprevo™ because none of the existing codes pertain to a patient-specific spinal interbody fusion device and, therefore, do not encompass aprevo™.

We have not identified an existing pass-through payment category that describes aprevo™. We are inviting public comment on whether aprevo™ meets the device category criterion.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) That a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization. for the indication covered by the Breakthrough Device designation. As previously discussed in section IV.2.a above, we finalized the alternative pathway for devices that are granted a Breakthrough Device designation and receive FDA marketing authorization for the indication covered by the Breakthrough Device designation in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61295).

Aprevo™ has a Breakthrough Device designation and marketing authorization from FDA for the

indication covered by the Breakthrough Device designation (as explained in more detail in the discussion of the newness criterion) and therefore is not evaluated for substantial clinical improvement. We note that the applicant was granted new technology add-on payments under the Alternative Pathway for Breakthrough Devices in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45132 through 45133).

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that aprevo™ would be reported with HCPCS codes in the following table.

TABLE 31: HCPCS Codes Reported with Aprevo™ Intervertebral Fusion Device

HCPCS Code	Long Descriptor	SI	APC
22853	Insertion of interbody biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace (List separately in addition to code for primary procedure)	N	N/A
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar	J1	5116
22633	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace; lumbar	J1	5115

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPSS final rule with comment period (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. For our calculations, we used APC 5115, which had a CY 2021 payment rate of \$12,314.76 at the time the application was received. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). HCPCS code

22633 had a device offset amount of \$6,851.93 at the time the application was received.

According to the applicant, the cost of aprevo™ is \$26,000.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of \$26,000 for aprevo™ is 211.13 percent of the applicable APC payment amount for the service related to the category of devices of \$12,314.76 ($(\$26,000 / \$12,314.76) \times 100 = 211.13$ percent). Therefore, we believe aprevo™ meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of \$26,000 for aprevo™ is 379.46 percent of the cost of the device-related portion of the APC payment amount for the related service of \$6,851.93 ($(\$26,000 / \$6,851.93) \times 100 = 379.46$ percent). Therefore, we believe aprevo™ meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of \$26,000 for aprevo™ and the portion of the APC payment amount for the device of \$6,851.93 is 155.49 percent of the APC payment amount for the related service of \$12,314.76 ($((\$26,000 - \$6,851.93) / \$12,314.76) \times 100 = 155.49$ percent). Therefore, we believe that aprevo™ meets the third cost significance requirement.

We are inviting public comment on whether aprevo™ meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(2) MicroTransponder® ViviStim® Paired Vagus Nerve Stimulation (VNS) System (Vivistim® System)

MicroTransponder, Inc. submitted an application for a new device category for transitional pass-through payment status for the ViviStim® Paired VNS System (Vivistim® System) for CY 2023. Per the applicant, the Vivistim® System is intended to be used to stimulate the vagus nerve during rehabilitation therapy in order to reduce upper extremity motor deficits and improve motor function in chronic ischemic stroke patients with moderate to severe arm impairment.

According to the applicant, the Vivistim® System is an active implantable medical device that is comprised of four main components: (1) an Implantable Pulse Generator (IPG), (2) an implantable Lead, (3) Stroke Application & Programming Software (SAPS), and (4) a Wireless Transmitter (WT). The IPG and Lead comprise the implantable components; the SAPS and WT comprise the non-implantable components.

The applicant asserts that the key feature of the biochemical process that underlies neural pathway development is called neuroplasticity. The applicant describes neuroplasticity as a complex biochemical process that is necessary for establishing new synaptic connections. The applicant further states it is widely understood that vagus nerve stimulation triggers the brain to release a burst of neuromodulators, such as acetylcholine and norepinephrine, which are enablers of neuroplasticity. In addition, the applicant further states it is understood that pairing neuromodulator bursts with events increases brain plasticity, which in turn increases the formation of new neural connections.¹⁴ Per the applicant, the use of the external paired

¹⁴ Meyers EC, Solorzano BR, James J, Ganzer PD, Lai ES, Rennaker RL 2nd, Kilgard MP, Hays SA. Vagus Nerve Stimulation Enhances Stable Plasticity and Generalization of Stroke Recovery. *Stroke*. 2018 Mar;49(3):710-717.

stimulation controller to precisely pair VNS with rehabilitation movements is essential to creating neuroplasticity in patients who have upper limb deficits, and this “event-pairing” of movement with VNS that generates long-lasting plasticity in the motor and sensory cortex leads to the restored motor function observed in clinical studies.¹⁵

The applicant specifies the SAPS and WT are non-implantable and are collectively called the External Paired Stimulation Controller. The applicant specifies the IPG and implantable Lead are implantable components. Per the applicant, the External Paired Stimulation Controller allow the implanted components (the IPG and Lead) to stimulate the vagus nerve while rehabilitation movement occurs through the following process: (1) The implantable Lead electrodes are attached to the left vagus nerve in the neck; (2) The implantable Lead is tunneled from the neck to the chest where it is connected to the IPG; (3) The IPG is placed subcutaneously (or sub-muscularly) in the pectoral region; (4) Following implantation of the IPG and stimulation Lead, the External Paired Stimulation Controller enables real-time “event-pairing” of vagus nerve stimulation and rehab movements; (5) The IPG and the implantable Lead stimulate the vagus nerve while rehabilitation movements occur; and (6) A therapist initiates the stimulation using a USB push-button or mouse click to synchronize the vagus nerve stimulation with rehabilitation movements to maximize the clinical effect. Patients undergo in-clinic rehabilitation, where vagus nerve stimulation is actively paired with rehabilitation by a therapist. Following in-clinic rehabilitation paired with vagus nerve stimulation, the patient can continue using the device at home. When directed by a physician, the patient can initiate at-home use by swiping a magnet over the IPG implant site which activates the IPG to deliver stimulation while rehabilitation movements are performed

With respect to the newness criterion at § 419.66(b)(1), Vivistim® System was granted FDA Breakthrough Device Designation effective February 10, 2021 for use in stimulating the

¹⁵ Hays SA, Rennaker RL, Kilgard MP. Targeting plasticity with vagus nerve stimulation to treat neurological disease. *Prog Brain Res.* 2013;207:275-299. doi:10.1016/B978-0-444-63327-9.00010-2

vagus nerve during rehabilitation therapy in order to reduce upper extremity motor deficits and improve motor function in chronic ischemic stroke patients with moderate to severe arm impairment. The applicant states the Vivistim® System received FDA premarket approval (PMA) on August 27, 2021 as a Class III implantable device for the same indication as the one covered by the Breakthrough Device designation. We received the application for a new device category for transitional pass-through payment status for the Vivistim® System on September 1, 2021, which is within 3 years of the date of the initial FDA marketing authorization. We are inviting public comment on whether the Vivistim® System meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, VNS System is integral to the service provided, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted (either permanently or temporarily) into the patient. We note that the external components SAPS and WT are not implanted in a patient and do not come in contact with the human tissue as required by § 419.66(b)(3). The applicant also claimed that VNS System meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. However, we note that the external non-implantable components SAPS and WT may be an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered and may be considered depreciable assets as described in § 419.66(b)(4). We are inviting public comments on whether VNS System meets the eligibility criteria at § 419.66(b).

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996.

According to the applicant, there are several device categories that are similar to or related to the proposed device category. The applicant stated that there are five HCPCS device category codes describing neurostimulation devices that are similar to the Vivistim® System, listed in the following table below.

TABLE 32: HCPCS CODES REPORTED WITH THE VIVISTIM® SYSTEM

HCPCS Code	Long Descriptor	Status Indicator	APC
C1767	Generator, neurostimulator (implantable), non-rechargeable	N	N/A
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system	N	N/A
C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system	N	N/A
C1823	Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads	H	2993
C1825	Generator, neurostimulator (implantable), non-rechargeable with carotid sinus baroreceptor stimulation lead(s)	H	2030

Per the applicant, the codes in the table above do not encompass the Vivistim® System because none of the codes feature an external paired stimulation controller to actively pair stimulation with rehabilitation by a clinician, which is integral to the function and clinical benefit of the device, and the ViviStim® System does not include a rechargeable battery or charging system. The following paragraphs include the applicant’s description of each related device category, the distinguishing device features and/or accessories of devices included in each of these categories, and the applicant’s rationale for why the Vivistim® System device is not encompassed by these existing device categories.

Per the applicant, the Vivistim® System and similar device category codes that have preceded it (C1820, C1822, C1823, C1825) are distinct from the C1767 device category because of distinguishing device features and/or accessories not currently described by C1767.

The applicant stated that the C1767 was created in 2000 and was the first category for non-rechargeable neurostimulator generators. Per the applicant, the C1767 code currently describes multiple non-rechargeable neurostimulator generator devices that are approved to treat a wide variety of conditions. The applicant stated it is aware of currently marketed implantable, non-rechargeable vagus nerve stimulation devices, such as the VNS Therapy® System (LivaNova, PLC) which are described by C1767. Further, the applicant stated it is aware that CMS does not acknowledge indication for use alone as a reasonable basis to establish a new device category. According to the applicant, the VNS Therapy® System (LivaNova, PLC) has different device components and therapy delivery than the Vivistim® System. Per the applicant, the LivaNova VNS Therapy® System implantable neurostimulators differ from the Vivistim® System in a number of ways. Specifically, according to the applicant, VNS Therapy® System neurostimulators are “always on” and send periodic pulses to deliver therapy over the life of the device, whereas the Vivistim® System is actively paired with rehabilitation movements by a clinician to deliver therapy. In addition, the applicant stated the VNS Therapy® System is used to treat neurological disorders such as epilepsy and treatment resistant depression, whereas the Vivistim® System is used to treat upper limb motor deficits in ischemic stroke survivors. The applicant concluded C1767 does not encompass the Vivistim® System.

Per the applicant, C1820 describes an implantable neurostimulator that includes a rechargeable battery and charging system. The applicant stated it is aware of several marketed devices that are described by device category C1820 which was created in CY 2006. The applicant concluded C1820 does not encompass the Vivistim® System. Per the applicant, C1822 describes an implantable neurostimulator, which delivers “high-frequency” stimulation (10 kHz) and is provided with a rechargeable battery and charging system. The applicant stated it is aware of only one currently marketed device that is described by this device category, the HF10® Spinal Cord Stimulator (Nevro Corp.). The applicant stated the Vivistim® System is not a “high-frequency” stimulator as described by C1822. The applicant stated the paired stimulation using

the Vivistim® System is delivered at a maximum of 30 Hz, whereas spinal cord stimulation using the HF10® (Nevro Corp.) is delivered at 10 kHz. The applicant concluded C1822 does not encompass the Vivistim® System.

According to the applicant, C1823 describes an implantable neurostimulator, which is nonrechargeable and includes transvenous sensing and stimulation leads. The applicant stated that it is aware of only one currently marketed device that is described by C1823, the remedē System® Phrenic Nerve Stimulator (Respocardia, Inc.). This device category code does not encompass the Vivistim® System. According to the applicant, the stimulation lead included in the Vivistim® System is placed onto the vagus nerve and is not transvenously placed to stimulate the phrenic nerve. In addition, the applicant asserted the Vivistim® System does not include a sensing lead. The applicant concluded C1823 does not encompass the Vivistim® System.

Per the applicant, C1825 describes an implantable neurostimulator which is nonrechargeable and includes a carotid sinus baroreceptor lead. The applicant stated it is aware of only one currently marketed device that is described by C1825, the BaroStim Neo™ (CVRx, Inc.). According to the applicant, the stimulation lead included in the Vivistim® System is placed onto the vagus nerve and is not placed on the carotid sinus. The applicant concluded C1825 does not encompass the Vivistim® System.

The applicant has asserted that the Vivistim® System is distinct from HCPCS codes C1820, C1822, C1823 and C1825 due to distinguishing features unique to these codes. These unique features include rechargeable batteries, high frequency stimulation, transvenous sensors and stimulators and unique placement of stimulators. With respect to C1767, however, the applicant's argument is that the Vivistim® System is not "always on" and is paired to an external stimulation controller to allow for clinician-controlled stimulation during rehabilitation, and therefore is unlike the non-rechargeable implantable neurostimulator of the VNS Therapy® System (LivaNova, PLC), which is described by C1767. It is our understanding, however, that

implantable neurostimulators for epilepsy and depression are not “always on”, but are programmed to turn on and off in specific cycles as determined by a clinician. Furthermore, in the case of treatment for epilepsy, a neurostimulator can be turned on by the patient with a hand held magnet if an impending seizure is sensed, and the neurostimulator can similarly be turned off by the patient during certain activities, such as speaking, exercising, or eating. As per the application, the IPG of the Vivistim® System can also be patient-engaged with a magnetic card, allowing the patient to continue therapy at home. In this context, we believe the Vivistim® System may be similar to the devices currently described by C1767, and therefore the Vivistim® System may also be appropriately described by C1767. We are inviting public comment on whether the Vivistim® System meets the device category criterion.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) That a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA’s Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. As previously discussed in section IV.2.a above, we finalized the alternative pathway for devices that are granted a Breakthrough Device designation and receive FDA marketing authorization for the indication covered by the Breakthrough Device designation in the CY 2020 OPPTS/ASC final rule with comment period (84 FR 61295). The Vivistim® System has a Breakthrough Device designation and marketing authorization from FDA for the indication covered by the Breakthrough Device designation (as explained in more detail in the discussion of the newness criterion) and therefore is not evaluated for substantial clinical improvement. We note that the applicant has also submitted an application for IPPS New

Technology Add-on payments for FY 2023 Payment under the Alternative Pathway for Breakthrough Devices (87 FR 28349 through 28350).

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the insertion procedure for the Vivistim® System implantable pulse generator (IPG) and stimulation lead would be reported with the HCPCS Level I CPT code 64568 (Incision for implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator).

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. For our calculations, we used APC 5465 Level 5 Neurostimulator and Related Procedures, which had a CY 2021 payment rate of \$29,444.52 at the time the application was received. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). HCPCS code 64568 had a device offset amount of \$25,236.9 at the time the application was received. According to the applicant, the cost of the Vivistim® System is \$36,000.00.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of \$36,000.00 for Vivistim® System is 122.26 percent of the applicable APC payment amount for the service related to the category of devices of \$29,444.52 ($(\$36,000.00$

$/$29,444.52) \times 100 = 122.26$ percent). Therefore, we believe Vivistim® System meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of \$36,000.00 for Vivistim® System is 142.65 percent of the cost of the device-related portion of the APC payment amount for the related service of \$25,236.90 ($($36,000.00 / $25,236.90) \times 100 = 142.65$ percent). Therefore, we believe that Vivistim® System meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of \$36,000.00 for Vivistim® System and the portion of the APC payment amount for the device of \$25,236.90 is 36.55 percent of the APC payment amount for the related service of \$29,444.52 ($($36,000.00 - $25,236.90) / $29,444.52) \times 100 = 36.55$ percent). Therefore, we believe that Vivistim® System meets the third cost significance requirement.

We are inviting public comment on whether Vivistim® System meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

2. Traditional Device Pass-through Applications

(1) The BrainScope TBI (model: Ahead 500)

BrainScope Company Inc. submitted an application for a new device category for transitional pass-through payment status for the BrainScope Ahead 500 system (hereinafter

referred to as the BrainScope TBI) for CY 2023. The BrainScope TBI is a handheld medical device and decision-support tool that uses artificial intelligence (AI) and machine learning technology to identify objective brain-activity based biomarkers of structural and functional brain injury in patients with suspected mild traumatic brain injury (mTBI). According to the applicant, the BrainScope TBI is an FDA-cleared, portable, non-invasive, point-of-care device and disposable headset intended to provide results and measures to aid in the rapid, objective, and accurate diagnosis of mTBI. Per the applicant, the BrainScope TBI is intended to be used in emergency departments (ED), urgent care centers, clinics, and other environments where used by trained medical professionals under the direction of a physician.

According to the applicant, the BrainScope TBI is comprised of two elements: (1) the Ahead 500, a disposable forehead-only 8-electrode headset temporarily applied to the patient's skin to assess brain injury (the wounded area) which records electroencephalogram (EEG) signals; and (2) a reusable handheld device (hereinafter "Handheld Device"), which includes a standard commercial off-the-shelf handheld computer connected to a custom manufactured Data Acquisition Board (DAB) via a permanently attached cable. The applicant stated that the BrainScope software (including proprietary BrainScope algorithms) and a kiosk mode application running on Android are loaded onto an off-the-shelf handheld computer configuration. The disposable headset is attached to the DAB, which collects the EEG signal and passes it as a digital signal to the Handheld Device to perform the data processing and analysis.

According to the applicant, the BrainScope TBI device is intended to record, measure, analyze, and display brain electrical activity utilizing the calculation of standard quantitative EEG (qEEG) parameters from frontal locations on a patient's forehead. Patient information is transferred to electronic health records via USB connected to a computer. The BrainScope TBI calculates and displays raw measures for the following standard qEEG measures: Absolute and Relative Power, Asymmetry, Coherence and Fractal Dimension. The applicant asserts that these raw measures are intended to be used for post-hoc analysis of EEG signals for interpretation by a

qualified user. Per the applicant, the device can be used as a screening tool and aid in determining the medical necessity of head computerized tomography (CT) scanning.

With respect to the newness criterion at § 419.66(b)(1), on September 11, 2019, the applicant received 510(k) clearance from FDA for the BrainScope TBI as a Class II device for use as an adjunct to standard clinical practice to aid in the evaluation of patients who have sustained a closed head injury, and have a Glasgow Coma Scale (GCS) score of 13-15 (including patients with concussion/mild traumatic brain injury (mTBI)). We received the application for a new device category for transitional pass-through payment status for the BrainScope TBI on February 23, 2022, which is within 3 years of the date of the initial FDA marketing authorization. We are inviting public comments on whether the BrainScope TBI meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the BrainScope TBI is integral to the service provided and is used for one patient only. Per the applicant, the Ahead 500 component records EEG signals via a disposable forehead-only 8-electrode headset and is temporarily applied to the patient's skin to assess brain injury. We note that while the Ahead 500 component is used for one patient only and it is temporarily applied to the patient's skin, the device is not surgically implanted or inserted or applied in or on a wound or other skin lesion, as required by 42 CFR 418.66(b)(3). We further note that the other component of the BrainScope TBI, the Handheld Device, does not come in contact with the patient's tissue, and the device is not surgically implanted or inserted or applied in or on a wound or other skin lesion, as required by § 418.66(b)(3). Per the applicant, the Handheld Device is used by multiple patients. We further question whether this device may be an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered in accordance with the device eligibility requirements of § 419.66(b)(4). The applicant did not indicate if the BrainScope TBI is a supply or material furnished incident to a service. We are

inviting public comments on whether the BrainScope TBI meets the eligibility criteria at § 419.66(b).

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. The applicant has not identified any existing pass-through payment category that describes the BrainScope TBI. Upon review, it does not appear that there are any existing pass-through payment categories that might apply to the BrainScope TBI. We are inviting public comment on whether the BrainScope TBI meets the device category criterion.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The applicant indicated that it is aware of a marketed medical device COGNISION, which fits the proposed additional device category in addition to the BrainScope TBI. According to the applicant, the COGNISION® System (COGNISION®) is cleared by FDA for use by qualified clinical professionals in private practice offices or small clinical settings for the acquisition, display, analysis, storage, reporting and management of EEG and auditory evoked potentials (AEP) information. The applicant stated that the COGNISION® cloud-powered electrophysiologic testing system evaluates patients with neurological disorders, such as dementia and concussion. According to the applicant, by measuring the electrical activity

in the brain that is responsible for information processing, COGNISION® assesses cognitive function. The applicant also pointed out that COGNISION® evaluates working memory, focal attention, executive function, and brain processing speed through Event Related Potential (ERP) and qEEG tests. The applicant acknowledged that COGNISION® also measures hearing deficits which can be co-morbid with cognitive disorders.

The applicant stated that the BrainScope TBI represents a substantial clinical improvement over existing technology. With respect to this criterion, the applicant submitted studies that examined the impact of the BrainScope TBI as a brain injury adjunctive interpretive electroencephalograph assessment aid. Broadly, the applicant outlined the following areas in which it stated the BrainScope TBI would provide a substantial clinical improvement over existing technologies: (1) decreased rate of repeat/subsequent diagnostic or therapeutic interventions, (2) more rapid beneficial resolution of the disease process treated because of the use of the device, and (3) reduced recovery time when used for the treatment mild head injuries (mTBI).

In support of its first claim that the BrainScope TBI decreases the rate of subsequent diagnostic or therapeutic interventions, the applicant provided five articles. The first was a multisite, prospective observational FDA validation trial performed in the U.S.¹⁶ A total of 720 patients (18–85 years) meeting inclusion/exclusion criteria were enrolled at 11 U.S. EDs. Ninety-seven percent of study participants had a Glasgow Coma Scale (GCS) of 15, with the first and third quartiles being 15 (interquartile range = 0) at the time of the evaluation. Standard clinical evaluations were conducted, and 5 to 10 minutes of EEG was acquired from frontal and frontotemporal scalp locations. Using an a priori derived EEG-based classification algorithm developed on an independent population and applied to this validation population prospectively, the likelihood of each subject being CT+ was determined, and performance metrics were

¹⁶ Hanley D, Prichep LS, Bazarian J, Huff JS, Naunheim R, Garrett J, Jones EB, Wright DW, O'Neill J, Badjatia N, Gandhi D. Emergency department triage of traumatic head injury using a brain electrical activity biomarker: a multisite prospective observational validation trial. *Academic emergency medicine*. 2017 May;24(5):617-27.

computed relative to adjudicated CT findings. The authors stated that by using an EEG-based biomarker, high accuracy of predicting the likelihood of being CT+ was obtained, with high normalized power variance (NPV) and sensitivity to any traumatic bleeding and to hematomas. Per the authors, specificity was significantly higher than standard CT decision rules and the short time to acquire results and the ease of use in the ED environment suggests that EEG-based classifier algorithms have potential to impact triage and clinical management of head-injured patients. Both the applicant and the authors indicated that the BrainScope TBI Structural Injury Classifier (SIC)¹⁷ biomarker demonstrated extremely high sensitivity in this validation study. Sensitivity for those who are CT+ with ≥ 1 mL blood was 98.6 percent (72/ 73, 95% CI = 92.6%–100.0 percent), with an area under the curve (AUC) of 0.82. It is noted that this study could not be run as a randomized controlled trial (RCT) as the individual site institutional review boards (IRBs) would not allow random assignment to determination to receive a CT, which was entirely at the discretion of the clinician. Results supported the potential to impact triage and clinical management and help in avoidance of unnecessary CT scans. High NPV supports confidence added to decisions not to perform a CT scan. In this validation study, the BrainScope TBI's SIC biomarker reported 2% false negatives (FNs), none of which were considered by clinical sites or FDA to be "clinically important," and all of which were confirmed in follow-up as requiring no further care. In the same large FDA prospective validation study, the BrainScope's SIC biomarker had specificity of 51.60 percent (291/564, 95 percent CI = 48.05 percent–55.13 percent). In the same population, SIC specificity outperformed that of the standard clinical CT decision rules, with the New Orleans Criteria (NOC)=8.6 percent and Canadian CT Head Rule (CCHR)=31 percent. Higher specificity relative to standard practice supports reduced CT referrals. In the same large FDA prospective validation study specificity of the BrainScope TBI's SIC biomarker was shown to scale with severity of clinical functional impairment, with

¹⁷ The SIC is an electrophysiological based biomarker derived from selected EEG features and a small set of clinical associated symptoms, using machine learning and advanced classification algorithms to identify those features which optimally characterize the pattern of changes in brain function that occur with head injury.

specificities of 76.7 percent, 58.8 percent, and 22.2 percent for none, mild, and moderate functional impairment, respectively.

The second article was a retrospective secondary study of the independent prospective FDA validation trial that demonstrated the efficacy of (1) an automatic SIC for the likelihood of injury visible on a CT (CT+) and (2) an EEG-based Brain Function Index (BFI) to assess functional impairment in minimally impaired, head-injured adults presenting within 3 days of injury.¹⁸ In this retrospective analysis, the impact on the biomarker performance in patients who presented with or without drug and alcohol (DA) was studied. DA– ED visits represent an increasing fraction of the head-injured population seen in the ED. Such patients present a challenge to the evaluation of head injury and determination of need for CT scan and further clinical pathways. This effort examined whether an EEG-based biomarker could aid in reducing unnecessary CT scans in the intoxicated ED population. SIC sensitivity was not significantly impacted by the presence of DA. Although specificity decreased, it remained several times higher than obtained using standard CT decision rules. Furthermore, according to the authors, the potential to reduce the number of unnecessary scans by approximately 30% was demonstrated when the BrainScope TBI SIC was integrated into CT clinical triage. According to the authors, the BFI was demonstrated to be independent of the presence of DA.

The third article was a retrospective clinical study conducted in the U.S.¹⁹ Two potential initial evaluation pathways were compared for CT referrals: a. Clinical Site Practice Referral, relying on clinical judgement of the ED physician according to site standard of care; and b. EEG-based classification algorithm assessment, relying on the ternary output of the SIC (positive, negative, equivocal) to inform CT referral decision. The SIC is an electrophysiological based biomarker derived from selected EEG features and a small set of clinical associated

¹⁸ Michelson, E., Huff, J. S., Garrett, J., & Naunheim, R. (2019). Triage of mild head-injured intoxicated patients could be aided by use of an electroencephalogram-based biomarker. *Journal of neuroscience nursing*, 51(2), 62-66.

¹⁹ Naunheim, R., Kosco, M. K., & Poirier, R. (2019). Reduction in unnecessary CT scans for head-injury in the emergency department using an FDA cleared device. *The American journal of emergency medicine*, 37(10), 1987-1988.

symptoms, using machine learning and advanced classification algorithms to identify those features which optimally characterize the pattern of changes in brain function that occur with head injury. Of the 91 patients referred to CT, 13 were read as positive and 78 as negative. These 91 CT referrals made using the clinical judgement decision pathway resulted in 78 patients who were found to be CT negative. Using the second pathway with input from the EEG based classification algorithm assessment (SIC) resulted in 63 patients who were positive for CT referral. Thus, the researchers stated that the use of the EEG-based algorithm decision pathway to aid in referral for CT scanning would have resulted in 63 patients being referred for CT scans instead of 91 referrals made following standard clinical site practice. Per the researchers, this represents a reduction of 28 fewer head CT scans, a 30.8 percent ($= (91-63)/91$) reduction. According to the researchers, while still early in the clinical use of this EEG based biomarker, this data demonstrates that the BrainScope TBI medical device can provide objective information to aid in the initial assessment of mTBI patients in the ED. The researchers suggested that integrating this data into the decision-making process for CT referrals would have led to a significant reduction of ~31 percent in CT scanning. The researchers concluded that this decrease in CT use and its associated radiation was achieved without incurring any false negative cases (100 percent sensitivity).

The fourth article was a retrospective clinical study conducted in the U.S.²⁰ The study authors found that heightened awareness of the potential short and long-term consequences of mild traumatic brain injury (mTBI or concussion) has resulted in an increase in ED visits for traumatic head injury, even as the volume of overall ED visits has remained stable over the same period of time.²¹ While the vast majority (~95%) of these head injured patients are mild, >80%

²⁰ Huff, J. S., Naunheim, R., Dastidar, S. G., Bazarian, J., & Michelson, E. A. (2017). Referrals for CT scans in mild TBI patients can be aided by the use of a brain electrical activity biomarker. *The American Journal of Emergency Medicine*, 35(11), 1777-1779.

²¹ Marin, J. R., Weaver, M. D., Yealy, D. M., & Mannix, R. C. (2014). Trends in visits for traumatic brain injury to emergency departments in the United States. *Jama*, 311(18), 1917-1919.

receive CT scans of which ~91% are found to be negative.²² The rising number of negative CT findings, cost, radiation exposure, and ED resource utilization, has led to an increased need for reliable predictors of intracranial injury in the mild head injured population.²³ Based on a retrospective analysis of data collected in the BrainScope's multisite independent FDA validation study, it was found that had the SIC been used in determination as an input for CT scan referral, there would have been a reduction of false positives of 33.3% (408272/408). In addition, according to the study, a significantly lower false discovery rate of 65% (= 272/416) was achieved compared to the clinical site practice (one-sided comparison, $p = 0.01$).

The fifth article was a retrospective clinical study conducted in the U.S.²⁴ This study compares the predictive power using that algorithm (which includes loss of consciousness (LOC) and amnesia), to the predictive power of LOC alone or LOC plus traumatic amnesia. Study participants consisted of ED patients 18–85 years who presented within 72 hours of closed head injury, with Glasgow Coma Scale (GCS) between 12–15. 680 patients with known absence or presence of LOC were enrolled (145 CT + and 535 CT – patients). 5–10 min of eyes closed EEG was acquired using the Ahead 300 handheld device, from frontal and frontotemporal regions. The same classification algorithm methodology was used for both the EEG-based and the LOC-based algorithms. Predictive power was evaluated using area under the receiver operator characteristic (ROC) curve (AUC) and odds ratios. The Quantitative EEG-based classification algorithm demonstrated significant improvement in predictive power compared with LOC alone, both in improved AUC (83% improvement) and odds ratio (increase from 4.65 to 16.22). Adding retrograde amnesia (RGA) and/or post-traumatic amnesia (PTA) to LOC was not improved over LOC alone. The AUC for LOC only predictive method was 0.68, and for LOC +RGA/PTA was

²² Korley, F. K., Kelen, G. D., Jones, C. M., & Diaz-Arrastia, R. (2016). Emergency department evaluation of traumatic brain injury in the United States, 2009–2010. *The Journal of head trauma rehabilitation*, 31(6), 379.

²³ American College of Emergency Physicians. (2015). ACEP Announces List of Tests as Part of Choosing Wisely Campaign.

²⁴ Hack, D., Huff, J. S., Curley, K., Naunheim, R., Dastidar, S. G., & Prichep, L. S. (2017). Increased prognostic accuracy of TBI when a brain electrical activity biomarker is added to loss of consciousness (LOC). *The American Journal of Emergency Medicine*, 35(7), 949-952.

0.69. The AUC for the BrainScope structural injury classifier is 0.83, which represents an 83% improvement over the standard clinical predictors (LOC and/or RGA). Rapid triage of TBI relies on strong initial predictors. The authors concluded that the addition of an electrophysiological based marker was shown to outperform report of LOC alone or LOC plus amnesia, in determining risk of an intracranial bleed. In addition, according to the authors, ease of use at point-of-care, non-invasive, and rapid result using such technology suggests significant value added to standard clinical prediction.

With respect to the claim that the BrainScope TBI provides for a more rapid, beneficial resolution of the disease process treated, the applicant provided a consensus modeling retrospective clinical study conducted in the U.S.²⁵ The study researchers developed a care map that included each step of evaluation of mTBI (Glasgow Coma Scale Score 13–15), from initial presentation to the ED to discharge. Time spent at each step was estimated by study-affiliated emergency physicians and nurses. The study subsequently validated time estimates using retrospectively collected, real-time data at two EDs. Length of stay (LOS) time differences between admission and discharged patients were calculated for patients being evaluated for mTBI. Evaluation of time from ED intake to discharge in a mTBI population was modeled by a medical consensus group and validated in retrospective review of real-time data. Mean time was 6.6 hours. Time related to head CT comprised about one-half of the total LOS. The authors concluded that limiting use of head CT as part of the workup of mTBI to more serious cases may reduce time spent in the ED and potentially improve overall ED throughput.

To support the claim of a decreased rate of subsequent diagnostic or therapeutic interventions and reduced recovery time using the device, the applicant provided a retrospective clinical pilot study conducted in the U.S.²⁶ that focused on the immediate use and

²⁵ Michelson, E. A., Huff, J. S., Loparo, M., Naunheim, R. S., Perron, A., Rahm, M., & Berger, A. (2018). Emergency department time course for mild traumatic brain injury workup. *Western Journal of Emergency Medicine*, 19(4), 635.

²⁶ Clay, M. S. Clinical Utility of an EEG Based Biomarker for the Triage of Head Injured Patients in the ED: INOVA Pilot Study.

implementation of the BrainScope TBI in the ED environment for the triage of 19 head-injured patients: ages 18 to 85, GCS 13-15, within 72 hours of injury, from April 26th to May 1, 2021. According to this study, the results reinforced the clinical utility of the BrainScope technology to be a reliable tool for clinicians to proactively catch injuries that may not have been sent for CT and to reduce unnecessary CT's, thus reducing LOS. The author indicated that the BrainScope TBI was an effective decision-making aide in determining the appropriate use of imaging for closed head injuries. The author stated that within one rapid EEG test at the point of care, the BrainScope provided objective data on both brain bleeds and concussions to assist healthcare providers evaluate head injured patients. According to the author, this study was successful in determining utilization, staff assessment, and patient experience of the BrainScope technology in daily use. The author noted the results of the trial were positive and demonstrated the following: (1) 100 percent patient satisfaction with BrainScope; (2) Improved CT utilization in the mild TBI patient population: 60 percent reduction in head CT. Decreased radiation exposure. One patient was sent for CT after receiving a positive result from BrainScope TBI SIC that was found CT positive and who may not have been sent otherwise; and (3) Decreased LOS for patients who were BrainScope negative for structural injury. An average of 16-minute testing times had a positive impact on LOS for patients who were BrainScope negative.

In support of the claim that the BrainScope TBI reduces recovery time, the applicant submitted four articles. The first was a prospective clinical study conducted in the U.S.²⁷ The potential clinical utility of a quantitative EEG-based BFI as a measure of the presence and severity of functional brain injury was studied as part of an independent prospective validation trial. The BFI was derived using qEEG features associated with functional brain impairment reflecting current consensus on the physiology of concussive injury. The applicant asserted that

²⁷ Hanley D, Prichep LS, Badjatia N, Bazarian J, Chiacchierini R, Curley KC, Garrett J, Jones E, Naunheim R, O'Neil B, O'Neill J, Wright DW, Huff JS. A Brain Electrical Activity Electroencephalographic-Based Biomarker of Functional Impairment in Traumatic Brain Injury: A Multi-Site Validation Trial. *J Neurotrauma*. 2018 Jan 1;35(1):41-47. doi: 10.1089/neu.2017.5004. Epub 2017 Sep 21. PMID: 28599608.

the results supported FDA clearance for the BFI as a quantitative marker of brain function impairment. Per the applicant, a multinomial logistic regression analysis demonstrated odds ratios (versus controls) of the mild and moderate functionally impaired groups were significantly different from the odds ratio of the severe group (CT+), ($p=0.0009$, $p=0.0026$, respectively). Per the applicant, regression slopes for likelihood of group membership demonstrated that BFI scaled with severity of impairment contributed to earlier identification and intervention of concussion, which is associated with better outcomes.

Another article provided by the applicant to support the claim of reduced recovery time associated with the use of the BrainScope TBI, was a multisite prospective observational validation trial conducted in the U.S.²⁸ The study was to validate the classification accuracy of a previously derived, machine learning, multimodal, brain electrical activity–based Concussion Index (CI) in an independent cohort of athletes with concussion. This prospective diagnostic cohort study was conducted at 10 clinical sites (i.e., U.S. universities and high schools) between February 4, 2017 and March 20, 2019. A cohort comprised of a consecutive sample of 207 athletes aged 13 to 25 years with concussion and 373 matched athlete controls without concussion were assessed with electroencephalography, cognitive testing, and symptom inventories within 72 hours of injury, at return to play, and 45 days after return to play. Variables from the multimodal assessment were used to generate a Concussion Index at each time point. Athletes with concussion had experienced a witnessed head impact, were removed from play for 5 days or more, and had an initial Glasgow Coma Scale score of 13 to 15. Participants were excluded for known neurologic disease or history within the last year of traumatic brain injury. Athlete controls were matched to athletes with concussion for age, sex, and type of sport played. Classification accuracy of the CI at time of injury using a prespecified cutoff of 70 or less (total

²⁸ Bazarian, J. J., Elbin, R. J., Casa, D. J., Hotz, G. A., Neville, C., Lopez, R. M., ... & Covassin, T. (2021). Validation of a machine learning brain electrical activity–based index to aid in diagnosing concussion among athletes. *JAMA network open*, 4(2), e2037349-e2037349.

range, 0-100, where ≤ 70 indicates it is likely the individual has a concussion and >70 indicates it is likely the individual does not have a concussion). Results included 580 eligible participants with analyzable data, of whom 207 had concussion (124 male participants [59.9 percent]; mean [standard deviation (SD)] age, 19.4 [2.5] years), and 373 were athlete controls (187 male participants [50.1 percent]; mean [SD] age, 19.6 [2.2] years). The CI had a sensitivity of 86.0 percent (95 percent CI, 80.5 percent-90.4 percent), specificity of 70.8 percent (95 percent CI, 65.9 percent-75.4 percent), negative predictive value of 90.1 percent (95 percent CI, 86.1 percent-93.3 percent), positive predictive value of 62.0 percent (95 percent CI, 56.1 percent-67.7 percent), and area under receiver operator characteristic (ROC) curve of 0.89. At day 0, the mean [SD] CI among athletes with concussion was significantly lower than among athletes without concussion (75.0 [14.0] vs 32.7 [27.2]; $P < .001$). The researchers noted that among athletes with concussion, there was a significant increase in the CI between day 0 and return to play, with a mean (SD) paired difference between these time points of -41.2 (27.0) ($P < .001$). The researchers concluded that these results suggest that the multimodal brain activity-based CI has high classification accuracy for identification of the likelihood of concussion at time of injury and may be associated with the return to control values at the time of recovery. According to the researchers, the CI has the potential to aid in the clinical diagnosis of concussion and in the assessment of athletes' readiness to return to play.

The final article provided by the applicant in support of the claim of reduced recovery time was a multisite prospective observational validation trial conducted in the U.S.²⁹ This study was to derive an objective multimodal CI using EEG at its core, to identify concussion, and to assess change over time throughout recovery. Male and female concussed ($n = 232$) and control ($n = 206$) subjects 13–25 years were enrolled at 12 US colleges and high schools. Evaluations occurred within 72 hours of injury, 5 days post-injury, at return-to-play (RTP), 45 days after RTP

²⁹ Jacquin AE, Bazarian JJ, Casa DJ, Elbin RJ, Hotz G, Schnyer DM, Yeargin S, Prichep LS, and Covassin T. Concussion assessment potentially aided by use of an objective multimodal concussion index. *Journal of Concussion*. January 2021. doi:10.1177/20597002211004333

(RTP + 45); and included EEG, neurocognitive performance, and standard concussion assessments. Concussed subjects had a witnessed head impact, were removed from play for ≥ 5 days using site guidelines and were divided into those with RTP < 14 or ≥ 14 days. Part 1 of this paper described the derivation and efficacy of the machine learning derived classifier as a marker of concussion. Part 2 of this paper described significance of differences in CI between groups at each time point and within each group across time points. Per the researchers, the CI was shown to have high accuracy as a marker of likelihood of concussion and stability of CI in controls supports reliable interpretation of CI change in concussed subjects. The researchers concluded that the objective identification of the presence of concussion and assessment of readiness to return to normal activity can be aided by use of the CI, a rapidly obtained, point of care assessment tool. Sensitivity = 84.9 percent, specificity = 76.0 percent, and AUC = 0.89 were obtained on a test Hold-Out group representing 20 percent of the total dataset. Per the study, EEG features reflecting connectivity between brain regions contributed most to the CI. CI was stable over time in controls. According to the researchers, significant differences in CI between controls and concussed subjects were found at time of injury, with no significant differences at RTP and RTP + 45. Within the concussed, the researchers were able to identify differences in rate of recovery.

Based on the evidence submitted with the application, we note the following concerns. We note that most articles and citations provided by BrainScope are prospective observational studies or retrospective review articles, and most findings appear to be suggestive, rather than conclusive, of an association or significant benefit. Within the retrospective and prospective studies lacking a control subset, we note that some level of selection bias may potentially influence outcomes seen in these studies. Further, we note that confounding often occurs in both prospective and retrospective studies, which may result in misinterpretation of the observed relationships between the dependent and independent values. In most of the studies, the

authors did not address potential confounding issues, which makes it difficult to determine whether the BrainScope TBI or the control was effective with its results.

We further note that the applicant provided retrospective clinical validation studies,^{30,31} which describe findings for previous BrainScope technology, the BrainScope Ahead 300 handheld device, not the nominated BrainScope Ahead 500 handheld device. Per the applicant, the BrainScope Ahead 500 improves upon the prior versions of BrainScope's own previously FDA-cleared devices. The applicant does not provide comparative outcome data between the current and previous versions. Additional information regarding comparative outcomes data would help inform our assessment of whether the BrainScope TBI Ahead 500 demonstrates a substantial clinical improvement over existing technologies, including the BrainScope Ahead 300. We note concern that even though the applicant states that it is a prospective trial the paper was noted to be a retrospective secondary study of an independent study by FDA.

Lastly, we note that the cited studies have a small sample size. In addition, conclusions in the application regarding the referenced observational and retrospective studies about substantial clinical improvement appear to be overly broad and imply statistical significance, when only a possible association may in fact be supported. We further note that the majority of the studies lacked a comparator to the existing technologies that the applicant identified when assessing the effectiveness of the BrainScope TBI. In addition, the applicant identified the COGNISION[®] System as an existing device, but we did not receive any citations or supporting references regarding comparability of these technologies. We also note that there are two additional FDA-cleared, potential alternate therapies^{32, 33} that could be relevant, but the applicant did not provide

³⁰ Hack, D., Huff, J. S., Curley, K., Naunheim, R., Dastidar, S. G., & Prichep, L. S. (2017). Increased prognostic accuracy of TBI when a brain electrical activity biomarker is added to loss of consciousness (LOC). *The American Journal of Emergency Medicine*, 35(7), 949-952.

³¹ Hanley D, Prichep LS, Bazarian J, Huff JS, Naunheim R, Garrett J, Jones EB, Wright DW, O'Neill J, Badjatia N, Gandhi D. Emergency department triage of traumatic head injury using a brain electrical activity biomarker: a multisite prospective observational validation trial. *Academic emergency medicine*. 2017 May;24(5):617-27.

³² <https://abbott.mediaroom.com/2021-01-11-Abbott-Receives-FDA-510-k-Clearance-for-the-First-Rapid-Handheld-Blood-Test-for-Concussions>

³³ <https://www.mobihealthnews.com/news/syncthink-scores-fda-clearance-ai-system-aid-concussion-diagnosis>

citations or supporting references regarding comparability specifically in the application.

Additional information regarding comparative outcomes data would help inform our assessment of whether the BrainScope TBI demonstrates a significant clinical improvement over existing technologies.

We are inviting public comments on whether the BrainScope TBI meets the substantial clinical improvement criterion.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d).

Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that BrainScope TBI would be reported with HCPCS codes listed in the following table:

TABLE 33: HCPCS CODES REPORTED WITH THE BRAINSCOPE TBI

HCPCS Code	Long Descriptor	Status Indicator	APC
95816	Electroencephalogram (eeg); including recording awake and drowsy	S	5722
96132	Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour	Q3	5722
96136	Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method; first 30 minutes	Q3	5734
96138	Psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; first 30 minutes	Q3	5735
96146	Psychological or neuropsychological test administration, with single automated, standardized instrument via electronic platform, with automated result only	Q3	5731

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule with comment period (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. For our calculations, we used APC 5731 – Level 1 Minor Procedures, which had a CY 2021 payment rate of \$24.67 at the time the application was received. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). However, we note that all the HCPCS codes identified by the applicant had a device offset amount of \$0.00 at the time the application was received, including the HCPCS code 96146. Accordingly, we are evaluating the cost significance requirements consistent with how we previously have treated other items with a device offset amount of \$0.00 (see 84 FR 61285). According to the applicant, the cost of BrainScope TBI (single use disposable electrode headset) is \$225.00.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of \$225.00 for BrainScope TBI is 912.04 percent of the applicable APC payment amount for the service related to the category of devices of \$24.67 ($(\$225/\$24.67) \times 100 = 912.04$ percent). Therefore, we believe BrainScope TBI meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). Given that there are no device-related costs in the

APC payment amount, and the BrainScope TBI has an estimated average reasonable cost of \$225, we believe that the BrainScope TBI meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of \$225 for BrainScope TBI and the portion of the APC payment amount for the device of \$0.00 exceeds the APC payment amount for the related service of \$225 by 912.04 percent ($((\$225 - \$0.00) / \$24.67) \times 100 = 912.04$ percent). Therefore, we believe that the BrainScope TBI meets the third cost significance requirement.

We are inviting public comment on whether the BrainScope TBI meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(2) NavSlim™ and NavPencil

Elucent Medical, Inc. submitted an application for a new device category for transitional pass-through payment status for CY 2023 for the NavSlim™ and NavPencil (referred to collectively as “the Navigators”). The applicant described the Navigators as single-use (disposable) devices for real-time, stereotactic, 3D navigation for the excision of pre-defined soft tissue specimens.

According to the FDA 510(k) Summary (K183400) provided by the applicant,³⁴ the Navigators are a component of the applicant’s EnVisio™ Navigation System³⁵ which is intended only for the non-imaging detection and localization (by navigation) of a SmartClip™ Soft Tissue Marker (SmartClip™) that has been implanted in a soft tissue biopsy site or a soft tissue site

³⁴ As explained later in this section, the applicant received FDA 510(k) clearance for the EnVisio™ Navigation System, which includes the Navigators.

³⁵ The FDA 510(k) Summary for the EnVisio™ Navigation System states that the EnVisio™ Navigation System “equipment components” are the Console, Heads Up Display, Patient Pad and Foot Pedal. The Navigator is listed as a separate, sterile, non-patient contacting, single-use system component. The applicant submitted an application for pass-through payment status only for the Navigator component of the EnVisio™ Navigation System.

intended for surgical removal.³⁶ We note that the applicant submitted a separate application for pass-through payment status for the SmartClip™ for CY 2023, as discussed in a subsequent section. The applicant explained that the sterile, single-use Navigators affix to an electrocautery (surgical cutting) tool and, in combination with the other EnVisio™ Navigation System components and the SmartClip™, provide real-time intraoperative 3D navigation to the tumor and margin. The applicant explained that, at the time of surgical intervention, electromagnetic waves delivered by the EnVisio™ Navigation System activate the implanted SmartClip™ within a 50cm x 50cm x 35cm volume. The applicant further explained that the SmartClip™ contains an application-specific integrated circuit (ASIC) which is activated at a specific frequency and communicates to the EnVisio™ Navigation System the precise, real-time location of both the SmartClip™ and the surgical margin, enabling the surgeon to plan the specimen (tumor and margin) for excision. The applicant asserted that this data is calibrated relative to the tip of the electrocautery device or other operating instrument and is displayed in 3D. According to the applicant, the Navigators enable intraoperative visualization by displaying real-time stereotactic 3D guidance from the tip of the surgical tool enabling minimally invasive removal of pre-defined tissue specimen (tumor and margin). The applicant stated that surgeons are able to visualize the directional distances to make excisional plane of each margin in-situ without using conventional imaging (e.g., ultrasound).

The applicant stated that there are two types of Navigators: (1) the NavSlim™ (which the applicant described as a lightweight model that allows integration with a broader range of electrosurgical tools, with or without smoke evacuation); and (2) the NavPencil (which, according to the applicant, incorporates a small screen in the surgical sightline that mimics the EnVisio™ Navigation System operating room monitor). The applicant also asserted that the integration of the Navigators with the single use, sterile electrocautery tool enables a single, light

³⁶ The SmartClip™ has a separate FDA 510(k) clearance. Based on the FDA 510(k) Summary for the EnVisio™ Navigation System, the SmartClip™ does not appear to be part of the EnVisio™ Navigation System.

weight tool that can be utilized in situ for a minimally invasive surgery without infection risk.

According to the applicant, the Navigators reduce the risk of tumor microenvironment caused by tissue disruption of non-targeted tissue. The applicant stated that the patient populations that can benefit from this technology are those that have biopsy proven cancers in organs that lack anatomic landmarks like breast, abdomen, and head and neck.

The applicant stated that the Navigators are the first devices to provide precise real-time navigation with a large patient volume of 50cm x 50cm x 35cm (per the applicant, encompassing > 99 percent of breast cancer patient habitus and > 90 percent of lung cancer patient habitus). In addition, the applicant asserted several other clinically differentiating features from prior products. First, the applicant stated that the Navigators process 240 simultaneous data streams solving for location 16 times per second with millimeter level of accuracy, and display it to the surgeon based upon actual location of the defined lesion as it is manipulated in situ, not based on imaging that occurred days or weeks before. The applicant asserted that as the tissue is moved or manipulated during a surgical intervention, the location is instantaneously updated. According to the applicant, this allows for intelligent, real-time, intraoperative visualization and guidance for the surgeon, enabling precise removal of a defined tissue specimen (including tumor and margin). Furthermore, the applicant asserted that the accurate and real-time wireless location eliminates any potential registration errors that are typically found in devices that use pre-procedure imaging for guidance. The applicant explained that no static pre-procedure imaging is necessary eliminating the potential of mis-registration due to patient or tissue movement. In addition, the applicant stated that the Navigators provide 3D guidance – medial/lateral, inferior/superior and anterior/posterior, as well as the most direct path, and asserted that this is increasingly important in treating lobular and deep tumors. The applicant also claimed that because the guidance is from the tip of the cutting tool, exact measurements can be taken in situ at the exact cutting location. In addition, per the applicant, the Navigators allow for an

oncoplastic³⁷ approach – the applicant stated that because the location is not tethered or constrained in any way, the surgeon can choose the best cutting approach to achieve the optimal oncoplastic outcome. Finally, the applicant added that the Navigators provide the ability to distinctly identify and navigate up to three separate lesions in the same patient.

With respect to the newness criterion at § 419.66(b)(1), on March 22, 2019, the applicant received 510(k) clearance from FDA to market the EnVisio™ Navigation System (which, as explained previously, includes the Navigators) for the non-imaging detection and localization (by navigation) of a SmartClip™ that has been implanted in a soft tissue biopsy site or a soft tissue site intended for surgical removal. The applicant submitted its application for consideration as a new device category for transitional pass-through payment status for the Navigators on February 28, 2022, which is within 3 years of the date of the initial FDA marketing authorization. We are inviting public comments on whether the Navigators meet the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the Navigators are an integral part of the service furnished and are used for one patient only. However, the applicant did not specifically indicate whether the Navigators come in contact with human tissue, and are surgically implanted or inserted or applied in or on a wound or other skin lesion, as required at § 419.66(b)(3).³⁸ The FDA 510(k) Summary (K183400) states that the Navigator is a sterile, non-patient contacting, single-use device. We would welcome comments on whether the Navigators meet the requirements of § 419.66(b)(3). The applicant also did not indicate whether the Navigators meet the device eligibility requirements at § 419.66(b)(4), which provide that the device may not be any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets; or (2) a material or supply furnished incident to a service (for example, a

³⁷ According to Columbia University Irving Medical Center, oncoplastic breast surgery combines the techniques of traditional breast cancer surgery with the cosmetic advantages of plastic surgery. <https://columbiasurgery.org/conditions-and-treatments/oncoplastic-breast-surgery>

³⁸ By contrast, the SmartClip™, discussed in the next section of this preamble, is inserted into human tissue.

suture, customized surgical kit, or clip, other than radiological site marker). We are inviting public comments on whether the Navigators meet the eligibility criteria at § 419.66(b).

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. The applicant stated that it was not aware of an existing pass-through payment category that describes the Navigators, and listed an existing device category that it considered for comparison to the Navigators – specifically, HCPCS code C1748 (Endoscope, single-use (i.e., disposable), upper GI, imaging/illumination device (insertable)). The applicant stated that the Navigators are designed to meet the demands within the clinical environment for a single-use (i.e., disposable) device to decrease infection rate, similar to the recent advancements of “disposable” endoscopes to address clinical demands for single-use to eliminate risks of cross contamination and improper sterilization. HCPCS code C1748 is a current pass-through payment category, effective beginning July 1, 2020. The applicant did not specifically differentiate the Navigators from devices in HCPCS code C1748. Upon review, it does not appear that there are any existing pass-through payment categories that might apply to the Navigators. We are inviting public comments on whether the Navigators meet the device category criterion.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA’s Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the

Breakthrough Device designation. The applicant claimed that the use of the Navigators results in substantial clinical improvement over existing technologies by (1) reducing positive margin and re-excision rates, thereby decreasing the rate of subsequent therapeutic interventions; (2) reducing the rate of device-related complications, including surgical site infections and wire migration and transection; and (3) improving the surgical approach (surgeons are not tethered to the best radiological approach, and the incision can be placed in the ideal location resulting in better oncological results, less complex path to the lesion, and better visualization during surgery). The applicant provided articles and case reports for the purpose of addressing the substantial clinical improvement criterion.

In support of the claim that use of the Navigators reduces positive margin and re-excision rates, the applicant submitted an abstract of a study performed to assess the impact of electromagnetic seed localization (ESL) using the EnVisio™ Navigation System and SmartClip™ compared to wire localization (WL) on operative times, specimen volumes, margin positivity, and margin re-excision rates.³⁹ Between August 2020 and August 2021, 97 patients underwent excisional biopsy (n=20), or lumpectomy with (n=53) or without (n=24) sentinel lymph node biopsy (SLNB) using ESL guidance at a single institution by 5 surgeons. The study authors matched these patients, one-to-one, with WL patients undergoing surgery between 2006 and 2021 based on surgeon, procedure type with stratification for those having and not having nodal procedures, and pathologic stage or benign pathology. When greater than one WL match was found, selection was randomized. The authors compared continuous variables (operative times, specimen volumes, excess volume excised) between patients undergoing ESL and WL using Wilcoxon rank sums tests. The authors compared categorical variables (positive margin rates, re-excision rates) using Fisher's exact tests. Median operative time for ESL versus WL for lumpectomy with SLNB was 66 versus 69 minutes (p=0.76) and without SLNB was 40 versus

³⁹ Jordan R, Rivera-Sanchez L, Kelley K, O'Brien M, et al. The Impact of an Electromagnetic Seed Localization Device as Versus Wire Localization on Breast Conserving Surgery: A Matched Pair Analysis. Abstract presented at: 23rd Annual Meeting of The American Society of Breast Surgeons; April 6-10, 2022. https://www.breastsurgeons.org/meeting/2022/docs/2022_Official_Proceedings_ASBrS.pdf

34.5 minutes ($p=0.17$). Median specimen volume was 55cm^3 with WL versus 36cm^3 with ESL ($p=0.0012$). In those with measurable tumor volume, excess tissue excised was larger with WL compared to ESL (median= 73.2cm^3 versus 52.5cm^3 , $p=0.017$). Main segment margins were positive in 18 of 97 (19 percent) WL patients compared to 10 of 97 (10 percent) ESL patients ($p=0.17$). In the WL group, 13 of 97 (13 percent) had margin re-excision at a separate procedure, compared to 6 of 97 (6 percent) in the ESL group, ($p=0.15$). The authors concluded that ESL is superior to WL because it provided more accurate localization, evidenced by smaller specimen volume with less excess tissue excised, despite similar operative times. In addition, the authors reported that, although not statistically significant, ESL resulted in lower positive margin rates and lower margin re-excision rates compared to WL. The authors further noted that ESL allows for preoperative localization, eliminating same day operative delays, and single tool 3D localization. The authors concluded that further studies comparing ESL to other non-wire localization techniques are required to refine which localization technology is most advantageous in breast conservation surgery.

The applicant provided a second article consisting of a clinical paper from the Moffitt Cancer Center that, per the applicant, is pending publication.⁴⁰ The paper presented three cases from the Moffitt Cancer Center, including radiographic and other images, employing three different methods of breast mass localization: (1) SmartClip™, (2) SAVI SCOUT® radar reflector localizer, and (3) traditional wire localizer. The authors stated that the purpose of the paper was to educate the audience about the technological advances regarding breast mass localization and to discuss the advantages and disadvantages of SmartClip™ localizers, SAVI SCOUT® localizers, and wire localizers.

The authors first discussed wire localization, stating that wire localization involves image-guided insertion of a guidewire into a targeted mass and that the use of multiple wires

⁴⁰ Ibanez J, Wotherspoon T, Mooney B, Advances in Image Guided Breast Mass Localization Techniques (undated). Submitted by the applicant with its application on February 28, 2022.

allows for bracketing of multiple lesions or a large lesion. The authors asserted that, while effective in localization, this procedure has drawbacks such as wire breakage, patient discomfort, wire migration while moving or transporting the patient, and the need to surgically remove the wire the same day that it is placed due to this risk of migration.

The authors also discussed radar reflector localizers such as SAVI SCOUT®, which are small devices that can be placed into a targeted mass at any time prior to lumpectomy. The authors explained that once a surgeon gains a general idea of the mass' location by looking at the post localizer placement mammogram, this localizer is “hunted” for intraoperatively using a special handheld device which provides auditory feedback, but does not provide location details until it is found via the auditory feedback. The authors cited a retrospective study at the Moffitt Cancer Center which, according to the authors, indicated that localization using SAVI SCOUT® was successful for 125 out of 129 patients (97 percent, 95 percent Confidence Interval 92-99 percent) and showed that in comparison to wire localization, SAVI SCOUT® provides improved patient comfort and eliminates the need to perform the surgery on the same day as the localization procedure.⁴¹

Finally, the authors discussed localization using the SmartClip™. The authors noted that the SmartClip™ is the first device to provide three-plane localization information. The authors stated that a monitor displays the approximate position of the SmartClip™ allowing everyone in the operating room to assist with the localization of the SmartClip™ and provide knowledge of its location prior to and throughout the surgery. They further noted that the SmartClip™ localizer can be visualized on a small screen mounted on the electrocautery tool which, similar to the monitor, depicts the direction and depth to the SmartClip™. According to the authors, this provides real-time visual feedback to surgeons as the electrocautery tool moves and allows them to find the clip without having to look up at the operating room monitor. The authors asserted

⁴¹ Falcon S, Weinfurter RJ, Mooney B, Niell BL. SAVI SCOUT® localization of breast lesions as a practical alternative to wires: Outcomes and suggestions for trouble-shooting. *Clin Imaging*. 2018 Nov-Dec;52:280-286. doi: 10.1016/j.clinimag.2018.07.008. Epub 2018 Jul 24. PMID: 30193186.

that the three-axis visualization eliminated the need to search for the clip since the location is always known, and that the availability of the SmartClip™ in three colors with different signals eases differentiation between localizers and allows for bracketing of masses.

The authors concluded that wire localization has drawbacks such as wire breakage, patient discomfort, high chances of migration, and narrow placement timeframes, which have been mitigated over the past decade by various soft tissue localizers such as SAVI SCOUT® (radar reflector localizer). The authors concluded that the SmartClip™, which they refer to as a new localizer, may potentially resolve other difficulties encountered with the soft tissue localizers that they currently use. Finally, the authors noted that a clinical study is currently underway at the Moffitt Cancer Center to evaluate the advantages of using the SmartClip™ in clinical practice.

In addition, the applicant provided two physician case reports, each describing the use of the EnVisio™ Navigation System and SmartClip™ in a single patient (62 and 59-year-old female breast cancer patients). Each case report described the patient's history, diagnostic tools utilized, pre-operative, peri-operative, and/or post-operative course, pathology results, as well as the physician's perceptions of the SmartClip™ or EnVisio™ Navigation System. In the first surgical case report,⁴² the surgeon noted that the foot pedal activation of the EnVisio™ Navigation System allowed toggling between two SmartClip™ devices, allowing complete dissection around the periphery of the mass to obtain a precise margin. The surgeon asserted that with one marker, there would have been a higher risk of a positive margin. In the second surgical case report,⁴³ the surgeon similarly noted that the EnVisio™ Navigation System helped her to map out and be more precise in her incision location and lumpectomy dissection.

The applicant also submitted several articles in general support of its application, which we summarize as follows. An article from the Mayo Clinic concluded that intraoperative

⁴² Kruper, Laura, Bracketing Lobulated Breast Lesion with the EnVisio™ Navigation System using Differentiated SmartClip.

⁴³ Henkel, Dana, Single SmartClip Case.

pathologic assessment with frozen-section margin evaluation of all neoplastic breast specimens allows for immediate re-excision of positive or close margins during the initial operation and results in an extremely low reoperation rate of <2%.⁴⁴ Another article addressed the relationship between post-surgery infection and breast cancer recurrence and concluded that there is association between surgical site infection and adverse cancer outcomes, but the cellular link between them remains elusive.⁴⁵ Furthermore, a study from the Mayo Clinic concluded there was no reduction in the surgical site infection rate among patients who received postoperative antibiotic prophylaxis after breast surgery.⁴⁶ In addition, a study from Washington University School of Medicine concluded that surgical site infection (SSI) after breast cancer surgical procedures was more common than expected for clean surgery and more common than SSI after non-cancer-related breast surgical procedures.⁴⁷ A review article from the Department of Radiation Oncology, Case Western Reserve University and University Hospitals in Cleveland surmised that precision medicine holds the promise of truly personalized treatment which provides every individual breast cancer patient with the most appropriate diagnostics and targeted therapies based on the specific cancer's genetic profile as determined by a panel of gene assays and other predictive and prognostic tests.⁴⁸ An abstract on the subject of prognostic factors for surgical margin status and recurrence in partial nephrectomy concluded that (1) surgical margin positivity after partial nephrectomy is not significantly associated with tumor characteristics and anatomical scoring systems, (2) surgical indication for partial nephrectomy

⁴⁴ Racz JM, Glasgow AE, Keeney GL, Degnim AC, Hieken TJ, Jakub JW, Cheville JC, Habermann EB, Boughey JC. Intraoperative Pathologic Margin Analysis and Re-Excision to Minimize Reoperation for Patients Undergoing Breast-Conserving Surgery. *Ann Surg Oncol*. 2020 Dec;27(13):5303-5311. doi: 10.1245/s10434-020-08785-z. Epub 2020 Jul 4. PMID: 32623609.

⁴⁵ O'Connor RÍ, Kiely PA, Dunne CP. The relationship between post-surgery infection and breast cancer recurrence. *J Hosp Infect*. 2020 Nov;106(3):522-535. doi: 10.1016/j.jhin.2020.08.004. Epub 2020 Aug 13. PMID: 32800825.

⁴⁶ Throckmorton AD, Boughey JC, Boostrom SY, Holifield AC, Stobbs MM, Hoskin T, Baddour LM, Degnim AC. Postoperative prophylactic antibiotics and surgical site infection rates in breast surgery patients. *Ann Surg Oncol*. 2009 Sep;16(9):2464-9. doi: 10.1245/s10434-009-0542-1. Epub 2009 Jun 9. PMID: 19506959.

⁴⁷ Olsen MA, Chu-Ongsakul S, Brandt KE, Dietz JR, Mayfield J, Fraser VJ. Hospital-associated costs due to surgical site infection after breast surgery. *Arch Surg*. 2008 Jan;143(1):53-60; discussion 61. doi: 10.1001/archsurg.2007.11. PMID: 18209153.

⁴⁸ Eleanor E. R. Harris, "Precision Medicine for Breast Cancer: The Paths to Truly Individualized Diagnosis and Treatment", *International Journal of Breast Cancer*, vol. 2018, Article ID 4809183, 8 pages, 2018. <https://doi.org/10.1155/2018/4809183>.

has a direct influence on positive surgical margin rates, and (3) tumor size and stage after partial nephrectomy are valuable parameters in evaluating the recurrence risk.⁴⁹ Lastly, a study examining the significance of resection margin in hepatectomy for hepatocellular carcinoma concluded that the width of the resection margin did not influence the postoperative recurrence rates after hepatectomy for hepatocellular carcinoma.⁵⁰

Based on the evidence submitted with the application, we note the following concerns. The first study appears to be unpublished, and it is not clear whether it has been submitted for publication in a peer-reviewed journal. In addition, the study involved a sample of 97 patients from one institution and appears to be written as a feasibility study for a potentially larger randomized control trial. Notably, the authors of this study stated that further studies are required to compare ESL to other non-wire localization techniques to refine which localization technology is most advantageous in breast conservation surgery. Furthermore, the authors did not report the sex or age of the study participants. Additionally, the authors reported that the differences in positive margin and re-excision rates between ESL and WL groups were not statistically significant. We also note a potential concern regarding practice/selection effects bias inherent in the methodology presented.

The second article is an undated,⁵¹ unpublished descriptive clinical paper comparing three different breast mass localization techniques in three cases from one institution. The applicant stated that this paper is pending publication, but provided no further details regarding the status of the paper. The paper did not systematically compare the techniques across any measurable variables, noting that a clinical study was underway at the institution to evaluate the SmartClip™ in clinical practice. Similarly, we note that the physician case reports were solely descriptive in

⁴⁹ Demirel HC, Çakmak S, Yavuzsan AH, Yeşildal C, Türk S, Dalkılıç A, Kireççi SL, Tokuç E, Horasanlı K. Prognostic factors for surgical margin status and recurrence in partial nephrectomy. *Int J Clin Pract.* 2020 Oct;74(10):e13587. doi: 10.1111/ijcp.13587. Epub 2020 Jul 14. PMID: 32558097.

⁵⁰ Poon, R. T., Fan, S. T., Ng, I. O., & Wong, J. (2000). Significance of resection margin in hepatectomy for hepatocellular carcinoma: A critical reappraisal. *Annals of surgery*, 231(4), 544–551. <https://doi.org/10.1097/00000658-200004000-00014>.

⁵¹ Although the applicant reported the date of the study as January 2021, the copy of the study provided by the applicant was not dated.

nature – they presented each physician’s anecdotal experience using the EnVisio™ Navigation System and SmartClip™. Furthermore, the applicant provided several additional articles that, while informative, did not involve the Navigators and do not appear to directly support the applicant’s claim of substantial clinical improvement. We would welcome additional information and evidence from larger, multi-center studies that provide comparative outcomes between the Navigators and existing technologies.

We further note that none of the articles and case reports provided conclusive evidence that the use of the Navigators reduces surgical site infection rates or the risk of tissue marker migration, as claimed by the applicant. In addition, the articles and case reports provided by the applicant described the use of the subject devices only in breast cancer surgery cases. As reported by the applicant, the Navigators can also be used for patients that have biopsy proven cancers in other organs that lack anatomic landmarks like the abdomen and head and neck. We would welcome additional evidence of substantial clinical improvement in cases related to non-breast cancer related procedures.

We are inviting public comments on whether the Navigators meet the substantial clinical improvement criterion.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the Navigators are used in surgical interventions described by the HCPCS codes listed in Table 34.

TABLE 34: HCPCS CODES REPORTED WITH THE NAVIGATORS

HCPCS Code	Long Descriptor	SI	APC
19101	Biopsy of breast; open, incisional	J1	5091
19301	Mastectomy, partial (eg, lumpectomy, tylectomy, quadrantectomy, segmentectomy)	J1	5091

19125	Excision of breast lesion identified by preoperative placement of radiological marker, open; single lesion	J1	5091
21552	Excision, tumor, soft tissue of neck or anterior thorax, subcutaneous; 3 cm or greater	J1	5073
22902	Excision, tumor, soft tissue of abdominal wall, subcutaneous; less than 3 cm	J1	5072
38500	Biopsy or excision of lymph node(s); open, superficial	J1	5091
38210	Transplant preparation of hematopoietic progenitor cells; specific cell depletion within harvest, t-cell depletion	S	5241
38525	Biopsy or excision of lymph node(s); open, deep axillary node(s)	J1	5091
38530	Biopsy or excision of lymph node(s); open, internal mammary node(s)	J1	5091
38740	Axillary lymphadenectomy; superficial	J1	5361

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. For our calculations, we used APC 5072– Level 2 Excision/ Biopsy/ Incision and Drainage, which had a CY 2021 payment rate of \$1,407 at the time the application was received. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). HCPCS code 22902 had a device offset amount of \$1.13 at the time the application was received. According to the applicant, the cost of the Navigators is \$499.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of \$499 for the Navigators is 35.5 percent of the applicable APC payment amount for the service related to the category of devices of \$1,407 ($(\$499/\$1,407) \times 100 = 35.5$ percent). Therefore, we believe the Navigators meet the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of \$499 for the Navigators is 44,159.3 percent of the cost of the device-related portion of the APC payment amount for the related service of \$1.13 ($(\$499/\$1.13) \times 100 = 44,159.3$ percent). Therefore, we believe that the Navigators meet the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of \$499 for the Navigators and the portion of the APC payment amount for the device of \$1.13 is 35.4 percent of the APC payment amount for the related service of \$1,407 ($((\$499-\$1.13)/\$1,407) \times 100 = 35.4$ percent). Therefore, we believe that the Navigators meet the third cost significance requirement.

We are inviting public comment on whether the Navigators meet the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(3) SmartClip™

Elucent Medical, Inc. submitted an application for a new device category for transitional pass-through payment status for CY 2023 for the SmartClip™ Soft Tissue Marker (SmartClip™). The applicant described the SmartClip™ as an electromagnetically activated, single-use, sterile soft tissue marker used for anatomical surgical guidance. According to the applicant, the SmartClip™ is the only soft tissue marker that delivers independent coordinates of location when used in conjunction with the applicant's EnVisio™ Navigation System (which includes the Navigators discussed previously in this proposed rule). Per the applicant, at the time

of surgical intervention, electromagnetic waves delivered by the EnVisio™ Navigation System activate the implanted SmartClip™ within a 50cm x 50cm x 35cm volume. The applicant further explained that the SmartClip™ contains an application-specific integrated circuit (ASIC), customized for use with the EnVisio™ Navigation System, which is activated at a specific frequency and communicates to the EnVisio™ Navigation System the precise, real-time location of both the SmartClip™ and the surgical margin, enabling the surgeon to plan the specimen (tumor and margin) for excision.⁵² The applicant asserted that this data is calibrated relative to the tip of the electrocautery device or other operating instrument and is displayed in 3D.

The applicant stated that the SmartClip™ is assembled into a hermetically sealed, Parylene C coated glass cylinder and provided pre-loaded into a 15-gauge introducer needle available in various lengths (5cm, 7.5cm, 10cm). Per the applicant, using the introducer needle, the SmartClip™ is implanted directly into a tumor at the time of biopsy or during a separate procedure in advance of surgery. According to the FDA 510(k) Summary (K180640), the SmartClip™ can be implanted into various types of soft tissue, such as lung, gastrointestinal system, and breast, and can subsequently be detected using the EnVisio™ Navigation System or by means of radiography (including mammographic imaging), ultrasound, and magnetic resonance imaging (MRI). Per the applicant, it is utilized frequently in breast conserving surgery, lymph nodes, and head/neck cancers.

According to the applicant, up to three SmartClips™, each with a unique electromagnetic signature, can be implanted in a patient to mark and provide continuous location of multiple targets (for example, 3 lesions, or 2 lesions/1 lymph node) or to bracket either a large lesion or microcalcifications. The applicant claimed that the SmartClip™ enables the surgeon to choose the safest, least disfiguring (oncoplastic) approach and path to the tumor before the surgery. According to the applicant, providing surgical planning and excision lessens the impact of the

⁵² Based on the FDA 510(k) Summary for the EnVisio™ Navigation System, the SmartClip™ does not appear to be a component of the EnVisio™ Navigation System; the SmartClip™ has a separate FDA 510(k) clearance as discussed later in this section.

disruption of non-targeted tissue. In addition, the applicant stated that the SmartClip™ enables the surgeon to measure and record specimen size post excision.

The applicant further asserted that the SmartClip™ is a significantly advanced version of an interstitial implant device, such as a gold fiducial marker, that is placed into a tumor directly to guide the surgeon to the location of a malignant lesion. The applicant claimed that the SmartClip™ has characteristics that differentiate it from conventional fiducial markers. First, the applicant stated that the SmartClip™ location is expressed relative to the patient's position – medial/lateral, inferior/superior, anterior/posterior with 2mm precision. Second, according to the applicant, the SmartClip™ location is instantaneous and updated 16 times per second reflecting any location change due to tissue manipulation and allowing alterations in the patient's position with no compromise in accuracy. Furthermore, the applicant asserted that the SmartClip™ provides seamless, real-time navigation, maintaining the 3D position of the lesion within the surgical space and relative to the surgical tools. The applicant added that the SmartClip™ is not subject to registration errors often seen with navigation that utilizes pre-procedure imaging for guidance. Furthermore, the applicant asserted that the SmartClip™ is ideal for minimally invasive procedures in that it does not require line of sight. The applicant also stated that the SmartClip™ does not utilize any radioactive materials or contain any ionizing radiation. Per the applicant, the SmartClip™ does not require a separate imaging modality, however, if another imaging modality is utilized, the SmartClip™ is radiopaque. Finally, the applicant stated that the SmartClip™ provides the following advantages compared to current localization methods (including preoperative wire localization): (1) no migration of the SmartClip™; (2) no depth limitation, addressing broader patient population clinical needs; (3) no limitations on clinical approach for placement or surgical excision; (4) permanently implantable, should continuum of care change; (5) no risks for multifocal or extensive lesion markings for complex cases; (6) no required workflow changes for varied surgical tools; (7) can be placed remote from surgery (days or weeks) at the patient's convenience; (8) nothing protruding from the skin so there is no

mechanical pathway for bacterial contamination; and (9) puncture is healed at the time of surgery.

With respect to the newness criterion at § 419.66(b)(1), on June 4, 2018, the applicant received 510(k) clearance from FDA to market the SmartClip™ for radiographic marking of sites in soft tissue and in situations where the soft tissue site needs to be marked for future medical procedures. The applicant submitted its application for consideration as a new device category for transitional pass-through payment status for the SmartClip™ on February 28, 2022, which is more than 3 years from the date of the initial FDA marketing authorization. We note that in accordance with 42 CFR 419.66(b)(1), the pass-through payment application for a medical device must be submitted within 3 years from the date of the initial FDA approval or clearance, unless there is a documented, verifiable delay in U.S. market availability after FDA approval or clearance is granted, in which case we will consider the pass-through payment application if it is submitted within 3 years from the date of market availability. The applicant asserted that the SmartClip™ could not be marketed until May 2019 because it is utilized in conjunction with the EnVisio™ Navigation System and FDA clearance for the EnVisio™ Navigation System was required prior to use of the SmartClip™ (as mentioned previously, the applicant received FDA clearance for the EnVisio™ Navigation System on March 22, 2019). We note that, according to the FDA 510(k) Summary and Indications for Use for the SmartClip™ (K180640) and the EnVisio™ Navigation System (K183400), the SmartClip™ also can be located and surgically removed through the use of imaging guidance such as x-ray, mammography, ultrasound, and MRI. According to the applicant, the EnVisio™ Navigation System enables the SmartClip™ as an intelligent interstitial soft tissue marker utilizing electromagnetic waves to display precise coordinates in each of three planes. The applicant further asserted that the SmartClip™ was designed to provide the surgeon the precise coordinates for target tissue removal and that this function requires the utilization of the electronic field generated by the EnVisio™ Navigation System. The applicant noted that while the SmartClip™

is visible and can be located using imaging guidance (such as ultrasound, MRI, or radiography), such imaging guidance would typically only be used in the removal of the targeted tissue should the SmartClip™ ASIC fault, so as to ensure patient care is not compromised. The applicant further stated that it did not consider pursuing marketability of the SmartClip™ as an unintelligent interstitial marker as the applicant believed that the action would not have resulted in meeting the unmet healthcare need for substantial clinical improvements. In addition, the applicant claimed that due to the impact of the COVID-19 pandemic, ambulatory surgical centers and outpatient facilities were restricted in performing breast cancer surgery, resulting in a verifiable delay. The applicant requested that CMS utilize the FDA clearance date for the EnVisio™ Navigation System (March 22, 2019) as the applicable date for the SmartClip™'s initial marketability. We are inviting public comments on whether the SmartClip™ meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the SmartClip™ is an integral part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted. The applicant did not indicate whether the SmartClip™ meets the device eligibility requirements of § 419.66(b)(4), which provide that the device may not be any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets; or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than radiological site marker). We are inviting public comments on whether the SmartClip™ meets the eligibility criteria at § 419.66(b).

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of

December 31, 1996. The applicant stated that it was not aware of an existing pass-through payment category that describes the SmartClip™.

The applicant identified three devices or device categories that it believes are most closely related to the SmartClip™: (1) hook-wire systems (the applicant did not provide an associated code, but listed Kopans (Bard and McKesson) and Dualok (McKesson) as types of such systems); (2) HCPCS code A4648 (Tissue marker, implantable, any type, each); and (3) HCPCS code 91112 (Gastrointestinal transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report (Smartpill™)).⁵³

Although HCPCS code A4648 is not an existing pass-through payment category, we note that a previous equivalent code, HCPCS code C1879 (Tissue marker (implantable)), was a pass-through payment category in effect between August 1, 2000 and December 31, 2002.⁵⁴ Pursuant to Change Request 8338, CMS deleted temporary HCPCS code C1879 on June 30, 2013, because this category of devices was described by permanent HCPCS code A4648. We stated in the Change Request that effective July 1, 2013, when using implantable tissue markers with any services provided in the OPPS, providers should report the use and cost of the implantable tissue marker with HCPCS code A4648 only.⁵⁵ According to the applicant, tissue markers described by HCPCS code A4648 are passive mechanical localization devices. The applicant explained that such tissue markers are generally made of gold or other radiographically opaque substances (usually metal). Per the applicant, compared to the SmartClip™, such tissue markers do not provide margin or 3D information, do not update in real-time, and require advanced radiographic capability (computed tomography, fluoroscopy, ultrasound) in order to be detected and localized. According to the applicant, these markers are only useful because they are visible either

⁵³ HCPCS code 91112 is not a current or previous pass-through payment category. According to the applicant, the Smartpill™ is an ingestible pill that is tracked using a wearable device for short term pH and pressure testing for intestinal tract diagnostics. By contrast, the applicant noted that the SmartClip™ is permanently implantable within soft tissue to direct a surgeon for the purposes of removal of a lesion and margin.

⁵⁴ Medicare Claims Processing Manual, Ch. 4, section 60.4.2.

⁵⁵ Change Request 8338, June 7, 2013. The Medicare Claims Processing Manual further defines the devices encompassed by HCPCS code C1879 as material that is placed in subcutaneous or parenchymal tissue (may also include bone) for radiopaque identification of an anatomic site and adds that these markers are distinct from topical skin markers, which are positioned on the surface of the skin to serve as anatomical landmarks. Medicare Claims Processing Manual, Ch. 4, section 60.4.3.

radiographically or to the naked eye. The applicant identified two types of gold fiducial markers – generic gold fiducial marker (IZI Medical) and generic soft tissue gold marker (Civco). The applicant explained that the SmartClip™ is an advanced interstitial implant that substantially improves upon both generic gold fiducial markers and common hook-wire localization systems. According to the applicant, passive mechanical tissue markers such as gold fiducial markers and hook-wire systems are related devices created for roughly the same purpose as the SmartClip™, but neither can be considered an adequate comparator due to the highly advanced technology embedded in the SmartClip™. In contrast to both generic gold fiducial markers and hook-wire systems, the applicant asserted that the SmartClip™ contains an ASIC which is activated at a specific frequency and provides location information regarding both the SmartClip™ and the surgical margins to the operating physician in near real-time. The applicant claimed that it is not aware of any other device that has this functionality. The applicant added that this data is calibrated relative to the tip of an electrocautery device or other operating instrument and is displayed in 3D so that the surgeon has an objective method of obtaining a negative concentric margin. According to the applicant, this is particularly useful for posterior and deep margins for which passive localization devices provide no information. The applicant asserted that it does not believe that the SmartClip™ is described by HCPCS code A4648.

We are inviting public comments on whether the SmartClip™ meets the device category criterion.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices

Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation.

The applicant claimed that the use of the SmartClip™ results in substantial clinical improvement over existing technologies by, (1) reducing positive margin and re-excision rates, thereby decreasing the rate of subsequent therapeutic interventions; (2) reducing the rate of device-related complications, including surgical site infections and wire migration and transection; and (3) improving the surgical approach (surgeons are not tethered to the best radiological approach, and the incision can be placed in the ideal location resulting in better oncological results, less complex path to the lesion, and better visualization during surgery). The applicant provided articles and case reports for the purpose of addressing the substantial clinical improvement criterion.

In support of the claim that use of the SmartClip™ reduces positive margin and re-excision rates, the applicant submitted an abstract of a study performed to assess the impact of electromagnetic seed localization (ESL) using the EnVisio™ Navigation System and SmartClip™ compared to wire localization (WL) on operative times, specimen volumes, margin positivity, and margin re-excision rates.⁵⁶ Between August 2020 and August 2021, 97 patients underwent excisional biopsy (n=20), or lumpectomy with (n=53) or without (n=24) sentinel lymph node biopsy (SLNB) using ESL guidance at a single institution by 5 surgeons. The study authors matched these patients, one-to-one, with WL patients undergoing surgery between 2006 and 2021 based on surgeon, procedure type with stratification for those having and not having nodal procedures, and pathologic stage or benign pathology. When greater than one WL match was found, selection was randomized. The authors compared continuous variables (operative times, specimen volumes, excess volume excised) between patients undergoing ESL and WL using Wilcoxon rank sums tests. The authors compared categorical variables (positive margin

⁵⁶ Jordan R, Rivera-Sanchez L, Kelley K, O'Brien M, et al. The Impact of an Electromagnetic Seed Localization Device as Versus Wire Localization on Breast Conserving Surgery: A Matched Pair Analysis. Abstract presented at: 23rd Annual Meeting of The American Society of Breast Surgeons; April 6-10, 2022.
https://www.breastsurgeons.org/meeting/2022/docs/2022_Official_Proceedings_ASBrS.pdf

rates, re-excision rates) using Fisher's exact tests. Median operative time for ESL versus WL for lumpectomy with SLNB was 66 versus 69 minutes ($p=0.76$) and without SLNB was 40 versus 34.5 minutes ($p=0.17$). Median specimen volume was 55cm^3 with WL versus 36cm^3 with ESL ($p=0.0012$). In those with measurable tumor volume, excess tissue excised was larger with WL compared to ESL (median= 73.2cm^3 versus 52.5cm^3 , $p=0.017$). Main segment margins were positive in 18 of 97 (19 percent) WL patients compared to 10 of 97 (10 percent) ESL patients ($p=0.17$). In the WL group, 13 of 97 (13 percent) had margin re-excision at a separate procedure, compared to 6 of 97 (6 percent) in the ESL group, ($p=0.15$). The authors concluded that ESL is superior to WL because it provided more accurate localization, evidenced by smaller specimen volume with less excess tissue excised, despite similar operative times. In addition, the authors reported that, although not statistically significant, ESL resulted in lower positive margin rates and lower margin re-excision rates compared to WL. The authors further noted that ESL allows for preoperative localization, eliminating same day operative delays, and single tool, 3D localization. The authors concluded that further studies comparing ESL to other non-wire localization techniques are required to refine which localization technology is most advantageous in breast conservation surgery.

The applicant provided a second article consisting of a clinical paper from the Moffitt Cancer Center that, per the applicant, is pending publication.⁵⁷ The paper presented three cases from the Moffitt Cancer Center, including radiographic and other images, employing three different methods of breast mass localization: (1) SmartClip™, (2) SAVI SCOUT® radar reflector localizer, and (3) traditional wire localizer. The authors stated that the purpose of the paper was to educate the audience about the technological advances regarding breast mass localization and to discuss the advantages and disadvantages of SmartClip™ localizers, SAVI SCOUT® localizers, and wire localizers.

⁵⁷ Ibanez J, Wotherspoon T, Mooney B, Advances in Image Guided Breast Mass Localization Techniques (undated). Submitted by the applicant with its application on February 28, 2022.

The authors first discussed wire localization, stating that wire localization involves image-guided insertion of a guidewire into a targeted mass and that the use of multiple wires allows for bracketing of multiple lesions or a large lesion. The authors asserted that, while effective in localization, this procedure has drawbacks such as wire breakage, patient discomfort, wire migration while moving or transporting the patient, and the need to surgically remove the wire the same day that it is placed due to this risk of migration.

The authors also discussed radar reflector localizers such as SAVI SCOUT®, which are small devices that can be placed into a targeted mass at any time prior to lumpectomy. The authors explained that once a surgeon gains a general idea of the mass' location by looking at the post localizer placement mammogram, this localizer is “hunted” for intraoperatively using a special handheld device which provides auditory feedback, but does not provide location details until it is found via the auditory feedback. The authors cited a retrospective study at the Moffitt Cancer Center which, according to the authors, indicated that localization using SAVI SCOUT® was successful for 125 out of 129 patients (97 percent, 95 percent Confidence Interval 92-99 percent) and showed that in comparison to wire localization, SAVI SCOUT® provides improved patient comfort and eliminates the need to perform the surgery on the same day as the localization procedure.⁵⁸

Finally, the authors discussed localization using the SmartClip™. The authors noted that the SmartClip™ is the first device to provide three-plane localization information. The authors stated that a monitor displays the approximate position of the SmartClip™ allowing everyone in the operating room to assist with the localization of the SmartClip™ and provide knowledge of its location prior to and throughout the surgery. They further noted that the SmartClip™ localizer can be visualized on a small screen mounted on the electrocautery tool which, similar to the monitor, depicts the direction and depth to the SmartClip™. According to the authors, this

⁵⁸ Falcon S, Weinfurter RJ, Mooney B, Niell BL. SAVI SCOUT® localization of breast lesions as a practical alternative to wires: Outcomes and suggestions for trouble-shooting. *Clin Imaging*. 2018 Nov-Dec;52:280-286. doi: 10.1016/j.clinimag.2018.07.008. Epub 2018 Jul 24. PMID: 30193186.

provides real-time visual feedback to surgeons as the electrocautery tool moves and allows them to find the clip without having to look up at the operating room monitor. The authors asserted that the three-axis visualization eliminated the need to search for the clip since the location is always known, and that the availability of the SmartClip™ in three colors with different signals eases differentiation between localizers and allows for bracketing of masses.

The authors concluded that wire localization has drawbacks such as wire breakage, patient discomfort, high chances of migration, and narrow placement timeframes, which have been mitigated over the past decade by various soft tissue localizers such as SAVI SCOUT® (radar reflector localizer). The authors concluded that the SmartClip™, which they refer to as a new localizer, may potentially resolve other difficulties encountered with the soft tissue localizers that they currently use. Finally, the authors noted that a clinical study is currently underway at the Moffitt Cancer Center to evaluate the advantages of using the SmartClip™ in clinical practice.

In addition, the applicant provided three physician case reports (two by surgeons and one by radiologists), each describing the use of the SmartClip™ in a single patient (62, 59, and 53-year-old female breast cancer patients). Each case report described the patient's history, diagnostic tools utilized, pre-operative, peri-operative, and/or post-operative course, pathology results, as well as the physician's perceptions of the SmartClip™ or EnVisio™ Navigation System. In the first surgical case report,⁵⁹ the surgeon noted that the foot pedal activation of the EnVisio™ Navigation System allowed toggling between two SmartClip™ devices, allowing complete dissection around the periphery of the mass to obtain a precise margin. The surgeon asserted that with one marker, there would have been a higher risk of a positive margin. In the second surgical case report,⁶⁰ the surgeon similarly noted that the EnVisio™ Navigation System helped her to map out and be more precise in her incision location and lumpectomy dissection.

⁵⁹ Kruper, Laura, Bracketing Lobulated Breast Lesion with the EnVisio™ Navigation System using Differentiated SmartClip.

⁶⁰ Henkel, Dana, Single SmartClip Case.

Finally, in the radiologists' case report,⁶¹ ultrasound guided SmartClip™ localization was ordered for definitive surgical management. The radiologists noted the visibility of the SmartClip™ relative to the coil clip, mass, and surrounding tissue, as well as the ease of the deployment.

The applicant also submitted several articles in general support of its application, which we summarize as follows. An article from the Mayo Clinic concluded that intraoperative pathologic assessment with frozen-section margin evaluation of all neoplastic breast specimens allows for immediate re-excision of positive or close margins during the initial operation and results in an extremely low reoperation rate of <2 percent.⁶² Another article addressed the relationship between post-surgery infection and breast cancer recurrence and concluded that there is association between surgical site infection and adverse cancer outcomes, but the cellular link between them remains elusive.⁶³ Furthermore, a study from the Mayo Clinic concluded there was no reduction in the surgical site infection rate among patients who received postoperative antibiotic prophylaxis after breast surgery.⁶⁴ In addition, a study from Washington University School of Medicine concluded that surgical site infection (SSI) after breast cancer surgical procedures was more common than expected for clean surgery and more common than SSI after non-cancer-related breast surgical procedures.⁶⁵ A review article from the Department of Radiation Oncology, Case Western Reserve University and University Hospitals in Cleveland surmised that precision medicine holds the promise of truly personalized treatment which provides every individual breast cancer patient with the most appropriate diagnostics and targeted therapies based on the specific cancer's genetic profile as determined by a panel of gene

⁶¹ Lee, Marie C., Mooney, Blaise, Right Breast IDC/DCIS.

⁶² Racz JM, Glasgow AE, Keeney GL, Degnim AC, Hieken TJ, Jakub JW, Cheville JC, Habermann EB, Boughey JC. Intraoperative Pathologic Margin Analysis and Re-Excision to Minimize Reoperation for Patients Undergoing Breast-Conserving Surgery. *Ann Surg Oncol.* 2020 Dec;27(13):5303-5311. doi: 10.1245/s10434-020-08785-z. Epub 2020 Jul 4. PMID: 32623609.

⁶³ O'Connor RÍ, Kiely PA, Dunne CP. The relationship between post-surgery infection and breast cancer recurrence. *J Hosp Infect.* 2020 Nov;106(3):522-535. doi: 10.1016/j.jhin.2020.08.004. Epub 2020 Aug 13. PMID: 32800825.

⁶⁴ Throckmorton AD, Boughey JC, Boostrom SY, Holifield AC, Stobbs MM, Hoskin T, Baddour LM, Degnim AC. Postoperative prophylactic antibiotics and surgical site infection rates in breast surgery patients. *Ann Surg Oncol.* 2009 Sep;16(9):2464-9. doi: 10.1245/s10434-009-0542-1. Epub 2009 Jun 9. PMID: 19506959.

⁶⁵ Olsen MA, Chu-Ongsakul S, Brandt KE, Dietz JR, Mayfield J, Fraser VJ. Hospital-associated costs due to surgical site infection after breast surgery. *Arch Surg.* 2008 Jan;143(1):53-60; discussion 61. doi: 10.1001/archsurg.2007.11. PMID: 18209153.

assays and other predictive and prognostic tests.⁶⁶ An abstract on the subject of prognostic factors for surgical margin status and recurrence in partial nephrectomy concluded that (i) surgical margin positivity after partial nephrectomy is not significantly associated with tumor characteristics and anatomical scoring systems, (ii) surgical indication for partial nephrectomy has a direct influence on positive surgical margin rates, and (iii) tumor size and stage after partial nephrectomy are valuable parameters in evaluating the recurrence risk.⁶⁷ Lastly, a study examining the significance of resection margin in hepatectomy for hepatocellular carcinoma concluded that the width of the resection margin did not influence the postoperative recurrence rates after hepatectomy for hepatocellular carcinoma.⁶⁸

Based on the evidence submitted with the application, we note the following concerns. The first study appears to be unpublished, and it is not clear whether it has been submitted for publication in a peer-reviewed journal. In addition, the study involved a sample of 97 patients from one institution and appears to be written as a feasibility study for a potentially larger randomized control trial. Notably, the authors of this study stated that further studies are required to compare ESL to other non-wire localization techniques to refine which localization technology is most advantageous in breast conservation surgery. Furthermore, the authors did not report the sex or age of the study participants. Additionally, the authors reported that the differences in positive margin and re-excision rates between ESL and WL groups were not statistically significant. We also note a potential concern regarding practice/selection effects bias inherent in the methodology presented.

⁶⁶ Eleanor E. R. Harris, "Precision Medicine for Breast Cancer: The Paths to Truly Individualized Diagnosis and Treatment", *International Journal of Breast Cancer*, vol. 2018, Article ID 4809183, 8 pages, 2018. <https://doi.org/10.1155/2018/4809183>.

⁶⁷ Demirel HC, Çakmak S, Yavuzsan AH, Yeşildal C, Türk S, Dalkılıç A, Kireççi SL, Tokuç E, Horasanlı K. Prognostic factors for surgical margin status and recurrence in partial nephrectomy. *Int J Clin Pract*. 2020 Oct;74(10):e13587. doi: 10.1111/ijcp.13587. Epub 2020 Jul 14. PMID: 32558097.

⁶⁸ Poon, R. T., Fan, S. T., Ng, I. O., & Wong, J. (2000). Significance of resection margin in hepatectomy for hepatocellular carcinoma: A critical reappraisal. *Annals of surgery*, 231(4), 544–551. <https://doi.org/10.1097/00000658-200004000-00014>.

The second article is an undated,⁶⁹ unpublished descriptive clinical paper comparing three different breast mass localization techniques in three cases from one institution. The applicant stated that this paper is pending publication, but provided no further details regarding the status of the paper. The paper did not systematically compare the techniques across any measurable variables, noting that a clinical study was underway at the institution to evaluate the SmartClip™ in clinical practice. Similarly, we note that the physician case reports were solely descriptive in nature – they presented each physician’s anecdotal experience using the EnVisio™ Navigation System and/or SmartClip™. Furthermore, the applicant provided several additional articles that, while informative, did not involve the SmartClip™ and do not appear to directly support the applicant’s claim of substantial clinical improvement. We would welcome additional information and evidence from larger, multi-center studies that provide comparative outcomes between the SmartClip™ and existing technologies.

We further note that none of the articles and case reports provide conclusive evidence that the use of the SmartClip™ reduces surgical site infection rates or the risk of tissue marker migration, as claimed by the applicant. In addition, the articles and case reports provided by the applicant described the use of the subject devices only in breast cancer surgery cases. As reported by the applicant, the SmartClip™ is utilized frequently in breast conserving surgery, lymph nodes, and head/neck cancers. We would welcome additional evidence of substantial clinical improvement in cases related to non-breast cancer related procedures. We are inviting public comments on whether the SmartClip™ meets the substantial clinical improvement criterion.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant

⁶⁹ Although the applicant reported the date of the study as January 2021, the copy of the study provided by the applicant was not dated.

provided the following information in support of the cost significance requirements. We note that the applicant stated that up to three SmartClips™ can be implanted in a patient to mark and provide continuous location of multiple targets, however, the applicant did not provide data on the average number of SmartClips™ used per patient. The applicant stated that the SmartClip™ is used in procedures described by the HCPCS codes in Table 35.

TABLE 35: HCPCS CODES REPORTED WITH THE SMARTCLIP™

HCPCS Code	Long Descriptor	SI	APC
19081	Biopsy, breast, with placement of breast localization device(s) (eg, clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; first lesion, including stereotactic guidance	J1	5072
19281	Placement of breast localization device(s) (eg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including mammographic guidance	Q1	5071
19283	Placement of breast localization device(s) (eg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including stereotactic guidance	Q1	5071
19825	**	**	**
49180	Biopsy, abdominal or retroperitoneal mass, percutaneous needle	J1	5072
38505	Biopsy or excision of lymph node(s); by needle, superficial (eg, cervical, inguinal, axillary)	J1	5072
A4648	N/A	N/A	N/A
91112	Gastrointestinal transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report	T	5301

** HCPCS code 19825 does not exist and thus we could not evaluate it as part of the cost criterion.

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. For our calculations

related to the SmartClip™, we used APC 5071—Level 1 Excision/ Biopsy/ Incision and Drainage, which had a CY 2021 payment rate of \$621.97 at the time the application was received. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). HCPCS code 19281 had a device offset amount of \$219.87 at the time the application was received. According to the applicant, the cost of the SmartClip™ is \$375.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of \$375 for the SmartClip™ is 60.3 percent of the applicable APC payment amount for the service related to the category of devices of \$621.97 ($(\$375/\$621.97) \times 100 = 60.3$ percent). Therefore, we believe the SmartClip™ meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of \$375 for the SmartClip™ is 170.6 percent of the cost of the device-related portion of the APC payment amount for the related service of \$219.87 ($(\$375/\$219.87) \times 100 = 170.6$ percent). Therefore, we believe that the SmartClip™ meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of \$375 for the SmartClip™ and the portion of the APC payment amount for the device of \$219.87 is

24.9 percent of the APC payment amount for the related service of \$621.97 ($((\$375-\$219.87)/\$621.97) \times 100 = 24.9$ percent). Therefore, we believe that the SmartClip™ meets the third cost significance requirement.

We are inviting public comment on whether the SmartClip™ meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(4) Evoke® Spinal Cord Stimulation (SCS) System

Saluda Medical Inc. submitted an application for a new device category for transitional pass-through payment status for the Evoke® Spinal Cord Stimulation (SCS) System for CY 2023. The applicant described the Evoke® SCS System as a rechargeable, upgradeable, implantable spinal cord stimulation system that provides closed-loop stimulation controlled by measured evoked compound action potentials (ECAPs). According to the applicant, the Evoke® SCS System is used in the treatment of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain and leg pain. Per the applicant, the Evoke® SCS System's rechargeable battery is indicated for use up to 10 years.

The applicant explained that SCS consists of applying an electrical stimulus to the spinal cord which causes the activated fibers (e.g., Aβ-fibers) to generate action potentials. Aβ-fibers are the low-threshold sensory fibers in the dorsal column that contribute to inhibition of pain signals in the dorsal horn. The action potentials summed together form the ECAP. Therefore, the applicant asserted that ECAPs are a direct measure of spinal cord fiber activation that generates pain inhibition for an individual.

According to the applicant, the Evoke® SCS System is comprised of 5 implanted and 12 external components. The applicant identified the following five implanted components of the Evoke® SCS System: (1) Closed Loop Stimulator (CLS): a rechargeable, 25-channel implantable pulse generator (IPG or stimulator) which generates an electrical stimulus and measures and

records the nerve fibers' response to stimulus (i.e., ECAPs). Although named "Closed Loop Stimulator," the applicant indicated that this stimulator delivers both open-loop and closed-loop stimulation modes; (2) Percutaneous Leads: Electrical current is delivered to the spinal cord via the electrodes on leads that are introduced into the epidural space through an epidural needle and connected to the stimulator. Per the applicant, ECAPs are measured using two non-stimulating contacts of the leads; (3) Lead Extension: Used to provide additional length if needed to connect the implanted lead to the CLS or external closed-loop stimulator (eCLS); (4) Suture Anchors and Active Anchors: Used to anchor the lead to the supraspinous ligament or deep fascia; and (5) CLS Port Plug: Used to block unused ports in the CLS header. Additionally, the applicant stated there are 12 external components of the Evoke[®] SCS System (e.g., surgical accessories, clinical interface, clinical system transceiver, pocket console and chargers).

According to the applicant, the Evoke[®] SCS System is the first and only SCS system that provides closed-loop stimulation. In closed-loop stimulation, the system automatically measures the impact of the prior stimulation signal on the nerve and adjusts the next stimulation signal accordingly to maintain the prescribed physiologic response. Per the applicant, this closed feedback loop provides consistency in the stimulation received by the nerve as opposed to the stimulation emitted from the device.

The applicant stated that the Evoke[®] SCS System measures ECAPs and adjusts the next stimulation accordingly as follows: (1) the Evoke[®] SCS System measures ECAPs following every stimulation pulse from two electrodes not involved in stimulation; (2) the recorded ECAP signal is sampled by the stimulator and provides a measurement of the ECAP amplitude; and (3) the Evoke[®] SCS System utilizes the ECAPs in a feedback mechanism to adjust the next stimulation pulse, thereby delivering closed-loop stimulation. The feedback mechanism minimizes the difference between the measured ECAP amplitude and the ECAP amplitude target by automatically adjusting the stimulation current for every stimulus. In doing so, the applicant asserted it maintains spinal cord activation near the target level. According to the applicant, this

addresses the challenge all currently available SCS systems face regarding the ever-changing distance between the electrode and spinal cord that results in variable spinal cord activation, and thus, less effective therapy. Per the applicant, although there have been numerous technological advances in SCS therapy over the years, every other SCS system on the market provides open-loop stimulation, where parameters are set by the physician and the patient can only modulate those parameters within defined limits based upon how they feel. However, physiological functions such as breathing, heartbeat and posture changes alter the distance between the spinal cord target fibers and SCS electrodes. Therefore, the applicant asserted that the number of nerve fibers activated by open-loop stimulation continually changes, resulting in inconsistent therapy delivery (i.e., under- or over-stimulation) and that ECAP-controlled closed-loop therapy produces a significantly higher degree of spinal cord activation that is maintained within the therapeutic window which drives superior outcomes. The applicant asserted that a consistent neural response at the prescribed level may only be achieved with a closed-loop system that continually adjusts on every stimulation pulse.

With respect to the newness criterion at § 419.66(b)(1), on February 28, 2022, the Evoke[®] SCS System received PMA approval from FDA as an aid in the management of chronic intractable pain of the trunk and/or limbs including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain and leg pain. The applicant submitted its application for consideration as a new device category for transitional pass-through payment status for the Evoke[®] SCS System on March 1, 2022, which is within 3 years of the date of the initial FDA marketing authorization. We are inviting public comment on whether the Evoke[®] SCS System meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the use of the Evoke[®] SCS System is integral to the service of treating and managing chronic intractable pain of the trunk and/or limbs using spinal cord stimulation. The applicant noted that some components of the system (described previously) are implanted in a patient and are in

contact with human tissue. The applicant indicated that all components of the system are used for one patient only. We note that the external components of the Evoke[®] SCS System (referenced previously) are not implanted in a patient and do not come in contact with human tissue as required by § 419.66(b)(3). The applicant did not indicate whether the Evoke[®] SCS System meets the device eligibility requirements of § 419.66(b)(4) in regard to whether it is an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, or whether it is a supply or material furnished incident to a service. We note that some of the external components (e.g., surgical accessories, clinical interface, clinical system transceiver, pocket console and chargers) noted previously may be considered capital as specified under § 419.66(b)(4). We are inviting public comments on whether the Evoke[®] SCS System meets the eligibility criteria at § 419.66(b).

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion for establishing a device category, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. The applicant asserted that none of the existing categories appropriately describe the Evoke[®] SCS System. The applicant provided a list of current and prior device categories for pass-through payments for other spinal cord stimulation systems (described in Table 36) and explained why each category does not describe the Evoke[®] SCS System. In summary, the applicant asserted that the existing codes do not adequately describe the Evoke[®] SCS System because the existing codes apply to devices that: provide stimulation to organs other than the spinal cord (e.g., heart, transvenous sensing and stimulation, baroreceptors in the carotid artery), only provide open-loop stimulation, and are non-rechargeable. According to the applicant, the Evoke[®] SCS System is a rechargeable, closed-loop neurostimulator that provides stimulation to spinal nerves. Upon review, it does not appear that there are any existing

pass-through payment categories that might apply to the Evoke® SCS System. We are inviting public comment on whether Evoke® SCS System meets the device category criterion.

TABLE 36: POTENTIAL EXISTING/PREVIOUS DEVICE CATEGORIES

HCPCS Code	Device Category	Why Category Does Not Include Evoke® SCS System
C1824	Generator, cardiac contractility modulation (implantable)	This category describes a generator that provides cardiac contractility modulation to the right ventricle in the heart. The Evoke SCS System does not provide stimulation to the heart. Therefore, this category does not describe the Evoke SCS System.
C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system	This category describes neurostimulators that are rechargeable, and provide high frequency stimulation. All devices described by this category provide open loop stimulation, and this category does not describe neurostimulators that provide closed-loop stimulation. As the Evoke SCS System is a closed-loop neurostimulator, this category does not appropriately describe this technology.
C1767	Generator, neurostimulator (implantable), non-rechargeable	This category describes neurostimulators that are non-rechargeable and provide non-high-frequency stimulation. All devices described by this category provide open loop stimulation, and this category does not describe neurostimulators that provide closed-loop stimulation. As the Evoke SCS System is a rechargeable, closed-loop neurostimulator, this category does not appropriately describe this technology.
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system	This category describes neurostimulators that are rechargeable, and provide non-high-frequency stimulation. All devices described by this category provide open loop stimulation, and this category does not describe neurostimulators that provide closed-loop stimulation. As the Evoke SCS System is a closed-loop neurostimulator, this category does not appropriately describe this technology.
C1823	Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads	This category describes neurostimulators that provide transvenous sensing and stimulation. The Evoke SCS System delivers stimulation to spinal nerves (via closed loop stimulation) and does not provide transvenous sensing and stimulation. Therefore, this category does not describe the Evoke SCS System.

HCPCS Code	Device Category	Why Category Does Not Include Evoke® SCS System
C1825	Generator, neurostimulator (implantable), non-rechargeable with carotid sinus baroreceptor stimulation lead(s)	This category describes a generator that provides stimulation to baroreceptors in the carotid artery. The Evoke SCS System does not stimulate baroreceptors in the carotid artery and therefore this category does not describe this technology

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of FDA’s Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The applicant asserted that the Evoke® SCS System represents a substantial clinical improvement over existing technology because its use of closed-loop stimulation provides greater improvements in key clinical outcomes over the open-loop stimulation that is currently used in existing technologies. Specifically, the applicant stated that the closed-loop stimulation of the Evoke® SCS System provides: (1) a greater responder rate in overall chronic leg and back pain with no increase in baseline pain medications in comparison to Open-Loop SCS at 3 and 12 months; (2) greater percentage change in back pain measured by Visual Analog Scale at 3 and 12 months; (3) greater incidence of 50 percent reduction in back pain at 3 and 12 months; (4) greater incidence of 50 percent reduction in leg pain at 12 months; (5) greater incidence of 80 percent reduction in overall back and leg pain at 12 months; (6) consistently greater visual improvement in remaining secondary endpoint measures at 3 and 12 months; (7) a balanced safety profile between treatment groups; (8) a greater percentage of time in the therapeutic window for closed-loop patients compared to open-loop patients; (9)

maintenance of clinical improvements in pain response and pain reduction at 24 months post-implantation; and (10) the results for the pivotal trial treatment group have been replicated in another multi-center trial with 12-month follow-up. With respect to this criterion, the applicant submitted three articles that supported these ten claims regarding the impact of the Evoke® SCS System on the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain and leg pain.

The first article provided by the applicant in support of claims 1-8 was for the Evoke pivotal clinical study, a prospective, multicenter, double-blind, randomized controlled trial designed to compare the use of ECAP-controlled, closed-loop stimulation to open-loop stimulation for the treatment of back and leg pain.⁷⁰ The trial was done at 13 specialist clinics, academic centers, and hospitals in the USA. Patients with chronic, intractable pain of the back and legs (Visual Analog Scale [VAS] pain score ≥ 60 mm; Oswestry Disability Index [ODI] score 41–80) who were refractory to conservative therapy, on stable pain medications, had no previous experience with spinal cord stimulation, and were appropriate candidates for a spinal cord stimulation trial were screened. Eligible patients were randomly assigned (1:1) to receive ECAP-controlled closed-loop spinal cord stimulation (investigational group) or fixed-output, open-loop spinal cord stimulation (control group). A total of 134 subjects (67 subjects in each treatment group) were randomized. Patients, investigators, and site staff were masked to the treatment assignment. The primary outcome was the proportion of patients with a reduction of 50 percent or more in overall back and leg pain with no increase in pain medications. Non-inferiority ($\delta=10$ percent) followed by superiority were tested in the intention-to-treat population at 3 months (primary analysis) and 12 months (additional prespecified analysis) after the permanent implant. This study is registered with ClinicalTrials.gov, NCT02924129.

⁷⁰ Mekhail N, Levy RM, Deer TR, Kapural L, Li S, Amirdelfan K, Hunter CW, Rosen SM, Costandi SJ, Falowski SM, Burgher AH, Pope JE, Gilmore CA, Qureshi FA, Staats PS, Scowcroft J, Carlson J, Kim CK, Yang MI, Stauss T, Poree L; Evoke Study Group. Long-term safety and efficacy of closed-loop spinal cord stimulation to treat chronic back and leg pain (Evoke): a double-blind, randomised, controlled trial. *Lancet Neurol.* 2020 Feb;19(2):123-134. Epub 2019 Dec 20.

The applicant stated that standard primary and secondary endpoints for spinal cord stimulation studies were employed. For the primary study endpoint, the study authors defined a responder as having at least 50 percent improvement in pain relative to baseline. The applicant explained that this level of improvement was found to represent a substantial improvement per the IMMPACT recommendations.⁷¹ The study authors stated that the secondary outcomes assessed the percentage change from baseline in leg pain VAS and back pain VAS, prevalence of high responders (≥ 80 percent reduction) for overall back and leg pain, and prevalence of responders (≥ 50 percent reduction) for back pain VAS, all at 3 months and 12 months. A host of additional efficacy measures including quality of life, pain medication use, and functional outcomes were also employed as per the IMMPACT recommendations.⁷² An independent, blinded Clinical Events Committee (CEC) reviewed and adjudicated all adverse events occurring in the study. The authors reported that, between February 21, 2017 and February 20, 2018, 134 patients were enrolled and randomly assigned (67 to each treatment group), and that there were no between-group differences in the diagnoses, previous treatments, or other baseline demographics or characteristics.⁷³ The intention-to-treat analysis comprised 125 patients at 3 months (62 in the closed-loop group and 63 in the open-loop group) and 118 patients at 12 months (59 in the closed-loop group and 59 in the open-loop group).

Regarding the applicant's first claim that the closed-loop stimulation of the Evoke[®] SCS System provides a greater responder rate in overall chronic leg and back pain with no increase in baseline pain medications in comparison to open-loop stimulation at 3 and 12 months, the applicant cited findings from this study that a greater responder rate in overall chronic leg and

⁷¹ Dworkin RH, Turk DC, Wyrwich KW, Beaton D, Cleeland CS, Farrar JT, Haythornthwaite JA, Jensen MP, Kerns RD, Ader DN, Brandenburg N, Burke LB, Cella D, Chandler J, Cowan P, Dimitrova R, Dionne R, Hertz S, Jadad AR, Katz NP, Kehlet H, Kramer LD, Manning DC, McCormick C, McDermott MP, McQuay HJ, Patel S, Porter L, Quessy S, Rappaport BA, Rauschkolb C, Revicki DA, Rothman M, Schmader KE, Stacey BR, Stauffer JW, von Stein T, White RE, Witter J, Zavisic S. Interpreting the clinical importance of treatment outcomes in chronic pain clinical trials: IMMPACT recommendations. *J Pain*. 2008 Feb;9(2):105-21. Epub 2007 Dec 11.

⁷² Dworkin RH, Turk DC, Farrar JT, Haythornthwaite JA, Jensen MP, Katz NP, et al. Core outcome measures for chronic pain clinical trials: IMMPACT recommendations. *Pain*. 2005 Jan;113(1-2):9-19.

⁷³ Mekhail N, Levy RM, Deer TR, Kapural L, Li S, Amirdelfan K, Hunter CW, Rosen SM, Costandi SJ, Falowski SM, Burgher AH, Pope JE, Gilmore CA, Qureshi FA, Staats PS, Scowcroft J, Carlson J, Kim CK, Yang MI, Stauss T, Poree L; Evoke Study Group. Long-term safety and efficacy of closed-loop spinal cord stimulation to treat chronic back and leg pain (Evoke): a double-blind, randomised, controlled trial. *Lancet Neurol*. 2020 Feb;19(2):123-134. Epub 2019 Dec 20.

back pain with no increase in baseline pain medications was achieved in a greater proportion of patients in the closed-loop group than in the open-loop group at 3 months (82.3 percent vs 60.3 percent; difference 21.9 percent; $p=0.0052$) and at 12 months (83.1 percent vs 61.0 percent; difference 22.0 percent; $p=0.0060$). Non-inferiority was met at 3 months ($p<0.0001$) and 12 months ($p<0.0001$), as was superiority (3 months, $p=0.0052$; 12 months, $p=0.0060$).

Regarding the applicant's second claim that the closed-loop stimulation of the Evoke[®] SCS System provides a greater percentage change in back pain measured by Visual Analog Scale at 3 and 12 months, the applicant cited Evoke pivotal clinical study findings that at 3 months, 72.1 percent (sd=29.4 percent) of patients in the closed-loop group reported improvements in back pain compared to 57.5 percent in the open-loop group (superiority $p=0.015$). At 12 months, 69.4 percent (sd=30.6 percent) of patients in the closed-loop group reported improvements in back pain compared versus 54 percent (sd=39.5 percent) in the open-loop group (superiority $p=0.020$).

Regarding the applicant's third claim that the closed-loop stimulation of the Evoke[®] SCS System provides a greater incidence of 50 percent reduction in back pain at 3 and 12 months, the applicant cited Evoke pivotal clinical study findings that at 3 months, 81 percent of patients in the closed-loop group reported a 50% or greater reduction in back pain compared to 57 percent in the open-loop group (superiority $p=0.0033$). Per the study, at 12 months, 80 percent of patients in the closed-loop group achieved this outcome compared to 58 percent in the open-loop group (superiority $p=0.0079$).

Regarding the applicant's fourth claim that the closed-loop stimulation of the Evoke[®] SCS System provides a greater incidence of 50 percent reduction in leg pain at 12 months, the applicant cited Evoke pivotal clinical study findings that at 12 months, this outcome was met by a statistically significantly greater proportion of patients in the closed-loop group (83 percent) than in the open-loop group (61 percent) (superiority $p=0.0060$).

Regarding the applicant's fifth claim that the closed-loop stimulation of the Evoke[®] SCS System provides a greater incidence of 80 percent reduction in overall back and leg pain at 12 months, the applicant cited findings from the Evoke pivotal clinical study that at 12 months, this outcome was met by a statistically significantly greater proportion of patients in the closed-loop group (56 percent) than in the open-loop group (37 percent) (superiority $p=0.039$).

Regarding the applicant's sixth claim that the closed-loop stimulation of the Evoke[®] SCS System provides consistently greater visual improvement in remaining secondary endpoint measures at 3 and 12 months, the applicant noted the Evoke pivotal clinical study authors observations that significant and clinically important improvements in both treatment groups in all other patient-reported outcomes at 3 and 12 months, including Oswestry Disability Index (ODI), Profile of Mood states Total Mood Disturbance (POMS-TMD), Pittsburgh Sleep Quality Index (PSQI), EQ-5D-5L Index Score, and Short Form Health Survey (SF-12) Physical Component Summary (PCS) and Mental Component Summary (MCS).⁷⁴ The authors noted that, in general, the improvement was greater in the closed-loop group than in the open-loop group at both 3 and 12 months, with significant differences seen in POMS-TMD scores ($p=0.0037$ at 3 months; $p=0.0003$ at 12 months) and SF-12 MCS scores ($p=0.0005$ at 3 months) and ($p=0.0004$ at 12 months).

Regarding the applicant's seventh claim that closed-loop patients spent a greater percentage of time in the therapeutic window compared to open-loop patients, the applicant cited Evoke pivotal clinical study findings that at 3 months, the time in therapeutic window averaged 91.1 percent in the closed-loop group compared to 59.5 percent in the open-loop group (superiority $p<0.0001$). At 12 months, the time in therapeutic window averaged 95.2 percent in the closed-loop group versus 47.9 percent in the open-loop group (superiority $p<0.0001$).

Regarding the applicant's eighth claim that the closed-loop stimulation of the Evoke[®] SCS System provides a balanced safety profile between treatment groups, the applicant cited

⁷⁴ Ibid.

findings from the Evoke pivotal clinical study that the type, nature, and severity of adverse events were similar between treatment groups. The authors reported that, among the findings, 34 study-related adverse events occurred in 24 patients (23 adverse events in the closed-loop group, in 13 [19 percent] patients [95 percent CI 10.8–30.9], and 11 adverse events in the open-loop group in 11 [16 percent] patients [95 percent CI 8.5–27.5]). The authors stated that the most frequently reported study-related adverse events in both treatment groups were lead migration (nine [7 percent] patients), implantable pulse generator pocket pain (five [4 percent]), and muscle spasm or cramp (three [2 percent]).

The second article provided by the applicant reported the results from the Evoke pivotal clinical study at 24 months follow-up.⁷⁵ The applicant submitted this article in support of its claim that the Evoke® SCS System maintained statistical superiority in pain response and pain reduction at 24 months. The authors reported that 50 closed-loop patients and 42 open-loop patients completed 24-month follow-up. The authors noted that the double-blind was maintained for the full study duration. The authors reported that, at 24 months, a significantly greater proportion of closed-loop patients (79.1 percent) were responders (≥ 50 percent reduction in overall back and leg pain) than open-loop patients (53.7 percent) ($p=0.001$). Similarly, the authors reported that there was a significantly greater proportion of high responders, (≥ 80 percent reduction in overall pain) in the closed-loop group (46.3 percent) compared to the open-loop (29.9 percent) ($p=0.047$). The authors report that reduction in overall back and leg pain was significantly greater for closed-loop patients (mean score=26.4; point decrease=55.6) than open-loop patients (mean score=38.3; point decrease=43.9) (mean score difference=-11.9, $p=0.02$).

⁷⁵ Mekhail N, Levy RM, Deer TR, Kapural L, Li S, Amirdelfan K, Hunter CW, Rosen SM, Costandi SJ, Falowski SM, Burgher AH, Pope JE, Gilmore CA, Qureshi FA, Staats PS, Scowcroft J, McJunkin T, Carlson J, Kim CK, Yang MI, Stauss T, Pilitsis J, Poree L; Evoke Study Group, Brounstein D, Gilbert S, Gmel GE, Gorman R, Gould I, Hanson E, Karantonis DM, Khurram A, Leitner A, Mugan D, Obradovic M, Ouyang Z, Parker J, Single P, Soliday N. Durability of Clinical and Quality-of-Life Outcomes of Closed-Loop Spinal Cord Stimulation for Chronic Back and Leg Pain: A Secondary Analysis of the Evoke Randomized Clinical Trial. *JAMA Neurol.* 2022 Jan 8; e214998. doi: 10.1001/jamaneurol.2021.4998. Epub ahead of print. PMID: 34998276; PMCID: PMC8742908.

The third article provided by the applicant reported the results from the Avalon study, a prospective, multicenter, single-arm study of the Evoke[®] SCS System.⁷⁶ While not a standalone claim of substantial clinical improvement, the applicant submitted this article in support of its other SCI claims to demonstrate that the relevant findings from the Evoke pivotal trial had been replicated in another multi-center trial with 12-month follow up. The authors of the third article stated that the purpose of the Avalon study was to determine whether maintaining stable SC activation has a beneficial outcome on pain relief by demonstrating the safety and performance of the new closed-loop Evoke[®] SCS System. The protocol was publicly registered at Australian New Zealand Clinical Trials Registry. Patients were consented at five clinical sites in Australia from August 2015 to April 2017 for the Avalon study.⁷⁷ A total of 70 patients underwent a trial procedure. Of these, 68 (97.1 percent) completed the end-of-trial assessments and were evaluable. Of the 68 patients, 56 (82.4 percent) with assessment data had a reduction of 40 percent or more from baseline in their overall VAS rating; of those, 48 patients elected to proceed with a permanent implant. Two additional patients with a segmental VAS reduction of 40 percent or more proceeded with a permanent implant as per the protocol inclusion criterion. Fifty subjects were implanted (71.4 percent of those trialed).

The authors of the Avalon study article stated that baseline assessments in this study included ratings of pain on the Visual Analog Scale (100-mm VAS), impact of pain (Brief Pain Inventory [BPI]), function (Oswestry Disability Index [ODI]), sleep (Pittsburgh Sleep Quality Index [PSQI]), quality of life (EuroQol instrument [EQ-5D-5L]), and medication usage. Adverse events were assessed throughout the study. Along with raw scores and percent change from baseline, VAS data were also analyzed as responders (≥ 50 percent pain relief) and high responders (≥ 80 percent pain relief). According to the article, the outcomes data were analyzed

⁷⁶ Russo M, Brooker C, Cousins MJ, Taylor N, Boesel T, Sullivan R, Holford L, Hanson E, Gmel GE, Shariati NH, Poree L, Parker J. Sustained Long-Term Outcomes with Closed-Loop Spinal Cord Stimulation: 12-Month Results of the Prospective, Multicenter, Open-Label Avalon Study. *Neurosurgery*. 2020 Feb 5. [Epub ahead of print]

⁷⁷ Ibid.

using paired t-tests with an alpha of 0.05 and results were presented for the permanently implanted patients only.

The authors reported favorable results for pain relief outcomes.⁷⁸ At 12 months, 76.9 percent of patients were back pain responders (≥ 50 percent pain reduction), with 56.4 percent being classified as high responders (≥ 80 percent pain reduction). The proportion of patients who were leg pain responders at 12 months was 79.3 percent (≥ 50 percent pain reduction), and 58.6 percent of patients were high responders (≥ 80 percent pain reduction). The proportion of patients who were overall pain responders at 12 months was 81.4 percent (≥ 50 percent pain reduction), and 53.5 percent of patients were high responders (≥ 80 percent pain reduction).

Based upon the evidence presented by the applicant, we have the following concerns regarding whether the Evoke[®] SCS System meets the substantial clinical improvement criterion. First, we note that none of the sources provided by the applicant compared the Evoke[®] SCS System to other currently available technologies, such as other open-loop spinal cord stimulation products. However, in the Evoke pivotal clinical study, all patients were implanted with the Evoke[®] SCS System, with the difference between study groups being that the implanted devices in the treatment group were set to closed-loop stimulation as opposed to open-loop stimulation. While the study is testing outcomes between different aspects of the Evoke[®] SCS System itself, additional information comparing the Evoke[®] SCS System to existing spinal cord stimulators would help inform our assessment of substantial clinical improvement. While the applicant asserted that the Evoke[®] SCS System is the only available closed-loop SCS, we invite public comment on whether there are other existing technologies which may be appropriate comparators.

Second, we have concern regarding the patient sample size cited in the studies. Furthermore, the applicant cites the Avalon study in Australia to support its claim that the pivotal

⁷⁸ Ibid.

clinical study's results were replicated internationally. We request additional details about how these two studies' results would be generalizable to the U.S. population.

We are inviting public comments on whether the Evoke[®] SCS System meets the substantial clinical improvement criterion.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d).

Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the Evoke[®] SCS System would be reported with HCPCS code 63685. To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. For our calculations, we used APC 5465 Level 5 Neurostimulator and Related Procedures, which had a CY 2021 payment rate of \$29,444.52 at the time the application was received. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). HCPCS code 63685 had a device offset amount of \$24,209.28 at the time the application was received. According to the applicant, the estimated average cost of the Evoke[®] SCS system is \$37,000. We note that the device cost provided by the applicant encompasses the entire Evoke[®] SCS. However, as previously discussed, the external components of the Evoke[®] SCS (the surgical accessories, clinical interface, clinical system transceiver, pocket console and chargers) may not meet the criteria required under § 419.66(b)(3), i.e., the external components are not implantable and/or do not come in contact with human tissue. Therefore, the cost of only the eligible internal components may be less than the cost of the entire system and could affect the calculations in the following formulas.

Section 419.66(d)(1), the first cost significance requirement provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of \$37,000 for the Evoke[®] SCS System is 125.7 percent of the applicable APC payment amount for the service related to the category of devices of \$29,444.52 ($(\$37,000/\$29,444.52) \times 100 = 125.7$ percent). Therefore, we believe the Evoke[®] SCS System meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of \$37,000 for the Evoke[®] SCS System is 152.8 percent of the cost of the device-related portion of the APC payment amount for the related service of \$24,209.28 ($(\$37,000/\$24,209.28) \times 100 = 152.8$ percent). Therefore, we believe that the Evoke[®] SCS System meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of \$37,000 for the Evoke[®] SCS System and the portion of the APC payment amount for the device of \$24,209.28 is 43.4 percent of the APC payment amount for the related service of \$29,444.52 ($((\$37,000-\$24,209.28)/\$29,444.52) \times 100 = 43.4$ percent). Therefore, we believe that the Evoke[®] SCS System meets the third cost significance requirement.

We have a concern regarding whether the Evoke[®] SCS System meets all of the cost criteria. Specifically, as previously discussed, the external components of the Evoke[®] SCS may

not meet the criteria required under § 419.66(b)(3), i.e., the external components (the surgical accessories, clinical interface, clinical system transceiver, pocket console and chargers) are not implantable and/or do not come in contact with human tissue. Therefore, the cost of only the eligible internal components may be less than the cost of the entire system. If the cost of the internal components is sufficiently lower than that of the whole system, then that could affect the calculations for the cost requirements to the point where some of those requirements are not met. We are inviting public comment on whether the Evoke® SCS System meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(5) Pathfinder® Endoscope Overtube

Neptune Medical submitted an application for a new device category for transitional pass-through payment status for the Pathfinder® Endoscope Overtube (the Pathfinder®) for CY 2023. According to the applicant, the Pathfinder® is a flexible, single use, overtube with stiffening capabilities that is used to manage endoscope looping and improve tip control of the endoscope. Per the applicant, the Pathfinder® is indicated for use with an endoscope to facilitate intubation and treatment in the gastrointestinal (GI) tract in adult patients (22 years of age and older). The applicant indicated that the flexible overtube may be connected to vacuum for rigidization. Specifically, the handle includes a vacuum line which is connected to free space within the device that is completely contained, forming the vacuumable volume. The applicant stated that the handle rotator has two positions: the first connects the vacuumable volume within the device to atmosphere (vent) to stay in the flexible position, and the second position connects the vacuumable volume to a source of vacuum to transition to the rigid condition. When transitioned to the rigid condition, the device maintains its shape at the time of rigidization, allowing the endoscope to advance or withdraw relative to the overtube with minimal disturbance to the surrounding anatomy. According to the applicant, when transitioned to the

flexible condition, the device can move relative to the patient anatomy and endoscope for navigation through the GI tract.

With respect to the newness criterion at § 419.66(b)(1), on August 20, 2019, the applicant received 510(k) clearance from FDA for the Pathfinder® as a Class II device to be used with an endoscope to facilitate intubation, change of endoscopes, and treatment in the GI tract in adult patients (22 years of age and older). We received the application for a new device category for transitional pass-through payment status for the Pathfinder® on November 30, 2021, which is within 3 years of the date of the initial FDA marketing authorization. We are inviting public comments on whether the Pathfinder® meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the Pathfinder® is integral to the service provided, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted. The applicant also claimed that the Pathfinder® meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. We are inviting public comments on whether the Pathfinder® meets the eligibility criteria at § 419.66(b).

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996.

The applicant provided a list of all established device categories used presently or previously for pass-through payment that describe related or similar products. The applicant indicated that while there are other endoscope overtubes available, there are no known competitive devices on the market that can be toggled from being flexible to rigid instantly to prevent/manage endoscope looping. The applicant stated that the Pathfinder® is unique in its

ability to do this using a proprietary technology called Dynamic Rigidization™. For each established device category, the applicant provided explanations as to why that category does not encompass the nominated device: (1) C1748 (endoscope, single-use (i.e., disposable) upper GI, imaging/illumination device (insertable)), and (2) C1749 (endoscope, retrograde imaging/illumination colonoscope device (implantable)). According to the applicant, the Pathfinder® is not an imaging/illumination device. Furthermore, the Pathfinder® can be used in upper and lower GI endoscope/colonoscope procedures to eliminate device looping. As such, the applicant does not believe that the existing codes encompass the Pathfinder®.

Upon review, it does not appear that there are any existing pass-through payment categories that might apply to the Pathfinder®. We are inviting public comment on whether the Pathfinder® meets the device category criterion.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The applicant states that the Pathfinder® represents a substantial clinical improvement over existing technologies. With respect to this criterion, the applicant submitted studies that examined the impact of the Pathfinder® when used with an endoscope to facilitate intubation, change of endoscopes, and treatment in the GI tract in adult patients (22 years of age and older).

Broadly, the applicant asserts the following areas in which the Pathfinder® would provide a substantial clinical improvement: (1) minimize scope looping and complications from scope

looping, (2) reduce endoscopist's workload during endoscope procedure, (3) provide endoscope tip stabilization, (4) enable endoscopic procedure in patients with altered anatomy, (5) enable crossing of anastomosis, and (6) enable antegrade and retrograde enteroscopy, in use for the prevention of endoscope looping. The applicant provided eleven articles specifically for the purpose of addressing the substantial clinical improvement criterion.

In support of the claim that the Pathfinder[®] minimizes scope looping and complications from scope looping, the applicant submitted a prospective single center study performed over 11 months by two endoscopists in the United States.⁷⁹ The study population consisted of 15 patients with a mean age of 63.2 years (range 23-88 y) and mean Body Mass Index (BMI) of 28.6 kg/m² (range 16.8 – 46.2 kg/m²). Two of the patients were placed under moderate sedation, 11 had monitored anesthesia care (MAC) and two patients underwent general anesthesia. The mean (standard deviation) Boston bowel preparation scale (BBPS) score was 6.9 (1.8), with a range of 6-9. Indications for colonoscopy included surveillance (n=9), evaluation of Crohn's disease (n=2), polyp resection (n=3), and other diagnostic purpose (n=1). To complete the colonoscopy, the endoscopist resorted to the use of the rigidizing overtube in all 15 cases due to several technical difficulties encountered. The authors noted the reasons for overtube use included a history of difficult colonoscopy due to a long, tortuous colon (n=9), inability to reach the cecum (n=3) or the ileocolonic anastomosis (n=1), inability to completely visualize the ileocecal valve (n=1), and inability to advance colonoscope due to looping and bradycardia (n=1). The authors noted that colonoscopy was successfully completed in all 15 cases using the overtube device.

The applicant provided a second article to support the claims that the Pathfinder[®] minimizes scope looping and complications from scope looping, provides endoscope tip stabilization, enables endoscopic procedure in patients with altered anatomy, and enables

⁷⁹ Park, N., Abadir, A., Chahine, A., Eng, D., Ji, S., Nguyen, P., Bernal, E., Simoni, R. & Samarasena, J. B. (2021). A Novel Dynamic Rigidizing Overtube Significantly Eases Difficult Colonoscopy. *Techniques and Innovations in Gastrointestinal Endoscopy*.

crossing of anastomosis. The article consists of an abstract from a set of case studies performed in two tertiary care endoscopy centers in the United States.⁸⁰ From May 2019 to February 2020, 29 patients were consecutively treated using the Pathfinder[®]. The patients were predominantly male with a median age of 66 years old. Of the 29 patients scoped, one patient received an upper endoscopy, 24 received colonoscopy, and four received enteroscopy. The types of anesthesia provided to these patients included: general anesthesia for four patients, MAC for 15 patients, moderate monitored anesthesia for nine patients, and no sedation for one patient. The indication for using the Pathfinder[®] was incomplete colonoscopy in 12 patients, enhancing insertion depth not feasible with standard endoscopy in six patients and endoscope stabilization during endoscopic resection in 11 patients, according to the study researchers.

The applicant submitted a third article,⁸¹ which described a 57-year-old male being evaluated for high-risk colon cancer screening due to positive Cologuard, to support the claim that the Pathfinder[®] minimizes scope looping and complications from scope looping. The applicant pointed out that an initial colonoscopy on the patient was incomplete due to severely redundant colon, i.e., an abnormally long colon with additional loops or twists. The patient was referred to the study's tertiary care center for a repeat attempt with advanced endoscopy. A second colonoscopy was attempted, but significant looping occurred due to the large redundant colon, resulting in another incomplete colonoscopy. Maneuvers like changing to supine position, scope torsion, abdominal pressure, use of colonic overtube and Naviaid balloon-assisted colonoscopy were all unsuccessful, according to the study researchers. The study's tertiary care center performed a virtual computerized tomography (CT) colonography, which revealed a polyp in the ascending colon and markedly redundant colon. This prompted a third colonoscopy, which again showed significant looping of the colon and the colonoscopy was incomplete, per the study

⁸⁰ Wei, M. T., Hwang, J. H., Watson, R. R., Park, W., & Friedland, S. (2021). Novel rigidizing overtube for colonoscope stabilization and loop prevention (with video). *Gastrointestinal Endoscopy*, 93(3), 740-749.

⁸¹ Patel, P., & Khara, H. (2021). S2537 Successful Polypectomy with Novel Rigidizing Overtube with Failed Previous Colonoscopies. *Official journal of the American College of Gastroenterology | ACG*, 116, S1070.

researchers. After three unsuccessful conventional colonoscopies, the patient had a colonoscopy with the rigidizing Pathfinder[®]. According to the study, the exam was technically challenging, requiring more than two hours of procedure time, but was successfully completed.

A fourth article⁸² was provided by the applicant to support the claim that the Pathfinder[®] minimizes scope looping and complications from scope looping. This article presented a challenging case of a laterally spreading tumor at the hepatic flexure in a difficult and unstable colon, which was removed by endoscopic submucosal dissection (ESD) using a novel injectable needle-type knife and with the assistance of the dynamic rigidizing Pathfinder[®]. The case involved a 66-year-old man with coronary artery disease, hypertension, hyperlipidemia, and diabetes mellitus who was found on screening colonoscopy to have a 35-mm laterally spreading tumor at the hepatic flexure (Paris IIa/Is). An attempted endoscopic mucosal resection was unsuccessful because of non-lifting of the lesion during submucosal injection; therefore, the patient was referred for ESD. Given the length of the procedure and the patient's medical comorbidities, the procedure was performed under general endotracheal anesthesia. A pediatric colonoscope (PCF-H190DL, Olympus America, Center Valley, Pa, USA) with a tapered-tip distal attachment cap (ST hood, Fujifilm Medical Systems, Stamford, Conn, USA) was initially advanced to the cecum and withdrawn to the hepatic flexure. However, because of a highly redundant left colon segment, the colonoscope could not be reduced into a stable, short position for ESD despite manual abdominal counterpressure and position changes. In the looped, long position at the hepatic flexure, the endoscope was noted to be in an extremely unstable position and therefore unsafe for ESD. The dynamic rigidizing Pathfinder[®] overtube allowed for a stable endoscopic position in a challenging ESD at the hepatic flexure per the applicant.

⁸² Coronel, M., Coronel, E., Romero, L., & Phillip, S. G. (2021). Combination of a dynamic rigidizing overtube and a novel injectable needle-type knife to facilitate colorectal endoscopic submucosal dissection. *VideoGIE*, 6(7), 297-300.

The applicant provided a fifth article⁸³ to support the claims that the Pathfinder[®] minimizes scope looping and complications from scope looping and enables endoscopic procedure in patients with altered anatomy. This article presents two cases demonstrating the utility of the rigidizing overtube in accomplishing altered-anatomy endoscopic retrograde cholangiopancreatography (ERCP), which consisted of the overtube reducing looping and allowing for increased distances that shorter scopes (such as a side-viewing duodenoscope) are unable to achieve. According to the authors, success varies with intubation and cannulation in ERCP for patients with surgically altered anatomy. The authors concluded that this is particularly important in managing gastric loops and tight angulation at surgical anastomoses, including jejunojejunostomy anastomosis.

A sixth article⁸⁴ the applicant provided in support of its claim that the Pathfinder[®] minimizes scope looping and complications from scope looping was a single site case study of a 64-year-old man with a history of C5 spinal cord injury due to a diving accident who presented for screening colonoscopy. A pediatric colonoscope was used initially, but given significant looping, the colonoscope could only reach the transverse colon. The colonoscope was withdrawn, and the Pathfinder[®] overtube was used. The applicant pointed out that with assistance from the overtube, the colonoscope reached the cecum easily in eight minutes. A 1-cm sessile polyp was found in the ascending colon and was removed by cold snare. An additional 3 polyps measuring less than one centimeter were identified and removed by cold snare, and the procedure was terminated. Three of the polyps (including the 1-cm polyp) were determined to be tubular adenoma. The fourth polyp was identified as a hyperplastic polyp.

⁸³ Wei, M. T., Friedland, S., Watson, R. R., & Hwang, J. H. (2020). Use of a rigidizing overtube for altered-anatomy ERCP. *VideoGIE*, 5(12), 664-666.

⁸⁴ Wei, M. T., Hwang, J. H., Watson, R., & Friedland, S. (2020). Use of a rigidizing overtube to complete an incomplete colonoscopy. *VideoGIE*, 5(11), 583-585.

A seventh article⁸⁵ provided in support of the same claim described a 72-year-old male who presented for surveillance colonoscopy. The colonoscope was successfully advanced to the ascending colon, however, it could not be advanced further due to loop formation. Every time the scope was advanced through the loop the patient became bradycardic to a heart rate in the 40s, presumably from a vasovagal reflex. Repeated attempts at advancing the colonoscope were unsuccessful due to looping and bradycardia despite abdominal counterpressure and position change. The scope was removed and the rigidizing overtube device was introduced onto the scope. The scope with overtube was advanced to the ascending colon in its flexible state. Once in the ascending colon, the overtube was rigidized which allowed for easy cecal intubation and successful completion of colonoscopy without any loop formation, as the applicant noted.

An eighth article⁸⁶ provided by the applicant in support of the claim of a reduction in the endoscopist's workload during the endoscope procedure was a prospective, single center study performed over 6 months. Difficult colonoscopy subjects were categorized based on looping that prevented reaching the cecum despite position change and abdominal counter pressure (LOOP group), or poor stabilization to perform therapeutic polypectomy (UNSTABLE group). Parameters assessed included successful/failed salvage of the procedure, and the in-procedure National Aeronautics and Space Administration (NASA) Task Load Index (TLX)⁸⁷ before and after use of the rigidizing overtube. The TLX raw and weighted scores were compared for each type of demand (mental, physical, effort, temporal, performance, and frustration). Over the study period, there were 14 difficult colonoscopy procedures: eight in the LOOP group and six in the UNSTABLE group. In the LOOP group, all eight cases were salvaged, and cecum was reached

⁸⁵ Abadir, A., Chehade, N. E. H., Park, N., Eng, D., & Samarasena, J. (2020). S1876 Use of a Novel Dynamic Rigidizing Overtube in Difficult Colonoscopy Due to Looping. *Official journal of the American College of Gastroenterology* | ACG, 115, S971.

⁸⁶ Abadir, A., Park, N., Eng, D. J., Chehade, N. E. H., & Samarasena, J. (2020, October). A Novel Dynamic Rigidizing Overtube Significantly Eases Difficult Colonoscopy. *American Journal of Gastroenterology* (Vol. 115, pp. S83-S83). Two Commerce Square, 2001 Market St., Philadelphia, PA 19103 USA: Lippincott Williams & Wilkins.

⁸⁷ TLX @ NASA Ames - Home

after the Pathfinder® overtube was used. The TLX weighted score decreased from 81.1 to 26.0 after use (P,0.01). In the UNSTABLE group, complete polypectomy was successful in all cases using the Pathfinder® overtube. The TLX weighted score decreased from 79.7 to 40.4 after use (P,0.01). In all procedures, the TLX raw scores for each type of demand was reduced. The applicant pointed out that all six dimensions of the NASA-TLX: mental demand, physical demand, temporal demand, effort, performance, and frustration level were significantly improved after using the overtube. All score changes were statistically significant per the study researchers. The overall weighted NASA-TLX score decreased from an average of 80.30 to 30.85 after using the device as the applicant identified. In this case series, the study showed that the novel rigidizing overtube decreases burden on the endoscopist by reducing the workload perceived during the procedure, according to the study researchers.

In support of the claims about a reduction in the endoscopist's workload during the endoscope procedure and enabling antegrade and retrograde enteroscopy, the applicant submitted a ninth article,⁸⁸ which was a retrospective single site study over a 6-month period, in which two endoscopists performed retrograde and antegrade enteroscopies using a rigidizing overtube. Retrograde enteroscopy was performed via the anus by advancing the overtube to the cecum in its flexible state with the pediatric colonoscope, reducing the scope and overtube construct, and then rigidizing at the cecum. Following rigidization, the scope was pushed through the ileocecal valve and advanced maximally. Antegrade enteroscopy was performed by inserting the dynamic rigidizing overtube with use of the pediatric colonoscope via the mouth, rigidizing in the duodenum or jejunum, and then advancing maximally. A total of nine retrograde and three antegrade enteroscopies were performed. On retrograde enteroscopy, small bowel depth ranged from 15 cm to 70 cm from the ileocecal valve, with a mean of 48.9 cm. There were no

⁸⁸ Park, N., Abadir, A., Eng, D., Chegade, N. E. H., & Samarasena, J. (2020). S0972 Enteroscopy Enabled Using a Novel Dynamic Rigidizing Overtube: An Initial Single Center Experience. Official journal of the American College of Gastroenterology| ACG, 115, S495-S496.

complications associated with use of the dynamic rigidizing overtube, both in antegrade and retrograde evaluation. Of note, in one case, initial attempts at retrograde double-balloon enteroscopy failed due to looping and unfavorable angulation of the ileocecal valve. Multiple attempts at intubation including manual abdominal pressure and position changes were unsuccessful. The dynamic rigidizing overtube was then introduced with successful intubation and subsequent exploration of the ileum. Overall, both endoscopists reported significant ease of enteroscopy compared to traditional double-balloon methods, with lower perceived mental and physical demand, according to the study.

The applicant supplied a tenth article⁸⁹ that described a single site case study in support of its claim that the Pathfinder[®] offers improved endoscope tip stabilization. The study described using a Pathfinder[®] overtube 85-centimeters long to accommodate a pediatric colonoscope, upper endoscope, or enteroscope. The study presented two contrasting cases demonstrating the rigidizing overtube in colorectal endoscopic submucosal dissection (ESD). In the first case, a 70-year-old man was referred for ESD of a 20mm polyp in the ascending colon. Following submucosal injection, partial circumferential incision was performed. According to the authors, the case was challenging due to poor tip control in the right colon. The cut made by the knife was irregular and of higher risk, requiring more time to make the incision. The polyp was identified as a tubular adenoma with clear margins. In the second case, a 44-year-old man presented following recent diagnosis of ulcerative colitis. Prior colonoscopy demonstrated a large 3-5cm tubulovillous adenoma in the ascending colon. A cap and rigidizing overtube was used during the colonoscopy. During ESD, there was severe fibrosis in the distal portion of the lesion. The rigidizing overtube offered improved scope stability and tip control, facilitating precise dissection of the narrowed fibrotic submucosal space, per the applicant. The lesion was removed en bloc and was identified as a tubular adenoma with low grade dysplasia, with clear margins.

⁸⁹ Wei, M. T., Hwang, J. H., & Friedland, S. (2021). S2027 Use of the Rigidizing Overtube in Assisting Endoscopic Submucosal Dissection Among Patients with Ulcerative Colitis. *Official journal of the American College of Gastroenterology* | ACG, 116, S880.

In support of its claim that the Pathfinder[®] enables endoscopic procedure in patients with altered anatomy, the applicant submitted an eleventh article⁹⁰ describing a single site case study about a 42-year-old female with a history of iatrogenic bile duct transection during cholecystectomy who underwent Roux-en-Y Hepaticojejunostomy (HJ). Her course was complicated by HJ stricture requiring double-balloon assisted enteroscopy with ERCP to place a fully covered metal stent. After three months the stent was removed, but restructing occurred six months later and she developed left-sided intrahepatic stone disease. Double-balloon assisted enteroscopy to reach the anastomosis became more difficult. As a result, multiple antegrade procedures via endoscopic ultrasound (EUS) guided hepaticogastrostomy with lithotripsy were used to treat accessible intrahepatic stones, but several more stones remained. To facilitate further endoscopic procedures, a shortcut was made using laparoscopic revision to create a new entero-enterostomy from the proximal jejunum to the pancreaticobiliary (PB) limb. Repeat enteroscopy with a slim colonoscope failed to enter the PB limb despite multiple attempts due to difficult angulation and looping in the stomach. A rigidizing overtube placed over the colonoscope allowed the scope to advance to the HJ without looping in the stomach and provided improved control up the ascending PB limb. The colonoscope then deployed a stone extraction balloon to remove biliary duct stones. According to the article, this case demonstrates the use of a rigidizing overtube to prevent looping and assist with complex stone removal via ERCP in altered anatomy.

While the applicant has provided articles that describe the clinical use of the Pathfinder[®] in challenging procedures, the majority of the articles are clinical case series which do not necessarily allow for a clear comparison with common mediation strategies.⁹¹ Additionally, the

⁹⁰ Abadir, A., Park, N., Eng, D. J., Lee, D., & Samarasena, J. (2020). S2330 Altered Anatomy ERCP Using a Novel Dynamic Rigidizing Overtube. Official journal of the American College of Gastroenterology| ACG, 115, S1235.

⁹¹ For example, repeat colonoscopy with a different sedation method, different instruments and/or different physicians, double-contrast barium enema, CT colonography, overtube-assisted colonoscopy, double-balloon enteroscopy and colonoscopy, single-balloon enteroscopy, integrated inflated balloon, spiral overtubes, colon capsule endoscopy, C-scan Cap imaging system, and/or robotic colonoscopes). See Franco, D. L., Leighton, J. A., &

applicant identified specific procedures for using the Pathfinder® when the physician needs to control looping or enhance endoscope tip control to successfully complete the procedure.⁹² The applicant has not provided studies comparing the efficacy of the Pathfinder® with other rigidization devices although the applicant has noted the existence of such devices. Furthermore, all the clinical case study series presented in the applicant's articles were based on small sample sizes. There are other devices available which can help assist the Endoscopist in procedures which are difficult to perform. We have a concern that there has not been adequate comparison to other available devices used for similar indication. We ask for public comment on whether Pathfinder shows superiority over the existing devices/ methods used in cases of endoscope looping and abnormal anatomy.

Finally, with respect to the two articles^{93,94} presented to support the substantial clinical improvement claim in reducing endoscopists' workload during endoscopy procedures; in both articles, the authorships were identical for the same study center and time frame, and there were only two participating endoscopists. Therefore, it may be difficult to make comparisons due to the lack of a diverse pool of endoscopists. Additionally, we note that factors such as center and clinical staff characteristics in both studies are difficult to control, and it is difficult to determine if observed differences resulted from the Pathfinder® or from confounding variables.

Furthermore, we note there is potential for some level of selection bias if providers are allowed to select the manner and order in which patients are treated, and thereby potentially influence outcomes seen in these studies.

Gurudu, S. R. (2017). Approach to Incomplete Colonoscopy: New Techniques and Technologies. *Gastroenterology & hepatology*, 13(8), 476-483.

⁹²According to the applicant, the Pathfinder® is used for the following procedures: difficult colonoscopy, endoscopic mucosal resection (EMR)/endoscopic submucosal dissection (ESD) of colon, EMR/ESD of the stomach, enteroscopy (both antegrade and retrograde), altered anatomy ERCP, and endoscopic ultrasonography in the colon.

⁹³ Abadir, A., Park, N., Eng, D. J., Chehade, N. E. H., & Samarasena, J. (2020, October). A Novel Dynamic Rigidizing Overtube Significantly Eases Difficult Colonoscopy. *American Journal of Gastroenterology* (Vol. 115, pp. S83-S83). Two Commerce Square, 2001 Market St., Philadelphia, PA 19103 USA: Lippincott Williams & Wilkins.

⁹⁴ Park, N., Abadir, A., Eng, D., Chehade, N. E. H., & Samarasena, J. (2020). S0972 Enteroscopy Enabled Using a Novel Dynamic Rigidizing Overtube: An Initial Single Center Experience. *Official journal of the American College of Gastroenterology| ACG*, 115, S495-S496.

We invite public comments on whether the Pathfinder[®] meets the substantial clinical improvement criterion.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d).

Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the Pathfinder[®] would be reported with the HCPCS codes listed in Table 37.

TABLE 37: HCPCS CODES REPORTED WITH THE PATHFINDER[®]

HCPCS Code	Long Descriptor	Status Indicator	APC
Colonoscopy			
45378	Colonoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)	T	5311
45379	Colonoscopy, flexible; with removal of foreign body(s)	T	5312
45380	Colonoscopy, flexible; with biopsy, single or multiple	T	5312
45381	Colonoscopy, flexible; with directed submucosal injection(s), any substance	T	5312
45382	Colonoscopy, flexible; with control of bleeding, any method	T	5312
45384	Colonoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps	T	5312
45385	Colonoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique	T	5312
45390	Colonoscopy, flexible; with endoscopic mucosal resection	J1	5313
45391	Colonoscopy, flexible; with endoscopic ultrasound examination limited to the rectum, sigmoid, descending, transverse, or ascending colon and cecum, and adjacent structures	T	5312
45392	Colonoscopy, flexible; with transendoscopic ultrasound guided intramural or transmural fine needle aspiration/biopsy(s), includes endoscopic ultrasound examination limited to the rectum, sigmoid, descending, transverse, or ascending colon and cecum, and adjacent structures	T	5312
Endoscopy, Small Intestine (Enteroscopy antegrade and retrograde)			
44360	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum, not including ileum; diagnostic, including collection of specimen(s) by	J1	5302

	brushing or washing, when performed (separate procedure)		
44361	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum, not including ileum; with biopsy, single or multiple	J1	5302
44363	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum, not including ileum; with removal of foreign body(s)	J1	5302
44364	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum, not including ileum; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique	J1	5302
44365	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum, not including ileum; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps or bipolar cautery	J1	5302
44366	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum, not including ileum; with control of bleeding (eg, injection, bipolar cautery, unipolar cautery, laser, heater probe, stapler, plasma coagulator)	J1	5302
44369	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum, not including ileum; with ablation of tumor(s), polyp(s), or other lesion(s) not amenable to removal by hot biopsy forceps, bipolar cautery or snare technique	J1	5302
44370	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum, not including ileum; with transendoscopic stent placement (includes predilation)	J1	5331
44372	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum, not including ileum; with placement of percutaneous jejunostomy tube	J1	5302
44373	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum, not including ileum; with conversion of percutaneous gastrostomy tube to percutaneous jejunostomy tube	J1	5302
44376	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum, including ileum; diagnostic, with or without collection of specimen(s) by brushing or washing (separate procedure)	J1	5302
44377	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum, including ileum; with biopsy, single or multiple	J1	5302
44378	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum, including ileum; with control of bleeding (eg, injection, bipolar cautery, unipolar cautery, laser, heater probe, stapler, plasma coagulator)	J1	5302
44379	Small intestinal endoscopy, enteroscopy beyond	J1	5331

	second portion of duodenum, including ileum; with transendoscopic stent placement (includes predilation)		
Endoscopic Retrograde Cholangiopancreatography (ERCP)			
43260	Endoscopic retrograde cholangiopancreatography (ercp); diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)	J1	5303
43261	Endoscopic retrograde cholangiopancreatography (ercp); with biopsy, single or multiple	J1	5303
43262	Endoscopic retrograde cholangiopancreatography (ercp); with sphincterotomy/papillotomy	J1	5303
43263	Endoscopic retrograde cholangiopancreatography (ercp); with pressure measurement of sphincter of oddi	J1	5303
43264	Endoscopic retrograde cholangiopancreatography (ercp); with removal of calculi/debris from biliary/pancreatic duct(s)	J1	5303
43265	Endoscopic retrograde cholangiopancreatography (ercp); with destruction of calculi, any method (eg, mechanical, electrohydraulic, lithotripsy)	J1	5331
43274	Endoscopic retrograde cholangiopancreatography (ercp); with placement of endoscopic stent into biliary or pancreatic duct, including pre- and post-dilation and guide wire passage, when performed, including sphincterotomy, when performed, each stent	J1	5331
43275	Endoscopic retrograde cholangiopancreatography (ercp); with removal of foreign body(s) or stent(s) from biliary/pancreatic duct(s)	J1	5303
43276	Endoscopic retrograde cholangiopancreatography (ercp); with removal and exchange of stent(s), biliary or pancreatic duct, including pre- and post-dilation and guide wire passage, when performed, including sphincterotomy, when performed, each stent exchanged	J1	5331
43277	Endoscopic retrograde cholangiopancreatography (ercp); with trans-endoscopic balloon dilation of biliary/pancreatic duct(s) or of ampulla (sphincteroplasty), including sphincterotomy, when performed, each duct	J1	5303
43278	Endoscopic retrograde cholangiopancreatography (ercp); with ablation of tumor(s), polyp(s), or other lesion(s), including pre- and post-dilation and guide wire passage, when performed	J1	5303

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final

rule (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. For our calculations, we used APC 5311—Level 1 Lower GI Procedures / Diagnostic colonoscopy, which had a CY 2021 payment rate of \$793.65 at the time the application was received. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). HCPCS code 45378 had a device offset amount of \$1.27 at the time the application was received.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of \$695 for Pathfinder® Endoscope Overtube is 87.57 percent of the applicable APC payment amount for the service related to the category of devices of \$793.65 ($(\$695/\$793.65) \times 100 = 87.57$ percent). Therefore, we believe the Pathfinder® Endoscope Overtube meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of \$695 for the Pathfinder® Endoscope Overtube is 54,724.41 percent of the cost of the device-related portion of the APC payment amount for the related service of \$1.27 ($(\$695/\$1.27) \times 100 = 54,724.41$ percent). Therefore, we believe that the Pathfinder® Endoscope Overtube meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of

the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of \$695 for the Pathfinder® Endoscope Overtube and the portion of the APC payment amount for the device of \$1.27 is 87.41 percent of the APC payment amount for the related service of \$793.65 $((\$695 - \$1.27)/\$793.65) \times 100 = 87.41$ percent). Therefore, we believe that the Pathfinder® meets the third cost significance requirement.

We are inviting public comment on whether the Pathfinder® Endoscope Overtube meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(6) The Uretero1

STERIS submitted an application for a new device category for transitional pass-through payment status for the Uretero1 for CY 2023. The applicant states that the Uretero1 is a sterile, single-use, disposable digital flexible ureteroscope. According to the applicant, the Uretero1™ Ureteroscope System consists of the following components: (1) the Uretero1, a sterile, single-use flexible disposable digital flexible ureteroscope; and (2) Vision 1, a touch screen camera control unit, with a high-resolution HD imaging system.

Per the applicant, the single use ureteroscope, the Uretero1, consists of: (1) handle, to hold scope (made of polycarbonate, and has no patient contact); (2) articulation lever, an angulated distal tip (polycarbonate 10 percent glass filled, and has no patient contact); (3) handle button, a button to take pictures, video, and zoom live image (made of silicone, and has no patient contact); (4) accessory Port with port cover to prevent backflow during procedures, pass instruments (Makrolon 2458, Indirect/limited patient contact); (5) irrigation port, for fluid access (Makrolon 2458, which has indirect or limited patient contact); (6) flexible shaft (Pebax, made of polyurethane, and has patient contact); (7) shaft strain relief (Santoprene and has contact with limited mucosal membrane); (8) bending/articulation section, which bends the tip of the scope to move the camera (made of stainless-steel compression coils and pull cables and has no patient

contact); (9) distal tip, (ABS, and has patient contact); (10) instrument channel (PFA and has indirect and limited patient contact); (11) illumination fiber (made of polymethyl methacrylate (PMMA)/fluorinated polymer and has no patient contact); and (12) the camera (consists of glass and has limited mucosal membrane patient contact), and connector cables and plugs, which have no patient contact.

The Uretero1™ Ureteroscopy System is a software-controlled system that consists of the Vision1 (Touch Screen Camera Control Unit (CCU)) and the sterile, single-use high-resolution flexible ureteroscope. Per the applicant, the Uretero1 is inserted to find the causes of problems in the ureters or kidney, and to visualize organs, cavities, and canals in the urinary tract by transurethral or percutaneous access routes. The applicant notes the Uretero1 can also be used with endoscopic accessories to perform various diagnostic and therapeutic procedures in the urinary tract, such as kidney stone management (treatment of nephrolithiasis).

According to the applicant, the device is used by urologists during ureteroscopy, a minimally invasive outpatient procedure typically performed under general anesthesia. The applicant states that once the patient is prepped and anesthesia takes effect, the urologist inserts a rigid scope into the urethra, to the bladder to examine the ureteral orifices. Per the applicant, a guidewire is placed through the instrument channel of the rigid scope via fluoroscopic guidance through the orifice, up to the ureter. The applicant states that the rigid scope is removed, and the access sheath is advanced over the inserted guidewire. According to the applicant, the position of the access sheath is confirmed via fluoroscopy, and the obturator is removed from the access sheath, as well as the guidewire (if desired by the surgeon). The applicant states that the flexible ureteroscope is inserted through the access sheath up into the ureters and kidneys. During a procedure, an appropriate sterile solution is passed through the instrument channel of the ureteroscope to fill the bladder to allow greater visibility. If a kidney stone is located (depending on its size), the surgeon will perform laser lithotripsy to fragment the stone into smaller pieces, then remove the fragments.

Per the applicant, the Uretero1 can be used for 4 hours (exceeding the average procedure time of 60 mins), and the device has a timer which notifies the user at three separate intervals of remaining use time: one at 60 minutes, the next at 30 minutes, and the last at 5 minutes of remaining use time. According to the applicant, when the 4 hours of usage time has elapsed, and if the scope is still plugged in, the user will be advised via a message on the screen that a new scope should be inserted and the current ureteroscope will no longer produce a live image. The applicant states that the scope timer only counts down while the device is powered on and plugged in; if it is unplugged, the time stops.

With respect to the newness criterion at § 419.66(b)(1), on November 23, 2021, the applicant received 510(k) clearance from FDA to market the Uretero1 to visualize organs, cavities, and canals in the urinary tract via transurethral or percutaneous access routes. The applicant submitted its application for consideration as a new device category for transitional pass-through payment status for the Uretero1 on March 1, 2022, which is within 3 years of the date of the initial FDA marketing authorization. We are inviting public comments on whether the Uretero1 meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the Uretero1 is integral to the service provided, is used for one patient only and comes in contact with human tissue when it is inserted to visualize organs, cavities, and canals in the urinary tract.⁹⁵ Per the applicant, the Uretero1 is reasonable and necessary to diagnose problems in the ureters and kidneys via transurethral or percutaneous access routes. The applicant claims that the Uretero1 meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. We are inviting public comments on whether the Uretero1 meets the eligibility criteria at § 419.66(b).

⁹⁵ Uretero1 Brochure_FINAL.pdf

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that the device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. The applicant describes the Uretero1 as a single use, disposable, digital flexible ureteroscope that is used in urologic procedures (ureteroscopy) that diagnose and treat conditions of the urinary tract (e.g., kidney stones, blockage, polyps, abnormal growths, etc.). According to the applicant, a possible existing pass-through code is C1748 (Endoscope, single use (i.e., disposable), upper GI, imaging/illumination device (insertable)), was made effective July 1, 2020.⁹⁶ The applicant notes that while this category is for a single use device, it is only appropriate for GI imaging, and more specifically, for endoscopic retrograde cholangiopancreatography (ERCP) procedures. Therefore, the applicant asserts this category would not apply to a single use, disposable, ureteroscope for use in urological procedures. We are inviting public comment on whether the Uretero1 meets the device category criterion.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The applicant stated that the Uretero1 represents a substantial clinical improvement over existing technology. With respect to this criterion, the applicant

⁹⁶ Uretero1 Brochure_FINAL.pdf

submitted studies that examined the impact of the Uretero1 on various diagnostic and therapeutic procedures in the urinary tract.

According to the applicant, the Uretero1 is a single use, disposable, digital flexible ureteroscope that is used in urologic procedures (ureteroscopy) to diagnose and treat conditions of the urinary tract, such as kidney stones, blockages, polyps, and abnormal growths. Broadly, the applicant outlined the following areas for which it claimed the Uretero1 would provide a substantial clinical improvement: (1) prevention of infection transmission, (2) reduced contamination risk, (3) improved deflection performance over reusable ureteroscopes, (4) reduced hospitalization rate and use of antibiotic therapy, (5) reduced complication rate, (6) reduced post-operative infection rate, (7) reduced procedure delay, (8) increased patient safety and education, and (9) improved patient outcome when the device is used to perform various diagnostic and therapeutic procedures and treatment in the urinary tract. The applicant provided five articles, an FDA advisory letter, and a set of manufacturer's instructions for cleaning and reprocessing flexible endoscopes specifically for the purpose of addressing the substantial clinical improvement criterion.

The applicant provided a journal pre-proof and two articles to support its claim that the Uretero1 is effective at preventing the transmission of infection. Each of these sources examine the steps required in the complex and time-consuming process to clean and sterilize flexible reusable ureteroscopes so they are fully reprocessed for use. The sources also describe the negative sequelae that follow instances of inefficient and or incomplete device reprocessing. The journal pre-proof of a literature review by Cori Ofstead et al. outlines the steps used to reprocess reusable ureteroscopes.⁹⁷ Studies summarized within this literature review described several instances of negative outcomes when ureteroscopes were processed incorrectly or inefficiently. As part of that literature review, Kumarage et al. described an outbreak of *Pseudomonas*

⁹⁷ Cori L. Ofstead MSPH, Krystina M. Hopkins MPH, Abigail G. Smart MPH, John E. Eiland RNMS, Harry P. Wetzler MD, MSPH, Seth K. Bechis MDMS. Reprocessing effectiveness for flexible ureteroscopes: A critical look at the evidence. *Urology* (2022), doi: <https://doi.org/10.1016/j.urology.2022.01.033>.

aeruginosa later found to be due to an infected flexible reusable ureteroscope that had been used.⁹⁸ Fourteen patients of the 40 who were exposed were infected (35 percent attack rate). The root cause of the infected ureteroscopes was attributed to substandard reprocessing of the devices, including processing that was delayed overnight. Kumarage et al. also noted a separate outbreak of a gram-positive cocci which was traced to the use of five ureteroscopes after five patients presented to the ED with urinary tract infections (UTIs) due to the same gram-positive cocci after having each undergone ureteroscopy. Research into the underlying causes and possible sources of the device contamination found that there had been breakdowns in the reprocessing steps.

Another article included in the literature review by Ofstead et al⁹⁹. describes the risks associated with inefficient processing of reusable ureteroscopes using a time-driven activity-based costing (TDABC).¹⁰⁰ This article, by Isaacson et al. (2017), notes the time and costs involved in the decontamination and sterilization processes of reusable flexible ureteroscopes.¹⁰¹ The authors also measured the time when reprocessing steps were performed inefficiently or were delayed as a result of repairs needed for any damaged ureteroscopes. After following ten ureteroscopes through the reprocessing steps required to fully clean them and determined, via process mapping, that the average reprocessing time was 229.0 ± 74.4 minutes. According to the authors' calculations, drying the ureteroscopes was the single most time-consuming step and

⁹⁸ Kumarage J, Khonyongwa K., Khan A., Desai, N., Hoffman P., Taori, SK. Transmission of multidrug resistant *Pseudomonas aeruginosa* between two flexible ureteroscopes and an outbreak of urinary tract infection: The fragility of endoscope decontamination. *J Hosp Infect.* 2019; 102(1):89-94.

⁹⁹ Ibid.

¹⁰⁰ TDABC is a process that uses process mapping in conjunction with activity-based costing to calculate and maximize efficiency of complex processes. It was developed by Kaplan and Anderson of the Department of Nephro-Urology, Nagoya City University Graduate School of Medical Sciences, Nagoya, Japan.

¹⁰¹ Isaacson D, Ahmad T, Metzler I, Tzou DT, Taguchi K, Usawachintachit M, Zetumer S, Sherer B, Stoller M, Chi T. Defining the costs of reusable flexible ureteroscope reprocessing using time-driven activity-based costing. *J Endourol.* 2017;31(10):1026-1031. doi: 10.1089/end.2017.0463. Epub 2017 Sep 20. PMID: 28830223; PMCID: PMC5652038.

took 126.5±55.7 minutes, and was further dependent on the optimal location and position of the ureteroscopes. Ureteroscopes that needed repair required approximately 143 minutes, causing further delays to availability of the devices.

To further support its claim that the Uretero1 can prevent infection transmission, the applicant cited an April 1, 2021, advisory letter to providers from FDA that outlines concerns about the effectiveness of reprocessing reusable urologic endoscopes.¹⁰² In the letter, FDA confirms it has received over 450 Medical Device Reports (MDRs) describing patient infections associated with reprocessing of reusable devices, which include ureteroscopes. FDA is still investigating these episodes but notes the importance of following manufacturer's instructions for device reprocessing. The applicant also references a report by Grandview Research which notes the market for disposable endoscopes is expected to experience compound growth at a rate of 17 percent between 2022 and 2030, largely due to the growing cross-contamination issue associated with reusable endoscopes.¹⁰³ Per the applicant, the projected market growth of disposable cystoscopes, endoscopes, and ureteroscopes is expected to continue to rise over the forecast period due to the advancement in the design of disposable devices and related to the risk of nosocomial infections following ureteroscopy procedures.¹⁰⁴

To support its second claim that the Uretero1 reduces risk of contamination, the applicant again cited the literature review by Ofstead et al.¹⁰⁵ Referencing the article by Lee et al., titled "Increasing potential risks of contamination from repetitive use of endoscope,"¹⁰⁶ Ofstead noted

¹⁰² Food and Drug Administration. Infections associated with reprocessed urological endoscopes - Letter to health care providers. Published April 1, 2021. Available from: <https://www.fda.gov/medical-devices/letters-health-care-providers/infections-associated-reprocessed-urological-endoscopes-letter-health-care-providers>.

¹⁰³ Grand View Research. "Disposable Endoscopes Market Size, Share & Trends Analysis Report by Application (Bronchoscopy, ENT Endoscopy), By End-use (Hospitals, Clinics) < By Region (Europe, North America, APAC), and Segment Forecasts, 2022-2030. Published February 2022.

¹⁰⁴ Ibid.

¹⁰⁵ Cori L. Ofstead MSPH, Krystina M. Hopkins MPH, Abigail G. Smart MPH, John E. Eiland RNMS, Harry P. Wetzler MD, MSPH, Seth K. Bechis MDMS. Reprocessing effectiveness for flexible ureteroscopes: A critical look at the evidence. *Urology* (2022), doi: <https://doi.org/10.1016/j.urology.2022.01.033>.

¹⁰⁶ Lee DH, Kim DB, Kim HY, Baek HS, Kwon SY, Lee MH, Park JC. Increasing potential risks of contamination from repetitive use of endoscope. *Am J Infect Control*. 2015 May 1;43(5): e13-7. doi: 10.1016/j.ajic.2015.01.017. Epub 2015 Feb 25. PMID: 25726130.

that wear and tear of the repeated-use devices contributes to the likelihood that infectious material will remain attached to the device even after reprocessing, as found during Lee et al.'s simulated-use study. Therefore, and per the applicant, the single use Uretero1 eliminates the risk of contamination.

The applicant's third claim with regard to the substantial clinical improvement offered by the Uretero1 is in relation to its improved deflection performance over that of reusable devices. When used in the context of describing ureteroscopes, "deflection" refers to the adjustability of the device, which enables the surgeon to see more of the urinary tract.¹⁰⁷ Therefore, improved deflection supports the surgeon's ability to access the kidneys and ureters and perform various diagnostic and therapeutic procedures in the urinary tract. The applicant cited a literature review by Ventimiglia et al. to support its claim.¹⁰⁸ Ventimiglia et al. conducted a literature review on available reusable flexible ureteroscopes and single-use flexible ureteroscopes with a focus on the related costs of each, in terms of performance, maintenance, and reprocessing. As part of its review, Ventimiglia et al. noted that the deflection capability of the Olympus URF-V and Karl Storz Flex-Xc, both single-use flexible ureteroscopes, was equivalent to the deflection capability of reusable flexible ureteroscopes. Ventimiglia et al. did not mention the Uretero1, nor its deflection capability, in the study. Of note, Ventimiglia's literature review referenced the original study by Hennessey et al., which compared the single-use flexible devices with the reusable flexible devices, and which found the performance of the single-use device was equivalent, if not better than the reusable flexible ureteroscopes.¹⁰⁹ The Uretero1 device was not included as a comparison in this study either.

¹⁰⁷ Rajamahanty, S., & Grasso, M. (2008). Flexible ureteroscopy update: indications, instrumentation and technical advances. *Indian journal of urology: IJU: journal of the Urological Society of India*, 24(4), 532–537. <https://doi.org/10.4103/0970-1591.44263>.

¹⁰⁸ Ventimiglia E, Godínez AJ, Traxer O, Somani BK. Cost comparison of single use versus reusable flexible ureteroscope: A systematic review. *Turk J Urol* 2020; 46(Supp. 1): S40-S45.

¹⁰⁹ Hennessey DB, Fojecki GL, Papa NP, Lawrentschuk N, Bolton D. Single-use disposable digital flexible ureteroscopes: an ex vivo assessment and cost analysis. *BJU Int*. 2018 May;121 Suppl 3:55-61. doi: 10.1111/bju.14235. PMID: 29656467.

The applicant referred to a study by Bozzini et al.¹¹⁰ to support its fourth, fifth, and sixth claims that the Uretero1 device demonstrates substantial clinical improvement over existing devices. These claims are that the Uretero1 enables, respectively: reduced hospitalization rate and antibiotic therapy, reduced complication rate, and reduced post-operative infection rate. Using a multicenter, randomized, clinical trial study format, Bozzini et al. enrolled 180 patients who had a renal stone and were scheduled to receive Retrograde Intrarenal Surgery (RIRS) into two groups: Group A (90 patients) underwent treatment with a reusable flexible ureteroscope and Group B (90 patients) (underwent treatment with a disposable flexible ureteroscope). While the outcome of the surgical procedure was not significantly different across the two groups (stone free rates of 86.6 percent for Group A and 90.0 percent for Group B, $p=0.11$), the number of hospitalization days and of antibiotic therapy were higher for Group A ($p\leq 0.05$), those subjects who had been in the reusable flexible ureteroscope trial group. In addition, Group A patients experienced more complications (8.8 percent) than Group B patients (3.3 percent, and with a p -value of ≤ 0.05), and Group A patients had more major complications. Finally, the overall postoperative infection rate was 16.6 percent for Group A patients compared with 3.3 percent for Group B patients ($p\leq 0.05$). It was noted that none of the Group B patients developed urosepsis, while three patients in Group A developed urosepsis ($p<0.05$).

The applicant referred to an article in *OR Manager* in support of its seventh and ninth claims that the Uretero1 single-use flexible ureteroscope reduces procedure delays and increases patient safety.¹¹¹ In addition to the discussion about the introduction of contamination during reprocessing of reusable flexible ureteroscopes, the article notes the high frequency of failures during procedures, resulting in the need for repair. Mathias specifically references a prospective

¹¹⁰ Bozzini G, Filippi B, Alriyalat S, Calori A, Besana U, Mueller A, Pushkar D, Romero-Otero J, Pastore A, Sighinolfi MC, Micali S, Buizza C, Rocco B. Disposable versus Reusable Ureteroscopes: A Prospective Multicenter Randomized Comparison. *Res Rep Urol*. 2021 Feb 10; 13:63-71. doi: 10.2147/RRU.S277049. PMID: 33604311; PMCID: PMC7882796.

¹¹¹ Mathias, JM. "Greater vigilance needed to combat ureteroscope contamination". *OR Manager*: December 2017;(33) 12:1-5.

study by Ofstead et al. (2017) conducted at two large healthcare facilities in the Midwest, in which 16 ureteroscopes were cultured and visually inspected after they had been cleaned and sterilized with hydrogen peroxide gas.¹¹² In this study, 100 percent of the devices were found to have substantial protein contamination, and two had visible bacteria, while others had debris, oily deposits, and residual fluid discoloration.¹¹³ The Mathias article also describes the “high frequency of damage and repairs” for reusable flexible ureteroscopes, noting that they then need to be sent out for repairs, resulting in delayed procedures, interrupted workflow, and wasted resources. Per Ofstead, the annual cost per ureteroscope is between \$4,000 and \$11,000, and findings from the same study showed that the average number of uses between repairs was 19.¹¹⁴ The Mathias article summarizes the steps that can be taken to reduce risks related to ureteroscope contamination and to focus on patient safety. In addition to following manufacturer’s steps for reprocessing the devices, Ofstead suggests the use of single-use endoscopes and accessories which are currently available in the list of recommendations.

Finally, the applicant referenced an FDA advisory letter to health care providers published April 1, 2021, which the applicant stated was released to raise awareness around the risk of infections associated with reprocessing urological endoscopes (e.g., ureteroscopes), although there is no mention of single use ureteroscopes. The applicant pointed to another FDA letter in support of single use duodenoscopes to reduce the risk of infection. The applicant cited these FDA letters in support of its eighth claim that the Uretero1 can be responsible for increased patient education, and patient safety.¹¹⁵

¹¹² Ofstead CL, Heymann OL, Quick MR, Johnson EA, Eiland JE, Wetzler HP. The effectiveness of sterilization for flexible ureteroscopes: A real-world study. *Am J Infect Control*. 2017 Aug 1;45(8):888-895. doi: 10.1016/j.ajic.2017.03.016. Epub 2017 Jun 15. PMID: 28625700.

¹¹³ *Ibid*.

¹¹⁴ Mathias, JM. “Greater vigilance needed to combat ureteroscope contamination”. *OR Manager*: December 2017;(33) 12:1-5.

¹¹⁵ Food and Drug Administration. Infections associated with reprocessed urological endoscopes - Letter to health care providers. Published April 1, 2021. Available from: <https://www.fda.gov/medical-devices/letters-health-care-providers/infections-associated-reprocessed-urological-endoscopes-letter-health-care-providers>. Accessed August 17, 2021.

In summary, the applicant references these citations to support its assertions that the Uretero1 single-use disposable digital flexible ureteroscope presents a substantial clinical improvement over existing devices. We note that many studies included provide details regarding the importance of following established reprocessing guidelines for reusable devices. The evidence provided in the clinical studies emphasizes the risks associated with reprocessing reusable devices. However, none of the studies the applicant includes reference another disposable device as a comparator against which to evaluate and assess the Uretero1. While we find that the source articles provide background about multiple risks associated with reprocessing reusable devices, we would welcome additional evidence demonstrating a comparison of the Uretero1's performance against other similarly disposable devices. We also note that the applicant cited an FDA news release¹¹⁶ in support of single use duodenoscopes to reduce risk of infection, but this is not the device in question. Additionally, the previously referenced FDA advisory letter¹¹⁷ regarding ureteroscopes does not mention single-use devices, and it is not clear how the recommendations in the letter support the applicant's claims of substantial clinical improvement related to the use of the Uretero1.

We are inviting public comments on whether the Uretero1 meets the substantial clinical improvement criterion.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The

¹¹⁶ Food and Drug Administration. (2019, December 13). *FDA clears first fully disposable duodenoscope, eliminating the potential for infections caused by ineffective reprocessing*. [News release]. Retrieved from <https://www.fda.gov/news-events/press-announcements/fda-clears-first-fully-disposable-duodenoscope-eliminating-potential-infections-caused-ineffective#:~:text=The%20U.S.%20Food%20and%20Drug,and%20other%20upper%20GI%20problems>.

¹¹⁷ Food and Drug Administration. Infections associated with reprocessed urological endoscopes - Letter to health care providers. Published April 1, 2021. Available from: <https://www.fda.gov/medical-devices/letters-health-care-providers/infections-associated-reprocessed-urological-endoscopes-letter-health-care-providers>. Accessed August 17, 2021

applicant stated that the Uretero1 would be reported with the following HCPCS codes listed in Table 38 below.

TABLE 38: HCPCS CODES REPORTED WITH THE URETERO1

HCPCS Code	Long Descriptor	SI	APC
50575	Renal endoscopy through nephrotomy or pyelotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with endopyelotomy (includes cystoscopy, ureteroscopy, dilation of ureter and ureteral pelvic junction, incision of ureteral pelvic junction and insertion of endopyelotomy stent)	J1	5375
52344	Cystourethroscopy with ureteroscopy; with treatment of ureteral stricture (eg, balloon dilation, laser, electrocautery, and incision)	J1	5374
52345	Cystourethroscopy with ureteroscopy; with treatment of ureteropelvic junction stricture (eg, balloon dilation, laser, electrocautery, and incision)	J1	5374
52346	Cystourethroscopy with ureteroscopy; with treatment of intra-renal stricture (eg, balloon dilation, laser, electrocautery, and incision)	J1	5375
52351	Cystourethroscopy, with ureteroscopy and/or pyeloscopy; diagnostic	J1	5374
52352	Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with removal or manipulation of calculus (ureteral catheterization is included)	J1	5374
52353	Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy (ureteral catheterization is included)	J1	5375
52354	Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with biopsy and/or fulguration of ureteral or renal pelvic lesion	J1	5375
52355	Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with resection of ureteral or renal pelvic tumor	J1	5375
52356	Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy including insertion of indwelling ureteral stent (eg, gibbons or double-j type)	J1	5375

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule with comment period (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance

test. For our calculations, we used APC 5374 - Level 4 Urology and Related Services, which had a CY 2021 payment rate of \$3,076.34 at the time the application was received. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). HCPCS code 52344 had a device offset amount of \$475.29 at the time the application was received. According to the applicant, the cost of the Uterero1 is \$1,500.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of \$1,500 for Uretero1 is 48.76 percent of the applicable APC payment amount for the service related to the category of devices of \$3,076.34 ($(\$1,500/\$3,076.34) \times 100 = 48.76$ percent). Therefore, we believe the Uretero1 meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of \$1,500 for Uretero1 is 315.60 percent of the cost of the device-related portion of the APC payment amount for the related service of \$475.29 ($(\$1,500/\$475.29) \times 100 = 315.60$ percent). Therefore, we believe that the Uretero1 meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of \$1,500 for the Uretero1 and the portion of the APC payment amount for the device of \$475.29 is 33.31 percent of the APC payment amount for the related service of \$3,076.34 ($((\$1,500-\$475.29)/\$$

3,076.34) x 100 = 33.31 percent). Therefore, we believe that the Uretero1 meets the third cost significance requirement.

We are inviting public comment on whether the Uretero1 meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

B. Proposal to Publicly Post OPSS Device Pass-through Applications

As noted in section X of this proposed rule, applicants seeking OPSS transitional pass-through status for medical devices (“OPSS device pass-through”) must submit an application to CMS containing certain information.¹¹⁸ The application is currently undergoing the Paperwork Reduction Act reapproval process, which has notice and comment periods separate from this proposed rule. The 60-day notice was published in the **Federal Register** on April 29, 2022 (87 FR 25488). CMS accepts OPSS device pass-through applications on an ongoing basis throughout the year, but must receive complete applications sufficiently in advance of the first calendar quarter in which OPSS device pass-through status is sought to allow time for analysis, decision-making, and systems changes. In particular, CMS must receive a completed application and all additional information by the first business days in March, June, September, or December of a year for the earliest possible potential pass-through effective dates of July 1, October 1, January 1, or April 1, respectively, of that year. We post complete application information and the timeframes for submitting applications on the CMS website at

¹¹⁸ The application form, titled “Process and Information Required to Apply for Additional Device Categories for Transitional Pass-Through Payment Status Under the OPSS,” describes the process and information required to apply for OPSS device-pass-through status for a medical device and is available on CMS’s website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/catapp.pdf>. Applicants must submit such information as: proposed name or description of additional category; trade/brand names of any known devices fitting the proposed additional category; list of all established categories used presently or previously for pass-through payment that describe related or similar products, along with an explanation as to why the a category does not encompass the nominated device(s); detailed description of clinical uses of each nominated device; a complete description of the nominated devices, including, but not limited to, what it is, what it does, and how it is used; its clinical characteristics; the HCPCS codes for procedures with which it is used; substantial clinical improvement information; sales and marketing information; cost information; FDA approval information; contact information; and other information CMS may require.

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.

In the CY 2016 OPSS/ASC final rule with comment period, we adopted a policy that beginning in CY 2016, all OPSS device pass-through applications submitted through the quarterly subregulatory process would be subject to notice-and-comment rulemaking in the next applicable OPSS annual rulemaking cycle, including those that were approved upon quarterly review (80 FR 70418). All applications that are approved upon quarterly review are automatically included in the next applicable OPSS annual rulemaking cycle, while submitters of applications that are not approved upon quarterly review have the option of having their application discussed in the next applicable OPSS annual rulemaking cycle or withdrawing their application from consideration entirely. We explained that no special reconsideration process would be necessary, as no denial decision would be made except through the annual rulemaking process. Applicants are able to submit new data, such as clinical trial results published in a peer-reviewed journal, for consideration during the public comment process for the proposed rule. We explained that this process allows those applications that we are able to determine meet all the criteria for device pass-through payment under the quarterly review process to receive timely pass-through payment status, while still allowing for a transparent, public review process for all applications.

In the proposed rule, CMS summarizes the information contained in the application, including the applicant's explanation of what the device does, the cost of the device, information about device's FDA approval/clearance, and the applicant's assertions and supporting data on how the device meets the OPSS device pass-through payment criteria under § 419.66. In summarizing this information for inclusion in the proposed rule, CMS restates or paraphrases information contained in the application and attempts to avoid misrepresenting or omitting any of an applicant's claims. CMS also tries to ensure that sufficient information is provided in the proposed rule to facilitate public comments on whether the medical device meets the OPSS

device pass-through criteria. Currently, however, CMS does not make the applications themselves, as submitted by the applicants, publicly available.

In the past, CMS has received requests from the public to access and review the OPPS device pass-through applications to further facilitate comment on whether a medical device meets the OPPS device pass-through payment criteria. After considering this issue, we agree that review of the original source information from the applications for OPPS device pass-through status may help to inform public comment. Further, making this information publicly available may foster greater input from experts in the interested party community based on their review of the completed application forms and related materials. Accordingly, as we discuss further in this section, we believe that providing additional information to the public by posting the applications and related materials online may help to further engage the public and foster greater input and insights on the various new medical devices and technologies presented annually for consideration for OPPS device pass-through payment.

We also believe that posting the applications online would reduce the risk that we may inadvertently omit or misrepresent relevant information submitted by applicants, or be perceived as misrepresenting such information, in our summaries in the rules. It also would streamline our evaluation process, including the identification of critical questions in the proposed rule, particularly as the number and complexity of the device pass-through applications we receive have been increasing over time. That is, by making the applications available to the public online, we would afford more time for CMS to process and analyze the supporting data and evidence in the applications rather than devoting significant time and resources to summarizing information from the applications in the rule.

Therefore, to increase transparency, enable increased interested party engagement, and further improve and streamline our evaluation process, we propose to publicly post future

applications for OPPS device pass-through payment online.¹¹⁹ Specifically, beginning with applications submitted on or after January 1, 2023, we propose to post online the completed OPPS device pass-through application forms and related materials (e.g., attachments, supportive materials) we receive from applicants. Additionally, we propose to post online information acquired subsequent to the application submission (e.g., updated application information, additional clinical studies, etc.). We propose that we would publicly post all completed application forms and related materials at the same time that the proposed rule is issued, which would afford interested parties the full public comment period to review the information provided by the applicant in its application in conjunction with the proposed rule. We are not proposing to change our policy that applicants whose applications are not approved through the quarterly review process may elect to withdraw their application from consideration in the next applicable rulemaking cycle.

With respect to copyrighted materials, we propose that on the application form itself, the applicant would be asked to provide a representation that the applicant owns the copyright or otherwise has the appropriate license to make all the copyrighted material included with its application public. For any material included with the application that the applicant indicates is copyrighted and/or not otherwise releasable to the public, we propose that the applicant must either provide a link to where the material can be accessed or provide an abstract or summary of the material that CMS can make public, and CMS will then post that link or abstract or summary online, along with the other posted application materials. We invite comments on this proposal.

We note that at times applicants furnish information marked as proprietary or trade secret information along with their applications for OPPS device pass-through payment. Currently, the OPPS device pass-through application instructions specify that data provided in the application may be subject to disclosure and instructs the applicant to mark any proprietary or trade secret

¹¹⁹ CMS is not proposing to make drug and biological pass-through applications public because the nature of the drug and biological application does not necessitate such an action.

information so that CMS can attempt, to the extent allowed under Federal law, to keep the information protected from public view.¹²⁰ Consistent with the current application instructions, should an applicant submit such information as part of its application, CMS will attempt, to the extent allowed by Federal Law, to keep this information protected from public view. We emphasize, however, that it is the applicant's responsibility to clearly identify data and information as such in its application.

Additionally, we note that in the past we have received applications in which all the data and information are marked as proprietary or confidential, or certain information, for example, information in support of a claim of substantial clinical improvement, is marked as such. In such cases, we reiterate that we generally would not be able to consider that data and information when determining whether a device meets the criteria for OPSS Device Pass-through payments. Our process provides for public input, so it is important that we provide the information needed for the public to meaningfully comment on the OPSS Device Pass-through payment applications, including the claims applicants make about meeting the OPSS Device Pass-through payment criteria. This proposal would not change the current timeline or evaluation process for OPSS device pass-through payments, the criteria used to assess applications, or the deadlines for various data submissions. Additionally, we do not expect our proposal would place additional burdens on future applicants because we are not proposing to change the information that must be submitted to apply for OPSS device pass-through status, including the supplemental information that could be furnished to support the application. As explained throughout this section, the aim of this proposed policy change is to increase accuracy, transparency, and efficiency for both CMS and interested parties, not to make the OPSS device pass-through process more onerous for applicants.

¹²⁰ See Guidance and Instructions for OPSS Device Pass-Through Applications (Updated 2/1/2022), available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/catapp.pdf>.

In connection with our proposal to post the OPPS device pass-through applications online, we expect we would also include less detail in the summaries of the device pass-through applications that we include in the annual OPPS proposed and final rules, given that the public would have access to the submitted applications themselves. We will, however, continue to provide sufficient information in the rules to facilitate public comments on whether a medical device meets the OPPS device pass-through payment criteria. Specifically, we do not anticipate summarizing in significant detail each OPPS device pass-through application in the **Federal Register** as we have in the past, given that the public would have access to the applications under our proposal. In some instances, such as in the discussions of whether devices meet the substantial clinical improvement criterion, we expect to provide a more concise summary of the evidence or a more targeted discussion of the applicant's claims about how that criterion is met based on the evidence and supporting data (although this may vary depending on the application, the medical device, and the nature of the supporting materials provided). We expect that we would continue to generally include, at a high level, the following information in the proposed and final rules: the medical device and applicant name; a description of what the device does; the cost significance calculation; the FDA approval/clearance information; and a summary of the applicant's assertions or claims. We also expect to provide more succinct summaries in the proposed and final rules regarding the applicant's assertions as to how the medical device meets the various OPPS device pass-through criteria under § 419.66. For example, we would include the applicant's assertions as to why the medical device meets the substantial clinical improvement criterion and a list of the sources of data submitted in support of those assertions, along with references to the application in support of this information. In the proposed rule, we would also continue to provide discussion of the concerns or issues we identified with respect to applications submitted. In the final rule, we would continue to provide an explanation of our determination of whether a medical device meets the applicable OPPS device pass-through payment criteria. As noted, we believe the proposal to post online the completed application

forms and other information described previously would afford greater transparency during the annual rulemaking for purposes of determining whether a medical device is eligible for OPPS device pass-through payment.

We note that if we adopt this proposal in the final rule, we would begin utilizing referring to publicly posted applications in CY 2024 rulemaking cycle, depending on when they are received. This would mean that there would be some OPPS device pass-through applications (those received as of December 31, 2022) that would follow the current process and be described fully in the proposed rule consistent with our historical practice, and other OPPS device pass-through applications (those received after the effective date of January 1, 2023) that would be summarized in the proposed rule with a cross-reference to the publicly posted application, consistent with our new policy. If our proposal is finalized effective January 1, 2023, we would allow applicants that submit an OPPS device pass-through application prior to December 31, 2022 to elect to have the application summarized and publicly posted in lieu of a full CMS write-up. Where applicants do not elect to have applications submitted prior to December 31, 2022 posted publicly and summarized in the proposed rule, we would discuss device pass-through applications in two different ways in the CY 2024 proposed and final rules (either with full write-ups or summaries and cross-references to the publicly posted applications, depending on when the application was submitted). We believe our goals of increasing transparency and ensuring there are sufficient CMS resources to review the increasing numbers of applications are sufficiently important justify use of two approaches for one year if our proposal is finalized. Nonetheless, we also solicit comment on whether we should consider an alternative implementation date of March 1, 2023, which would mean that all OPPS device pass-through applications discussed in the CY 2024 OPPS proposed and final rules would follow the current process and would appear in the rule as a full write-up. Under this alternative approach, CMS would begin publicly posting all OPPS device pass-through applications and summarize and

cross-reference the applications beginning in the CY 2025 proposed and final rules consistent with this policy.

We note that for many of the same reasons, we included a similar proposal in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28355 through 28357) that, beginning with applications for FY 2024, we would publicly post online new technology add-on payment applications and certain related materials, as discussed further in that proposed rule. Our goal in making these proposals under both the hospital OPPS and IPPS is not only to increase accuracy, transparency, and efficiency in the device pass-through and new technology add-on payment application review process for both CMS and interested parties, but also to further consistency, where possible, in our procedures and approach for addressing and engaging the public on new technologies in our annual rulemakings.

We are seeking public comment on our proposal to publicly post online the completed OPPS device pass-through application forms and supporting materials and updated application information submitted subsequent to the initial application submission for OPPS device pass-through payment, beginning January 1, 2023.

C. Proposed Device-Intensive Procedures

1. Background

Under the OPPS, prior to CY 2017, device-intensive status for procedures was determined at the APC level for APCs with a device offset percentage greater than 40 percent (79 FR 66795). Beginning in CY 2017, CMS began determining device-intensive status at the HCPCS code level. In assigning device-intensive status to an APC prior to CY 2017, the device costs of all the procedures within the APC were calculated and the geometric mean device offset of all of the procedures had to exceed 40 percent. Almost all of the procedures assigned to device-intensive APCs utilized devices, and the device costs for the associated HCPCS codes exceeded the 40-percent threshold. The no cost/full credit and partial credit device policy

(79 FR 66872 through 66873) applies to device-intensive procedures and is discussed in detail in section IV.B.4 of this proposed rule. A related device policy was the requirement that certain procedures assigned to device-intensive APCs require the reporting of a device code on the claim (80 FR 70422) and is discussed in detail in section IV.B.3 of this proposed rule. For further background information on the device-intensive APC policy, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70421 through 70426).

a. HCPCS Code-Level Device-Intensive Determination

As stated earlier, prior to CY 2017, under the device-intensive methodology we assigned device-intensive status to all procedures requiring the implantation of a device that were assigned to an APC with a device offset greater than 40 percent and, beginning in CY 2015, that met the three criteria listed below. Historically, the device-intensive designation was at the APC level and applied to the applicable procedures within that APC. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658), we changed our methodology to assign device-intensive status at the individual HCPCS code level rather than at the APC level. Under this policy, a procedure could be assigned device-intensive status regardless of its APC assignment, and device-intensive APC designations were no longer applied under the OPPS or the ASC payment system.

We believe that a HCPCS code-level device offset is, in most cases, a better representation of a procedure's device cost than an APC-wide average device offset based on the average device offset of all of the procedures assigned to an APC. Unlike a device offset calculated at the APC level, which is a weighted average offset for all devices used in all of the procedures assigned to an APC, a HCPCS code-level device offset is calculated using only claims for a single HCPCS code. We believe that this methodological change results in a more accurate representation of the cost attributable to implantation of a high-cost device, which ensures consistent device-intensive designation of procedures with a significant device cost. Further, we believe a HCPCS code-level device offset removes inappropriate device-intensive

status for procedures without a significant device cost that are granted such status because of their APC assignment.

Under our existing policy, procedures that meet the criteria listed in section IV.B.1.b of this proposed rule are identified as device-intensive procedures and are subject to all the policies applicable to procedures assigned device-intensive status under our established methodology, including our policies on device edits and no cost/full credit and partial credit devices discussed in sections IV.B.3 and IV.B.4 of this proposed rule.

b. Use of the Three Criteria to Designate Device-Intensive Procedures

We clarified our established policy in the CY 2018 OPSS/ASC final rule with comment period (82 FR 52474), where we explained that device-intensive procedures require the implantation of a device and additionally are subject to the following criteria:

- All procedures must involve implantable devices that would be reported if device insertion procedures were performed;
- The required devices must be surgically inserted or implanted devices that remain in the patient's body after the conclusion of the procedure (at least temporarily); and
- The device offset amount must be significant, which is defined as exceeding 40 percent of the procedure's mean cost.

We changed our policy to apply these three criteria to determine whether procedures qualify as device-intensive in the CY 2015 OPSS/ASC final rule with comment period (79 FR 66926), where we stated that we would apply the no cost/full credit and partial credit device policy--which includes the three criteria listed previously--to all device-intensive procedures beginning in CY 2015. We reiterated this position in the CY 2016 OPSS/ASC final rule with comment period (80 FR 70424), where we explained that we were finalizing our proposal to continue using the three criteria established in the CY 2007 OPSS/ASC final rule with comment period for determining the APCs to which the CY 2016 device intensive policy will apply. Under the policies we adopted in CYs 2015, 2016, and 2017, all procedures that

require the implantation of a device and meet the previously described criteria are assigned device-intensive status, regardless of their APC placement.

2. Device-Intensive Procedure Policy for CY 2019 and Subsequent Years

As part of our effort to better capture costs for procedures with significant device costs, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58944 through 58948), for CY 2019, we modified our criteria for device-intensive procedures. We had heard from interested parties that the criteria excluded some procedures that interested parties believed should qualify as device-intensive procedures. Specifically, we were persuaded by interested party arguments that procedures requiring expensive surgically inserted or implanted devices that are not capital equipment should qualify as device-intensive procedures, regardless of whether the device remains in the patient's body after the conclusion of the procedure. We agreed that a broader definition of device-intensive procedures was warranted, and made two modifications to the criteria for CY 2019 (83 FR 58948). First, we allowed procedures that involve surgically inserted or implanted single-use devices that meet the device offset percentage threshold to qualify as device-intensive procedures, regardless of whether the device remains in the patient's body after the conclusion of the procedure. We established this policy because we no longer believe that whether a device remains in the patient's body should affect a procedure's designation as a device-intensive procedure, as such devices could, nonetheless, comprise a large portion of the cost of the applicable procedure. Second, we modified our criteria to lower the device offset percentage threshold from 40 percent to 30 percent, to allow a greater number of procedures to qualify as device intensive. We stated that we believe allowing these additional procedures to qualify for device-intensive status will help ensure these procedures receive more appropriate payment in the ASC setting, which will help encourage the provision of these services in the ASC setting. In addition, we stated that this change would help to ensure that more procedures containing relatively high-cost devices are subject to the device edits, which leads to more correctly coded claims and greater accuracy in our claims data. Specifically, for

CY 2019 and subsequent years, we finalized that device-intensive procedures will be subject to the following criteria:

- All procedures must involve implantable devices assigned a CPT or HCPCS code;
- The required devices (including single-use devices) must be surgically inserted or implanted; and
- The device offset amount must be significant, which is defined as exceeding 30 percent of the procedure's mean cost (83 FR 58945).

In addition, to further align the device-intensive policy with the criteria used for device pass-through payment status, we finalized, for CY 2019 and subsequent years, that for purposes of satisfying the device-intensive criteria, a device-intensive procedure must involve a device that:

- Has received FDA marketing authorization, has received an FDA investigational device exemption (IDE), and has been classified as a Category B device by FDA in accordance with §§ 405.203 through 405.207 and 405.211 through 405.215, or meets another appropriate FDA exemption from premarket review;

- Is an integral part of the service furnished;
- Is used for one patient only;
- Comes in contact with human tissue;
- Is surgically implanted or inserted (either permanently or temporarily); and
- Is not either of the following:
 - (a) Equipment, an instrument, apparatus, implement, or item of the type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15-1); or
 - (b) A material or supply furnished incident to a service (for example, a suture, customized surgical kit, scalpel, or clip, other than a radiological site marker) (83 FR 58945).

In addition, for new HCPCS codes describing procedures requiring the implantation of devices that do not yet have associated claims data, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658), we finalized a policy for CY 2017 to apply device-intensive status with a default device offset set at 41 percent for new HCPCS codes describing procedures requiring the implantation or insertion of a device that did not yet have associated claims data until claims data are available to establish the HCPCS code-level device offset for the procedures. This default device offset amount of 41 percent was not calculated from claims data; instead, it was applied as a default until claims data were available upon which to calculate an actual device offset for the new code. The purpose of applying the 41-percent default device offset to new codes that describe procedures that implant or insert devices was to ensure ASC access for new procedures until claims data become available.

As discussed in the CY 2019 OPPS/ASC proposed rule and final rule with comment period (83 FR 37108 through 37109 and 58945 through 58946, respectively), in accordance with our policy stated previously to lower the device offset percentage threshold for procedures to qualify as device-intensive from greater than 40 percent to greater than 30 percent, for CY 2019 and subsequent years, we modified this policy to apply a 31-percent default device offset to new HCPCS codes describing procedures requiring the implantation of a device that do not yet have associated claims data until claims data are available to establish the HCPCS code-level device offset for the procedures. In conjunction with the policy to lower the default device offset from 41 percent to 31 percent, we continued our current policy of, in certain rare instances (for example, in the case of a very expensive implantable device), temporarily assigning a higher offset percentage if warranted by additional information such as pricing data from a device manufacturer (81 FR 79658). Once claims data are available for a new procedure requiring the implantation or insertion of a device, device-intensive status is applied to the code if the HCPCS code-level device offset is greater than 30 percent, according to our policy of determining device-intensive status by calculating the HCPCS code-level device offset.

In addition, in the CY 2019 OPPTS/ASC final rule with comment period, we clarified that since the adoption of our policy in effect as of CY 2018, the associated claims data used for purposes of determining whether or not to apply the default device offset are the associated claims data for either the new HCPCS code or any predecessor code, as described by CPT coding guidance, for the new HCPCS code. Additionally, for CY 2019 and subsequent years, in limited instances where a new HCPCS code does not have a predecessor code as defined by CPT, but describes a procedure that was previously described by an existing code, we use clinical discretion to identify HCPCS codes that are clinically related or similar to the new HCPCS code but are not officially recognized as a predecessor code by CPT, and to use the claims data of the clinically related or similar code(s) for purposes of determining whether or not to apply the default device offset to the new HCPCS code (83 FR 58946). Clinically related and similar procedures for purposes of this policy are procedures that have few or no clinical differences and use the same devices as the new HCPCS code. In addition, clinically related and similar codes for purposes of this policy are codes that either currently or previously describe the procedure described by the new HCPCS code. Under this policy, claims data from clinically related and similar codes are included as associated claims data for a new code, and where an existing HCPCS code is found to be clinically related or similar to a new HCPCS code, we apply the device offset percentage derived from the existing clinically related or similar HCPCS code's claims data to the new HCPCS code for determining the device offset percentage. We stated that we believe that claims data for HCPCS codes describing procedures that have minor differences from the procedures described by new HCPCS codes will provide an accurate depiction of the cost relationship between the procedure and the device(s) that are used, and will be appropriate to use to set a new code's device offset percentage, in the same way that predecessor codes are used. If a new HCPCS code has multiple predecessor codes, the claims data for the predecessor code that has the highest individual HCPCS-level device offset percentage is used to determine whether the new HCPCS code qualifies for device-intensive status. Similarly, in the event that a

new HCPCS code does not have a predecessor code but has multiple clinically related or similar codes, the claims data for the clinically related or similar code that has the highest individual HCPCS level device offset percentage is used to determine whether the new HCPCS code qualifies for device-intensive status.

As we indicated in the CY 2019 OPPTS/ASC proposed rule and final rule with comment period, additional information for our consideration of an offset percentage higher than the default of 31 percent for new HCPCS codes describing procedures requiring the implantation (or, in some cases, the insertion) of a device that do not yet have associated claims data, such as pricing data or invoices from a device manufacturer, should be directed to the Division of Outpatient Care, Mail Stop C4-01-26, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850, or electronically at outpatientpps@cms.hhs.gov. Additional information can be submitted prior to issuance of an OPPTS/ASC proposed rule or as a public comment in response to an issued OPPTS/ASC proposed rule. Device offset percentages will be set in each year’s final rule.

As discussed in section X.E of the CY 2022 OPPTS/ASC final rule with comment period (86 FR 63751 through 63754), given our concerns regarding CY 2020 data as a result of the COVID–PHE, we adopted a policy to use CY 2019 claims data to establish CY 2022 prospective rates. While we believed CY 2019 represented the best full year of claims data for ratesetting for CY 2022, we stated that our policy of temporarily assigning a higher offset percentage if warranted by additional information would provide a more accurate device offset percentage for certain procedures. Specifically, for procedures that were assigned device-intensive status, but were assigned a default device offset percentage of 31 percent or a device offset percentage based on claims from a clinically-similar code in the absence of CY 2019 claims data, we adopted a policy to assign device offset percentages for such procedures based on CY 2020 data if CY 2020 claims information is available.

For CY 2023, consistent with our broader proposal to use CY 2021 claims for CY 2023 OPPS and ASC ratesetting purposes and our historical practice, we propose to use CY 2021 claims information for determining device offset percentages and assigning device-intensive status.

The full listing of the proposed CY 2023 device-intensive procedures can be found in Addendum P to this proposed rule (which is available via the internet on the CMS website).

3. Device Edit Policy

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66795), we finalized a policy and implemented claims processing edits that require any of the device codes used in the previous device-to-procedure edits to be present on the claim whenever a procedure code assigned to any of the APCs listed in Table 5 of the CY 2015 OPPS/ASC final rule with comment period (the CY 2015 device-dependent APCs) is reported on the claim. In addition, in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70422), we modified our previously existing policy and applied the device coding requirements exclusively to procedures that require the implantation of a device that are assigned to a device-intensive APC. In the CY 2016 OPPS/ASC final rule with comment period, we also finalized our policy that the claims processing edits are such that any device code, when reported on a claim with a procedure assigned to a device-intensive APC (listed in Table 42 of the CY 2016 OPPS/ASC final rule with comment period (80 FR 70422)) will satisfy the edit.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658 through 79659), we changed our policy for CY 2017 and subsequent years to apply the CY 2016 device coding requirements to the newly defined device-intensive procedures. For CY 2017 and subsequent years, we also specified that any device code, when reported on a claim with a device-intensive procedure, will satisfy the edit. In addition, we created HCPCS code C1889 to recognize devices furnished during a device-intensive procedure that are not described by a specific Level II HCPCS Category C-code. Reporting HCPCS code C1889 with a

device-intensive procedure will satisfy the edit requiring a device code to be reported on a claim with a device-intensive procedure. In the CY 2019 OPPS/ASC final rule with comment period, we revised the description of HCPCS code C1889 to remove the specific applicability to device-intensive procedures (83 FR 58950). For CY 2019 and subsequent years, the description of HCPCS code C1889 is “Implantable/insertable device, not otherwise classified”.

We are not proposing any changes to this policy for CY 2023.

4. Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices

a. Background

To ensure equitable OPPS payment when a hospital receives a device without cost or with full credit, in CY 2007, we implemented a policy to reduce the payment for specified device-dependent APCs by the estimated portion of the APC payment attributable to device costs (that is, the device offset) when the hospital receives a specified device at no cost or with full credit (71 FR 68071 through 68077). Hospitals were instructed to report no cost/full credit device cases on the claim using the “FB” modifier on the line with the procedure code in which the no cost/full credit device is used. In cases in which the device is furnished without cost or with full credit, hospitals were instructed to report a token device charge of less than \$1.01. In cases in which the device being inserted is an upgrade (either of the same type of device or to a different type of device) with a full credit for the device being replaced, hospitals were instructed to report as the device charge the difference between the hospital’s usual charge for the device being implanted and the hospital’s usual charge for the device for which it received full credit. In CY 2008, we expanded this payment adjustment policy to include cases in which hospitals receive partial credit of 50 percent or more of the cost of a specified device. Hospitals were instructed to append the “FC” modifier to the procedure code that reports the service provided to furnish the device when they receive a partial credit of 50 percent or more of the cost of the new device. We refer readers to the CY 2008 OPPS/ASC final rule with comment period for more

background information on the “FB” and “FC” modifiers payment adjustment policies (72 FR 66743 through 66749).

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75007), beginning in CY 2014, we modified our policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. For CY 2013 and prior years, our policy had been to reduce OPPS payment by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device. For CY 2014, we reduced OPPS payment, for the applicable APCs, by the full or partial credit a hospital receives for a replaced device. Specifically, under this modified policy, hospitals are required to report on the claim the amount of the credit in the amount portion for value code “FD” (Credit Received from the Manufacturer for a Replaced Device) when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device. For CY 2014, we also limited the OPPS payment deduction for the applicable APCs to the total amount of the device offset when the “FD” value code appears on a claim. For CY 2015, we continued our policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit and to use the three criteria established in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68072 through 68077) for determining the APCs to which our CY 2015 policy will apply (79 FR 66872 through 66873). In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70424), we finalized our policy to no longer specify a list of devices to which the OPPS payment adjustment for no cost/full credit and partial credit devices would apply and instead apply this APC payment adjustment to all replaced devices furnished in conjunction with a procedure assigned to a device-intensive APC when the hospital receives a credit for a replaced specified device that is 50 percent or greater than the cost of the device.

b. Policy for No Cost/Full Credit and Partial Credit Devices

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79659 through 79660), for CY 2017 and subsequent years, we finalized a policy to reduce OPPS payment for device-intensive procedures, by the full or partial credit a provider receives for a replaced device, when a hospital furnishes a specified device without cost or with a full or partial credit. Under our current policy, hospitals continue to be required to report on the claim the amount of the credit in the amount portion for value code “FD” when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device.

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75007), we adopted a policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit by the lesser of the device offset amount for the APC or the amount of the credit. We adopted this change in policy in the preamble of the CY 2014 OPPS/ASC final rule with comment period and discussed it in subregulatory guidance, including Chapter 4, Section 61.3.6 of the Medicare Claims Processing Manual. Further, in the CY 2021 OPPS/ASC final rule with comment period (85 FR 86017 through 86018, 86302), we made conforming changes to our regulations at § 419.45(b)(1) and (2) that codified this policy.

We are not proposing any changes to our policies regarding payment for no cost/full credit and partial credit devices for CY 2023.

V. Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals

A. Proposed OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals

1. Background

Section 1833(t)(6) of the Act provides for temporary additional payments or “transitional pass-through payments” for certain drugs and biologicals. Throughout the proposed rule, the term “biological” is used because this is the term that appears in section 1861(t) of the Act. A “biological” as used in the proposed rule includes (but is not necessarily limited to) a “biological

product” or a “biologic” as defined under section 351 of the PHS Act. As enacted by the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106-113), this pass-through payment provision requires the Secretary to make additional payments to hospitals for: current orphan drugs for rare diseases and conditions, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act; current drugs and biologicals and brachytherapy sources used in cancer therapy; and current radiopharmaceutical drugs and biologicals. “Current” refers to those types of drugs or biologicals mentioned above that are hospital outpatient services under Medicare Part B for which transitional pass-through payment was made on the first date the hospital OPPS was implemented.

Transitional pass-through payments also are provided for certain “new” drugs and biologicals that were not being paid for as an HOPD service as of December 31, 1996, and whose cost is “not insignificant” in relation to the OPPS payments for the procedures or services associated with the new drug or biological. For pass-through payment purposes, radiopharmaceuticals are included as “drugs.” As required by statute, transitional pass-through payments for a drug or biological described in section 1833(t)(6)(C)(i)(II) of the Act can be made for a period of at least 2 years, but not more than 3 years, after the payment was first made for the drug as a hospital outpatient service under Medicare Part B. Proposed CY 2023 pass-through drugs and biologicals and their designated APCs are assigned status indicator “G” in Addenda A and B to this proposed rule (which are available via the Internet on the CMS website).

Section 1833(t)(6)(D)(i) of the Act specifies that the pass-through payment amount, in the case of a drug or biological, is the amount by which the amount determined under section 1842(o) of the Act for the drug or biological exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the drug or biological. The methodology for determining the pass-through payment amount is set forth in regulations at 42 CFR 419.64. These regulations specify that the pass-through payment equals

the amount determined under section 1842(o) of the Act minus the portion of the APC payment that CMS determines is associated with the drug or biological.

Section 1847A of the Act establishes the average sales price (ASP) methodology, which is used for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. The ASP methodology, as applied under the OPSS, uses several sources of data as a basis for payment, including the ASP, the wholesale acquisition cost (WAC), and the average wholesale price (AWP). In this proposed rule, the term “ASP methodology” and “ASP-based” are inclusive of all data sources and methodologies described therein. Additional information on the ASP methodology can be found on our website at:

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html>.

The pass-through application and review process for drugs and biologicals is described on our website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html.

2. Transitional Pass-Through Payment Period for Pass-Through Drugs, Biologicals, and Radiopharmaceuticals and Quarterly Expiration of Pass-Through Status

As required by statute, transitional pass-through payments for a drug or biological described in section 1833(t)(6)(C)(i)(II) of the Act can be made for a period of at least 2 years, but not more than 3 years, after the payment was first made for the drug or biological as a hospital outpatient service under Medicare Part B. Our current policy is to accept pass-through applications on a quarterly basis and to begin pass-through payments for approved pass-through drugs and biologicals on a quarterly basis through the next available OPSS quarterly update after the approval of a drug’s or biological’s pass-through status. However, prior to CY 2017, we expired pass-through status for drugs and biologicals on an annual basis through notice-and-comment rulemaking (74 FR 60480). In the CY 2017 OPSS/ASC final rule with comment period (81 FR 79662), we finalized a policy change, beginning with pass-through

drugs and biologicals approved in CY 2017 and subsequent calendar years, to allow for a quarterly expiration of pass-through payment status for drugs, biologicals, and radiopharmaceuticals to afford a pass-through payment period that is as close to a full 3 years as possible for all pass-through drugs, biologicals, and radiopharmaceuticals.

This change eliminated the variability of the pass-through payment eligibility period, which previously varied based on when a particular application was initially received. We adopted this change for pass-through approvals beginning on or after CY 2017, to allow, on a prospective basis, for the maximum pass-through payment period for each pass-through drug without exceeding the statutory limit of 3 years. Notice of drugs for which pass-through payment status is ending during the calendar year is included in the quarterly OPPS Change Request transmittals.

3. Drugs and Biologicals with Expiring Pass-Through Payment Status in CY 2022

There are 32 drugs and biologicals for which pass-through payment status expires on December 31, 2022 or for which the equitable adjustment to mimic continued pass-through payment will end on December 31, 2022, as listed in Table 39. Most of these drugs and biologicals will have received OPPS pass-through payment for 3 years during the period of January 1, 2019 through December 31, 2022. In accordance with the policy finalized in CY 2017 and described earlier, pass-through payment status for drugs and biologicals approved in CY 2017 and subsequent years will expire on a quarterly basis, with a pass-through payment period as close to 3 years as possible.

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63755 through 63756), we also recognized the effects of the Public Health Emergency (PHE) on drugs and biologicals whose pass-through payment status expired or expires between December 31, 2021, and September 30, 2022, by adopting a one-time equitable adjustment under section 1833(t)(2)(E) of the Act to continue separate payment for the remainder of CY 2022 to mimic continued pass-through status for that year. Because pass-through payment status can expire at

the end of a quarter, we finalized that the adjusted payment would be made for between one and four quarters, depending on when the pass-through period expires for the drug or biological. For a detailed discussion of the equitable adjustment for drugs with expiring pass-through status in CY 2022, we refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63755 through 63756).

With the exception of those groups of drugs and biologicals that are always packaged when they do not have pass-through payment status (specifically, anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including diagnostic radiopharmaceuticals, contrast agents, and stress agents); and drugs and biologicals that function as supplies when used in a surgical procedure), our standard methodology for providing payment for drugs and biologicals with expiring pass-through payment status in an upcoming calendar year is to determine the product's estimated per day cost and compare it with the OPPS drug packaging threshold for that calendar year (which is proposed to be \$135 for CY 2023), as discussed further in section V.B.1 of this proposed rule). If the estimated per day cost for the drug or biological is less than or equal to the applicable OPPS drug packaging threshold, we would package payment for the drug or biological into the payment for the associated procedure in the upcoming calendar year. If the estimated per day cost of the drug or biological is greater than the OPPS drug packaging threshold, we propose to provide separate payment at the applicable ASP-based payment amount (which is proposed at ASP+6 percent for non-340B drugs for CY 2023 and subsequent years), as discussed further in section V.B.2 of this proposed rule.

Refer to Table 39 for the list of drugs and biologicals for which pass-through payment will expire or for which separate payment to mimic pass-through payment status will end on December 31, 2022. The packaged or separately payable status of each of these drugs or biologicals is listed in Addendum B of this proposed rule (which is available via the internet on the CMS website).

**TABLE 39: DRUGS AND BIOLOGICALS FOR WHICH PASS - THROUGH
PAYMENT STATUS OR SEPARATE PAYMENT TO MIMIC PASS-THROUGH
PAYMENT WILL END ON DECEMBER 31, 2022**

CY 2022 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass- Through Payment Effective Date	Pass- Through or *Adjusted Mimicked Pass- Through Payment End Date
A9590	Iodine i-131 iobenguane, therapeutic, 1 millicurie	G	9182	01/01/2019	12/31/2022*
J0222	Injection, Patisiran, 0.1 mg	G	9180	01/01/2019	12/31/2022*
J0291	Injection, plazomicin, 5 mg	G	9183	01/01/2019	12/31/2022*
J1943	Injection, aripiprazole lauroxil, (aristada initio), 1 mg	G	9179	01/01/2019	12/31/2022*
J2798	Injection, risperidone, (perseris), 0.5 mg	G	9181	01/01/2019	12/31/2022*
J9204	Injection, mogamulizumab-kpkc, 1 mg	G	9182	01/01/2019	12/31/2022*
C9046	Cocaine hydrochloride nasal solution for topical administration, 1 mg	G	9307	04/01/2019	12/31/2022*
J0642	Injection, levoleucovorin (khapzory), 0.5 mg	G	9334	01/01/2020	12/31/2022
J1095	Injection, dexamethasone 9 percent, intraocular, 1 microgram	G	9172	04/01/2019	12/31/2022*
J3031	Injection, fremanezumab-vfrm, 1 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)	G	9197	04/01/2019	12/31/2022*
J3245	Injection, tildrakizumab, 1 mg	G	9306	04/01/2019	12/31/2022*

CY 2022 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through or *Adjusted Mimicked Pass-Through Payment End Date
J7169	Injection, coagulation factor Xa (recombinant), inactivated (andexxa), 10mg	G	9198	04/01/2019	12/31/2022*
J7208	Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl (jivi) 1 i.u.	G	9299	04/01/2019	12/31/2022*
J9119	Injection, cemiplimab-rwlc, 1 mg	G	9304	04/01/2019	12/31/2022*
J9313	Injection, moxetumomab pasudotox-tdfk, 0.01 mg	G	9305	04/01/2019	12/31/2022*
Q5108	Injection, pegfilgrastim-jmdb, biosimilar, (fulphila), 0.5 mg	G	9173	04/01/2019	12/31/2022*
Q5110	Injection, filgrastim-aafi, biosimilar, (nivestym), 1 microgram	G	9193	04/01/2019	12/31/2022*
Q5111	Injection, pegfilgrastim-cbqv, biosimilar, (udenyca), 0.5 mg	G	9195	04/01/2019	12/31/2022*
C9047	Injection, caplacizumab-yhdp, 1 mg	G	9199	07/01/2019	12/31/2022*
J0121	Injection, omadacycline, 1 mg	G	9311	07/01/2019	12/31/2022*
J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg	G	9308	07/01/2019	12/31/2022*
J1303	Injection, ravulizumab-cwvz, 10 mg	G	9312	07/01/2019	12/31/2022*
J9036	Injection, bendamustine hydrochloride (belrapzo/bendamustine), 1 mg	G	9313	07/01/2019	12/31/2022*
J9210	Injection, emapalumab-lzsg, 1 mg	G	9310	07/01/2019	12/31/2022*
J9269	Injection, tagraxofusp-erzs, 10 micrograms	G	9309	07/01/2019	12/31/2022*
J3111	Injection, romosozumab-aqgg, 1 mg	G	9327	10/01/2019	12/31/2022*
J9356	Injection, trastuzumab, 10 mg and hyaluronidase-oysk	G	9314	10/01/2019	12/31/2022*

CY 2022 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through or *Adjusted Mimicked Pass-Through Payment End Date
J0691	Injection, lefamulin, 1 mg	G	9332	01/01/2020	12/31/2022
J1632	Injection, brexanolone, 1mg	G	9333	01/01/2020	12/31/2022
J9309	Injection, polatuzumab vedotin-piiq, 1 mg	G	9331	01/01/2020	12/31/2022
Q5107	Injection, bevacizumab-awwb, biosimilar, (mvasi), 10 mg	G	9329	01/01/2020	12/31/2022
Q5117	Injection, trastuzumab-anns, biosimilar, (kanjinti), 10 mg	G	9330	01/01/2020	12/31/2022

4. Proposed Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Payment Status Expiring in CY 2023

We propose to end pass-through payment status in CY 2023 for 43 drugs and biologicals. These drugs and biologicals, which were initially approved for pass-through payment status between April 1, 2020 and January 1, 2021, are listed in Table 40. The APCs and HCPCS codes for these drugs and biologicals, which have pass-through payment status that will end by December 31, 2023, are assigned status indicator “G” in Addenda A and B to this proposed rule (which are available via the Internet on the CMS website). The APCs and HCPCS codes for these drugs and biologicals, which have pass-through payment status, are assigned status indicator “G” only for the duration of their pass-through status as shown in Table 40.

Section 1833(t)(6)(D)(i) of the Act sets the amount of pass-through payment for pass-through drugs and biologicals (the pass-through payment amount) as the difference between the amount authorized under section 1842(o) of the Act and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological. For CY 2023, we propose to continue to pay for pass-through drugs and biologicals

at ASP+6 percent, equivalent to the payment rate these drugs and biologicals would receive in the physician's office setting in CY 2023. We note that, under the OPD fee schedule, separately payable drugs assigned to an APC are generally payable at ASP+6 percent. Therefore, we propose that a \$0 pass-through payment amount would be paid for pass-through drugs and biologicals under the CY 2023 OPDS because the difference between the amount authorized under section 1842(o) of the Act, which is proposed at ASP+6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which is also proposed at ASP+6 percent, is \$0.

In the case of policy-packaged drugs (which include the following: anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including contrast agents, diagnostic radiopharmaceuticals, and stress agents); and drugs and biologicals that function as supplies when used in a surgical procedure), we propose that their pass-through payment amount would be equal to ASP+6 percent for CY 2023 minus a payment offset for the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological as described in section V.A.6 of this proposed rule. We propose this policy because, if not for the pass-through payment status of these policy-packaged products, payment for these products would be packaged into the associated procedure and therefore, there are associated OPD fee schedule amounts for them.

We propose to continue to update pass-through payment rates on a quarterly basis on the CMS website during CY 2023 if later quarter ASP submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments to the payment rates for these pass-through payment drugs or biologicals are necessary. For a full description of this policy, we refer readers to the CY 2006 OPDS/ASC final rule with comment period (70 FR 68632 through 68635).

For CY 2023, consistent with our CY 2022 policy for diagnostic and therapeutic radiopharmaceuticals, we propose to continue to provide payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through payment status based on the ASP

methodology. As stated earlier, for purposes of pass-through payment, we consider radiopharmaceuticals to be drugs under the OPPTS. Therefore, if a diagnostic or therapeutic radiopharmaceutical receives pass-through payment status during CY 2023, we propose to follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which is proposed at ASP+6 percent. If ASP data are not available for a radiopharmaceutical, we propose to provide pass-through payment at WAC+3 percent (consistent with our proposed policy in section V.B.2.b of this proposed rule), the equivalent payment provided for pass-through drugs and biologicals without ASP information. Additional detail on the WAC+3 percent payment policy can be found in section V.B.2.b of this proposed rule. If WAC information also is not available, we propose to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP. We refer readers to Table 40 below for the list of drugs and biologicals for which we propose to expire pass-through payment status during CY 2023.

TABLE 40: DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS PROPOSED TO EXPIRE DURING CY 2023

CY 2022 HCPCS Code	CY 2023 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J0179	J0179	Injection, brolocizumab-dbl, 1 mg	G	9340	04/01/2020	03/31/2023
J0223	J0223	Injection, givosiran, 0.5 mg	G	9343	04/01/2020	03/31/2023
J0791	J0791	Injection, crizanlizumab-tmca, 1 mg	G	9359	04/01/2020	03/31/2023
J1201	J1201	Injection, cetirizine hydrochloride, 1 mg	G	9361	04/01/2020	03/31/2023
J7331	J7331	Hyaluronan or derivative, synojoynt, for intra-articular injection, 1 mg	G	9337	04/01/2020	03/31/2023

CY 2022 HCPCS Code	CY 2023 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
Q5114	Q5114	Injection, trastuzumab-dkst, biosimilar, (ogivri), 10 mg	G	9341	04/01/2020	03/31/2023
Q5115	Q5115	Injection, rituximab-abbs, biosimilar (truxima), 10 mg	G	9336	04/01/2020	03/31/2023
Q5120	Q5120	Injection, pegfilgrastim-bmez, biosimilar, (ziextenzo) 0.5 mg	G	9345	04/01/2020	03/31/2023
J0742	J0742	Injection, imipenem 4 mg, cilastatin 4 mg and relebactam 2 mg	G	9362	07/01/2020	06/30/2023
J0896	J0896	Injection, luspatercept-aamt, 0.25 mg	G	9347	07/01/2020	06/30/2023
J1429	J1429	Injection, golodirsen, 10 mg	G	9356	07/01/2020	06/30/2023
J1738	J1738	Injection, meloxicam, 1 mg	G	9371	07/01/2020	06/30/2023
J3032	J3032	Injection, eptinezumab-jjmr, 1 mg	G	9357	07/01/2020	06/30/2023
J3241	J3241	Injection, teprotumumab-trbw, 10 mg	G	9355	07/01/2020	06/30/2023
J7204	J7204	Injection, factor VIII, antihemophilic factor (recombinant), (esperoct), glycopegylated-exei, per iu	G	9354	07/01/2020	06/30/2023

CY 2022 HCPCS Code	CY 2023 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J7402	J7402	Mometasone furoate sinus implant, 10 micrograms (Sinuva)	G	9346	07/01/2020	06/30/2023
J9177	J9177	Injection, enfortumab vedotin-ejfv, 0.25 mg	G	9364	07/01/2020	06/30/2023
J9358	J9358	Injection, fam-trastuzumab deruxtecan-nxki, 1 mg	G	9353	07/01/2020	06/30/2023
Q5116	Q5116	Injection, trastuzumab-qyyp, biosimilar, (trazimera), 10 mg	G	9350	07/01/2020	06/30/2023
Q5118	Q5118	Injection, bevacizumab-bvcr, biosimilar, (Zirabev), 10 mg	G	9348	07/01/2020	06/30/2023
Q5119	Q5119	Injection, rituximab-pvvr, biosimilar, (Ruxience), 10 mg	G	9367	07/01/2020	06/30/2023
A9591	A9591	Fluoroestradiol F 18, diagnostic, 1 millicurie	G	9370	10/01/2020	09/30/2023
C9067	C9067	Gallium ga-68, dotatoc, diagnostic, 0.01 mCi	G	9323	10/01/2020	09/30/2023
J7351	J7351	Injection, bimatoprost, intracameral implant, 1 microgram	G	9351	10/01/2020	09/30/2023
J9144	J9144	Injection, daratumumab, 10 mg and	G	9378	10/01/2020	09/30/2023

CY 2022 HCPCS Code	CY 2023 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
		hyaluronidase-fihj				
J9227	J9227	Injection, isatuximab-irfc, 10 mg	G	9377	10/01/2020	09/30/2023
J9281	J9281	Mitomycin pyelocalyceal instillation, 1 mg	G	9374	10/01/2020	09/30/2023
J9317	J9317	Injection, sacituzumab govitecan-hziy, 2.5 mg	G	9376	10/01/2020	09/30/2023
J9318	J9318	Injection, romidepsin, non-lyophilized, 0.1 mg	G	9428	10/01/2020	09/30/2023
Q5112	Q5112	Injection, trastuzumab-dttb, biosimilar, (Ontruzant), 10 mg	G	9382	10/01/2020	09/30/2023
Q5113	Q5113	Injection, trastuzumab-pkrb, biosimilar, (Herzuma), 10 mg	G	9349	10/01/2020	09/30/2023
Q5121	Q5121	Injection, infliximab-axxq, biosimilar, (AVSOLA), 10 mg	G	9381	10/01/2020	09/30/2023
J0699	J0699	Injection, cefiderocol, 10 mg	G	9380	01/01/2021	12/31/2023
J1437	J1437	Injection, ferric derisomaltose, 10 mg	G	9388	01/01/2021	12/31/2023
J9198	J9198	Gemcitabine hydrochloride, (Infugem), 100 mg	G	9387	01/01/2021	12/31/2023

CY 2022 HCPCS Code	CY 2023 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
A9592	A9592	Copper Cu-64, dotatate, diagnostic, 1 millicurie	G	9383	01/01/2021	12/31/2023
J1427	J1427	Injection, viltolarsen, 10 mg	G	9386	01/01/2021	12/31/2023
J1554	J1554	Injection, immune globulin (Asceniv), 500 mg	G	9392	01/01/2021	12/31/2023
J9037	J9037	Injection, belantamab mafodotin-blmf, 0.5 mg	G	9384	01/01/2021	12/31/2023
J9223	J9223	Injection, lurbinectedin, 0.1 mg	G	9389	01/01/2021	12/31/2023
J9316	J9316	Injection, pertuzumab, trastuzumab, and hyaluronidase-zzxf, per 10 mg	G	9390	01/01/2021	12/31/2023
J9349	J9349	Injection, tafasitamab-cxix, 2 mg	G	9385	01/01/2021	12/31/2023
Q2053	Q2053	Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9391	01/01/2021	12/31/2023

5. Proposed Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Payment Status

Continuing in CY 2023

We propose to continue pass-through payment status in CY 2023 for 32 drugs and biologicals. These drugs and biologicals, which were approved for pass-through payment status with effective dates beginning between April 1, 2021, and April 1, 2022, are listed in Table 41. The APCs and HCPCS codes for these drugs and biologicals, which have pass-through payment status that will continue after December 31, 2022, are assigned status indicator “G” in Addenda A and B to this proposed rule (which are available via the Internet on the CMS website).

Section 1833(t)(6)(D)(i) of the Act sets the amount of pass-through payment for pass-through drugs and biologicals (the pass-through payment amount) as the difference between the amount authorized under section 1842(o) of the Act and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological. For CY 2023, we propose to continue to pay for pass-through drugs and biologicals at ASP+6 percent, equivalent to the payment rate these drugs and biologicals would receive in the physician’s office setting in CY 2023. We propose that a \$0 pass-through payment amount would be paid for pass-through drugs and biologicals that are not policy-packaged as described in section V.B.1.c under the CY 2023 OPPS because the difference between the amount authorized under section 1842(o) of the Act, which is proposed at ASP+6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which is proposed at ASP+6 percent, is \$0.

In the case of policy-packaged drugs (which include the following: anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including contrast agents, diagnostic radiopharmaceuticals, and stress agents); and drugs and biologicals that function as supplies when used in a surgical procedure), we propose that their pass-through payment amount would be equal to ASP+6 percent for CY 2023 minus a payment offset for any predecessor drug products contributing to the pass-through payment as described in section V.A.6 of this proposed rule. We propose this policy because, if not for the pass-through payment status of these policy-packaged products, payment for these

products would be packaged into the associated procedure and therefore, there are associated OPD fee schedule amounts for them.

We propose to continue to update pass-through payment rates on a quarterly basis on our website during CY 2023 if later quarter ASP submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments to the payment rates for these pass-through payment drugs or biologicals are necessary. For a full description of this policy, we refer readers to the CY 2006 OPPI/ASC final rule with comment period (70 FR 68632 through 68635).

For CY 2023, consistent with our CY 2022 policy for diagnostic and therapeutic radiopharmaceuticals, we propose to continue to provide payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through payment status based on the ASP methodology. As stated earlier, for purposes of pass-through payment, we consider radiopharmaceuticals to be drugs under the OPPI. Therefore, if a diagnostic or therapeutic radiopharmaceutical receives pass-through payment status during CY 2023, we propose to follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which is proposed at ASP+6 percent. If ASP data are not available for a radiopharmaceutical, we propose to provide pass-through payment at WAC+3 percent (consistent with our proposed policy in section V.B.2.b of this proposed rule), the equivalent payment provided to pass-through drugs and biologicals without ASP information. Additional detail on the WAC+3 percent payment policy can be found in section V.B.2.b of this proposed rule. If WAC information also is not available, we propose to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

The drugs and biologicals that we propose would have pass-through payment status expire after December 31, 2023, are shown in Table 41.

TABLE 41: DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS PROPOSED TO EXPIRE AFTER CY 2023

CY 2022 HCPCS Code	CY 2023 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment	Pass-Through Payment End Date
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					Effective Date	
J0224	J0224	Injection, lumasiran, 0.5 mg	G	9407	04/01/2021	03/31/2024
J7212	J7212	Factor viia (antihemophilic factor, recombinant)-jncw (sevenfact), 1 microgram	G	9395	04/01/2021	03/31/2024
Q5122	Q5122	Injection, pegfilgrastim-apgf, biosimilar, (nyvepria), 0.5 mg	G	9406	04/01/2021	03/31/2024
A9593	A9593	Gallium ga-68 psma-11, diagnostic, (ucsf), 1 millicurie	G	9409	07/01/2021	06/30/2024
A9594	A9594	Gallium ga-68 psma-11, diagnostic, (ucla), 1 millicurie	G	9410	07/01/2021	06/30/2024
J0741	J0741	Injection, cabotegravir and rilpivirine, 2mg/3mg	G	9414	07/01/2021	06/30/2024
J1305	J1305	Injection, evinacumab-dgnb, 5mg	G	9416	07/01/2021	06/30/2024
J1426	J1426	Injection, casimersen, 10 mg	G	9412	07/01/2021	06/30/2024
J1448	J1448	Injection, trilaciclib, 1mg	G	9415	07/01/2021	06/30/2024
J9247	J9247	Injection, melphalan flufenamide, 1mg	G	9417	07/01/2021	06/30/2024
J9348	J9348	Injection, naxitamab-gqgk, 1 mg	G	9408	07/01/2021	06/30/2024
J9353	J9353	Injection, margetuximab-cmkb, 5 mg	G	9418	07/01/2021	06/30/2024
Q2054	Q2054	Lisocabtagene maraleucel, up to 110 million autologous anti-cd19 car-positive viable t cells, including leukapheresis and dose preparation	G	9413	07/01/2021	06/30/2024

		procedures, per therapeutic dose				
C9081	Q2055	Idecabtagene vicleucel, up to 460 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9422	10/01/2021	09/30/2024
C9082	J9272	Injection, dostarlimab-gxly, 100 mg	G	9431	10/01/2021	09/30/2024
C9083	J9061	Injection, amivantamab-vmjw, 10 mg	G	9432	10/01/2021	09/30/2024
C9084	J9359	Injection, loncastuximab tesirine-lpyl, 0.075 mg	G	9205	10/01/2021	09/30/2024
J1823	J1823	Injection, inebilizumab-cdon, 1 mg	G	9394	10/01/2021	09/30/2024
J2406	J2406	Injection, oritavancin (kimyrsa), 10 mg	G	9427	10/01/2021	09/30/2024
C9087	J9071	Injection, cyclophosphamide, (auromedics), 5 mg	G	9203	01/01/2022	12/31/2024
J9021	J9021	Injection, asparaginase, recombinant, (rylaze), 0.1 mg	G	9437	01/01/2022	12/31/2024
N/A	A9595	Piflufolastat f-18, diagnostic, 1 millicurie	G	9430	01/01/2022	12/31/2024
N/A	C9085	Injection, avalglucosidase alfa-ngpt, 2 mg	G	9433	01/01/2022	12/31/2024
N/A	C9086	Injection, anifrolumab-fnia, 1 mg	G	9434	01/01/2022	12/31/2024
N/A	J0248	Injection, remdesivir, 1 mg)	G	9200	04/01/2022	03/31/2025

N/A	J9304	Injection, pemetrexed (PEMFEXY), 10mg	G	9442	04/01/2022	03/31/2025
N/A	C9092	Injection, triamcinolone acetonide, suprachoroidal (xipere), 1 mg	G	9358	04/01/2022	03/31/2025
N/A	C9093	Injection, ranibizumab, via sustained release intravitreal implant (susvimo), 0.1 mg	G	9439	04/01/2022	03/31/2025
N/A	C9091	Injection, sirolimus protein-bound particles, 1 mg	G	9241	04/01/2022	03/31/2025
N/A	C9090	Injection, plasminogen, human-tvmh, 1 mg	G	9206	04/01/2022	03/31/2025
N/A	J9273	Injection, tisotumab vedotin-tftv, 1 mg	G	9204	04/01/2022	03/31/2025
N/A	C9088	Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg	G	9440	04/01/2022	03/31/2025

6. Proposed Provisions for Reducing Transitional Pass-Through Payments for Policy-Packaged Drugs, Biologicals, and Radiopharmaceuticals to Offset Costs Packaged into APC Groups

Under the regulation at 42 CFR 419.2(b)(15), nonpass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure are packaged in the OPSS. This category includes diagnostic radiopharmaceuticals, contrast agents, stress agents, and other diagnostic drugs. Also, under the regulation at 42 CFR 419.2(b)(16), nonpass-through drugs and biologicals that function as supplies in a surgical procedure are packaged in the OPSS. This category includes skin substitutes and other surgical-supply drugs and biologicals. Finally, under the regulation at 42 CFR 419.2(b)(4), anesthesia drugs are packaged in the OPSS. As described earlier, section 1833(t)(6)(D)(i) of the Act specifies that the transitional pass-through payment amount for pass-through drugs and biologicals is the

difference between the amount paid under section 1842(o) of the Act and the otherwise applicable OPD fee schedule amount. Because a payment offset is necessary in order to provide an appropriate transitional pass-through payment, we deduct from the pass-through payment for policy-packaged drugs, biologicals, and radiopharmaceuticals an amount reflecting the portion of the APC payment associated with predecessor products in order to ensure no duplicate payment is made. This amount reflecting the portion of the APC payment associated with predecessor products is called the payment offset.

The payment offset policy applies to all policy-packaged drugs, biologicals, and radiopharmaceuticals. For a full description of the payment offset policy as applied to policy-packaged drugs, which include diagnostic radiopharmaceuticals, contrast agents, stress agents, and skin substitutes, we refer readers to the discussion in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70430 through 70432). For CY 2023, as we did in CY 2022, we propose to continue to apply the same policy-packaged offset policy to payment for pass-through diagnostic radiopharmaceuticals, pass-through contrast agents, pass-through stress agents, and pass-through skin substitutes. The proposed APCs to which a payment offset may be applicable for pass-through diagnostic radiopharmaceuticals, pass-through contrast agents, pass-through stress agents, and pass-through skin substitutes are identified in Table 42.

TABLE 42: PROPOSED APCS TO WHICH A POLICY-PACKAGED DRUG OR RADIOPHARMACEUTICAL OFFSET MAY BE APPLICABLE IN CY 2023

CY 2023 APC	CY 2023 APC Title
Diagnostic Radiopharmaceutical	
5591	Level 1 Nuclear Medicine and Related Services
5592	Level 2 Nuclear Medicine and Related Services
5593	Level 3 Nuclear Medicine and Related Services
5594	Level 4 Nuclear Medicine and Related Services
Contrast Agent	
5571	Level 1 Imaging with Contrast
5572	Level 2 Imaging with Contrast
5573	Level 3 Imaging with Contrast
Stress Agent	
5722	Level 2 Diagnostic Tests and Related Services
5593	Level 3 Nuclear Medicine and Related Services
Skin Substitute	

CY 2023 APC	CY 2023 APC Title
5054	Level 4 Skin Procedures
5055	Level 5 Skin Procedures

We propose to continue to post annually on our website at:

[https://www.cms.gov/Medicare/Medicare-Fee-for-Service-](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Annual-Policy-Files.html)

[Payment/HospitalOutpatientPPS/Annual-Policy-Files.html](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Annual-Policy-Files.html) a file that contains the APC offset amounts that will be used for that year for purposes of both evaluating cost significance for candidate pass-through payment device categories and drugs and biologicals and establishing any appropriate APC offset amounts. Specifically, the file will continue to provide the amounts and percentages of APC payment associated with packaged implantable devices, policy-packaged drugs, and threshold packaged drugs and biologicals for every OPSS clinical APC.

B. Proposed OPSS Payment for Drugs, Biologicals, and Radiopharmaceuticals without Pass-Through Payment Status

1. Proposed Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals
 - a. Proposed Packaging Threshold

In accordance with section 1833(t)(16)(B) of the Act, the threshold for establishing separate APCs for payment of drugs and biologicals was set to \$50 per administration during CYs 2005 and 2006. In CY 2007, we used the four-quarter moving average Producer Price Index (PPI) levels for Pharmaceutical Preparations (Prescription) to trend the \$50 threshold forward from the third quarter of CY 2005 (when the Pub. L. 108-173 mandated threshold became effective) to the third quarter of CY 2007. We then rounded the resulting dollar amount to the nearest \$5 increment in order to determine the CY 2007 threshold amount of \$55. Using the same methodology as that used in CY 2007 (which is discussed in more detail in the CY 2007 OPSS/ASC final rule with comment period (71 FR 68085 through 68086)), we set the packaging threshold for establishing separate APCs for drugs and biologicals at \$130 for CY 2022 (86 FR 63635 through 63637).

Following the CY 2007 methodology, for this proposed rule, we use the most recently available four quarter moving average PPI levels to trend the \$50 threshold forward from the third quarter of CY 2005 to the third quarter of CY 2023 and rounded the resulting dollar amount (\$133.73) to the nearest \$5 increment, which yielded a figure of \$135. In performing this calculation, we used the most recent forecast of the quarterly index levels for the PPI for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics series code WPUSI07003) from CMS's Office of the Actuary. Based on these calculations using the CY 2007 OPPS methodology, we propose a packaging threshold for CY 2023 of \$135.

b. Proposed Packaging of Payment for HCPCS Codes that Describe Certain Drugs, Certain Biologicals, and Certain Therapeutic Radiopharmaceuticals Under the Cost Threshold (“Threshold-Packaged Drugs”)

To determine the proposed CY 2023 packaging status for all nonpass-through drugs and biologicals that are not policy packaged, we calculated, on a HCPCS code-specific basis, the per day cost of all drugs, biologicals, and therapeutic radiopharmaceuticals that had a HCPCS code in CY 2021 and were paid (via packaged or separate payment) under the OPPS. We used data from CY 2021 claims processed through June 30, 2021, for this calculation. However, we did not perform this calculation for those drugs and biologicals with multiple HCPCS codes that include different dosages, as described in section V.B.1.d of this proposed rule, or for the following policy-packaged items that we propose to continue to package in CY 2023: anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure.

In order to calculate the per day costs for drugs, biologicals, and therapeutic radiopharmaceuticals to determine their proposed packaging status in CY 2023, we use the methodology that was described in detail in the CY 2006 OPPS proposed rule (70 FR 42723 through 42724) and finalized in the CY 2006 OPPS final rule with comment period

(70 FR 68636 through 68638). For each drug and biological HCPCS code, we used an estimated payment rate of ASP+6 percent (which is the payment rate we propose for separately payable drugs and biologicals (other than 340B drugs)) for CY 2023, as discussed in more detail in section V.B.2.b of this proposed rule) to calculate the CY 2023 proposed rule per day costs. We used the manufacturer-submitted ASP data from the fourth quarter of CY 2021 (data that were used for payment purposes in the physician's office setting, effective April 1, 2022) to determine the proposed rule per day cost.

As is our standard methodology, for CY 2023, we propose to use payment rates based on the ASP data from the fourth quarter of CY 2021 for budget neutrality estimates, packaging determinations, impact analyses, and completion of Addenda A and B to this proposed rule (which are available via the Internet on the CMS website) because these are the most recent data available for use at the time of development of this proposed rule. These data also were the basis for drug payments in the physician's office setting, effective April 1, 2022. For items that did not have an ASP-based payment rate, such as some therapeutic radiopharmaceuticals, we used their mean unit cost derived from the CY 2021 hospital claims data to determine their per day cost.

We propose to package items with a per day cost less than or equal to \$135 and identify items with a per day cost greater than \$135 as separately payable unless they are policy-packaged. Consistent with our past practice, we cross-walked historical OPPS claims data from the CY 2021 HCPCS codes that were reported to the CY 2022 HCPCS codes that we display in Addendum B to this proposed rule (which is available via the Internet on the CMS website) for proposed payment in CY 2023.

Our policy during previous cycles of the OPPS has been to use updated ASP and claims data to make final determinations of the packaging status of HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals for the OPPS/ASC final rule with comment period. We note that it is also our policy to make an annual packaging determination for a HCPCS code only

when we develop the OPPS/ASC final rule with comment period for the update year. Only HCPCS codes that are identified as separately payable in the final rule with comment period are subject to quarterly updates. For our calculation of per day costs of HCPCS codes for drugs and biologicals in this proposed rule, we propose to use ASP data from the fourth quarter of CY 2021, which is the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective April 1, 2022, along with updated hospital claims data from CY 2021. We note that we also propose to use these data for budget neutrality estimates and impact analyses for this proposed rule.

Payment rates for HCPCS codes for separately payable drugs and biologicals included in Addenda A and B of the final rule with comment period will be based on ASP data from the second quarter of CY 2022. These data will be the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective October 1, 2022. These payment rates would then be updated in the January 2023 OPPS update, based on the most recent ASP data to be used for physicians' office and OPPS payment as of January 1, 2023. For items that do not currently have an ASP-based payment rate, we propose to recalculate their mean unit cost from all of the CY 2021 claims data and updated cost report information available for the CY 2023 OPPS/ASC final rule with comment period to determine their final per day cost.

Consequently, the packaging status of some HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals in this proposed rule may be different from the same drugs' HCPCS codes' packaging status determined based on the data used for the final rule with comment period. Under such circumstances, we propose to continue to follow the established policies initially adopted for the CY 2005 OPPS (69 FR 65780) in order to more equitably pay for those drugs whose costs fluctuate relative to the proposed CY 2023 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2022. These established policies have not changed for many years and are the same as described in the

CY 2016 OPPTS/ASC final rule with comment period (80 FR 70434). Specifically, for CY 2023, consistent with our historical practice, we propose to apply the following policies to those HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals whose relationship to the drug packaging threshold changes based on the updated drug packaging threshold and on the final updated data:

- HCPCS codes for drugs and biologicals that were paid separately in CY 2022 and that are proposed for separate payment in CY 2023, and that then have per day costs equal to or less than the CY 2023 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2023 final rule, would continue to receive separate payment in CY 2023.

- HCPCS codes for drugs and biologicals that were packaged in CY 2022 and that are proposed for separate payment in CY 2023, and that then have per day costs equal to or less than the CY 2023 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2023 final rule, would remain packaged in CY 2023.

- HCPCS codes for drugs and biologicals for which we proposed packaged payment in CY 2023 but that then have per-day costs greater than the CY 2023 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2023 final rule, would receive separate payment in CY 2023.

c. Policy-Packaged Drugs, Biologicals, and Radiopharmaceuticals

As mentioned earlier in this section, under the OPPTS, we package several categories of nonpass-through drugs, biologicals, and radiopharmaceuticals, regardless of the cost of the products. Because the products are packaged according to the policies in 42 CFR 419.2(b), we refer to these packaged drugs, biologicals, and radiopharmaceuticals as “policy-packaged” drugs,

biologicals, and radiopharmaceuticals. These policies are either longstanding or based on longstanding principles and inherent to the OPPS and are as follows:

- Anesthesia, certain drugs, biologicals, and other pharmaceuticals; medical and surgical supplies and equipment; surgical dressings; and devices used for external reduction of fractures and dislocations (§ 419.2(b)(4));
- Intraoperative items and services (§ 419.2(b)(14));
- Drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including, but not limited to, diagnostic radiopharmaceuticals, contrast agents, and pharmacologic stress agents) (§ 419.2(b)(15)); and
- Drugs and biologicals that function as supplies when used in a surgical procedure (including, but not limited to, skin substitutes and similar products that aid wound healing and implantable biologicals) (§ 419.2(b)(16)).

The policy at § 419.2(b)(16) is broader than that at § 419.2(b)(14). As we stated in the CY 2015 OPPS/ASC final rule with comment period: “We consider all items related to the surgical outcome and provided during the hospital stay in which the surgery is performed, including postsurgical pain management drugs, to be part of the surgery for purposes of our drug and biological surgical supply packaging policy” (79 FR 66875). The category described by § 419.2(b)(15) is large and includes diagnostic radiopharmaceuticals, contrast agents, stress agents, and some other products. The category described by § 419.2(b)(16) includes skin substitutes and some other products. We believe it is important to reiterate that cost consideration is not a factor when determining whether an item is a surgical supply (79 FR 66875).

d. Packaging Determination for HCPCS Codes that Describe the Same Drug or Biological but Different Dosages

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60490 through 60491), we finalized a policy to make a single packaging determination for a drug, rather than an

individual HCPCS code, when a drug has multiple HCPCS codes describing different dosages because we believe that adopting the standard HCPCS code-specific packaging determinations for these codes could lead to inappropriate payment incentives for hospitals to report certain HCPCS codes instead of others. We continue to believe that making packaging determinations on a drug-specific basis eliminates payment incentives for hospitals to report certain HCPCS codes for drugs and allows hospitals flexibility in choosing to report all HCPCS codes for different dosages of the same drug or only the lowest dosage HCPCS code. Therefore, we propose to continue our policy to make packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, for those HCPCS codes that describe the same drug or biological but different dosages in CY 2023.

For CY 2023, in order to propose a packaging determination that is consistent across all HCPCS codes that describe different dosages of the same drug or biological, we aggregated both our CY 2021 claims data and our pricing information at ASP+6 percent across all of the HCPCS codes that describe each distinct drug or biological in order to determine the mean units per day of the drug or biological in terms of the HCPCS code with the lowest dosage descriptor. The following drugs did not have pricing information available for the ASP methodology for this proposed rule; and, as is our current policy for determining the packaging status of other drugs, we used the mean unit cost available from the CY 2021 claims data to make the proposed packaging determinations for these drugs: HCPCS code C9257 (Injection, bevacizumab, 0.25 mg); HCPCS code J1840 (Injection, kanamycin sulfate, up to 500 mg); HCPCS code J1850 (Injection, kanamycin sulfate, up to 75 mg); HCPCS code J3472 (Injection, hyaluronidase, ovine, preservative free, per 1000 usp units); HCPCS code J7100 (Infusion, dextran 40, 500 ml); and HCPCS code J7110 (Infusion, dextran 75, 500 ml).

For all other drugs and biologicals that have HCPCS codes describing different doses, we then multiplied the proposed weighted average ASP+6 percent per unit payment amount across all dosage levels of a specific drug or biological by the estimated units per day for all HCPCS

codes that describe each drug or biological from our claims data to determine if the estimated per day cost of each drug or biological is less than or equal to the proposed CY 2023 drug packaging threshold of \$135 (in which case all HCPCS codes for the same drug or biological would be packaged) or greater than the proposed CY 2023 drug packaging threshold of \$135 (in which case all HCPCS codes for the same drug or biological would be separately payable). The proposed packaging status of each drug and biological HCPCS code to which this methodology would apply in CY 2023 is displayed in Table 43.

TABLE 43: PROPOSED HCPCS CODES TO WHICH THE CY 2023 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY APPLIES

CY 2023 HCPCS Code	CY 2023 Long Descriptor	CY 2023 Status Indicator (SI)
C9257	Injection, bevacizumab, 0.25 mg	K
J9035	Injection, bevacizumab, 10 mg	K
J1020	Injection, methylprednisolone acetate, 20 mg	N
J1030	Injection, methylprednisolone acetate, 40 mg	N
J1040	Injection, methylprednisolone acetate, 80 mg	N
J1460	Injection, gamma globulin, intramuscular, 1 cc	K
J1560	Injection, gamma globulin, intramuscular over 10 cc	K
J1642	Injection, heparin sodium, (heparin lock flush), per 10 units	N
J1644	Injection, heparin sodium, per 1000 units	N
J2788	Injection, rho d immune globulin, human, minidose, 50 micrograms (250 i.u.)	N
J2790	Injection, rho d immune globulin, human, full dose, 300 micrograms (1500 i.u.)	N
J2920	Injection, methylprednisolone sodium succinate, up to 40 mg	N
J2930	Injection, methylprednisolone sodium succinate, up to 125 mg	N
J3471	Injection, hyaluronidase, ovine, preservative free, per 1 usp unit (up to 999 usp units)	N
J3472	Injection, hyaluronidase, ovine, preservative free, per 1000 usp units	N
J7030	Infusion, normal saline solution, 1000 cc	N
J7040	Infusion, normal saline solution, sterile (500 ml=1 unit)	N
J7050	Infusion, normal saline solution, 250 cc	N
J7100	Infusion, dextran 40, 500 ml	N
J7110	Infusion, dextran 75, 500 ml	N
J7515	Cyclosporine, oral, 25 mg	N
J7502	Cyclosporine, oral, 100 mg	N
J8520	Capecitabine, oral, 150 mg	N
J8521	Capecitabine, oral, 500 mg	N
J9250	Methotrexate sodium, 5 mg	N
J9260	Methotrexate sodium, 50 mg	N

2. Proposed Payment for Drugs and Biologicals without Pass-Through Status that are Not Packaged

a. Proposed Payment for Specified Covered Outpatient Drugs (SCODs) and Other Separately Payable Drugs and Biologicals

Section 1833(t)(14) of the Act defines certain separately payable radiopharmaceuticals, drugs, and biologicals and mandates specific payments for these items. Under section 1833(t)(14)(B)(i) of the Act, a “specified covered outpatient drug” (known as a SCOD) is defined as a covered outpatient drug, as defined in section 1927(k)(2) of the Act, for which a separate APC has been established and that either is a radiopharmaceutical agent or is a drug or biological for which payment was made on a pass-through basis on or before December 31, 2002.

Under section 1833(t)(14)(B)(ii) of the Act, certain drugs and biologicals are designated as exceptions and are not included in the definition of SCODs. These exceptions are—

- A drug or biological for which payment is first made on or after January 1, 2003, under the transitional pass-through payment provision in section 1833(t)(6) of the Act.
- A drug or biological for which a temporary HCPCS code has not been assigned.
- During CYs 2004 and 2005, an orphan drug (as designated by the Secretary).

Section 1833(t)(14)(A)(iii) of the Act requires that payment for SCODs in CY 2006 and subsequent years be equal to the average acquisition cost for the drug for that year as determined by the Secretary, subject to any adjustment for overhead costs and taking into account the hospital acquisition cost survey data collected by the Government Accountability Office (GAO) in CYs 2004 and 2005, and later periodic surveys conducted by the Secretary as set forth in the statute. If hospital acquisition cost data are not available, the law requires that payment be equal to payment rates established under the methodology described in section 1842(o), section 1847A, or section 1847B of the Act, as calculated and adjusted by the Secretary as necessary for

purposes of paragraph (14). We refer to this alternative methodology as the “statutory default.” Most physician Part B drugs are paid at ASP+6 percent in accordance with section 1842(o) and section 1847A of the Act.

Section 1833(t)(14)(E)(ii) of the Act provides for an adjustment in OPSS payment rates for SCODs to take into account overhead and related expenses, such as pharmacy services and handling costs. Section 1833(t)(14)(E)(i) of the Act required MedPAC to study pharmacy overhead and related expenses and to make recommendations to the Secretary regarding whether, and if so how, a payment adjustment should be made to compensate hospitals for overhead and related expenses. Section 1833(t)(14)(E)(ii) of the Act authorizes the Secretary to adjust the weights for ambulatory procedure classifications for SCODs to take into account the findings of the MedPAC study.¹²¹

It has been our policy since CY 2006 to apply the same treatment to all separately payable drugs and biologicals, which include SCODs, and drugs and biologicals that are not SCODs. Therefore, we apply the payment methodology in section 1833(t)(14)(A)(iii) of the Act to SCODs, as required by statute, but we also apply it to separately payable drugs and biologicals that are not SCODs, which is a policy determination rather than a statutory requirement. For CY 2023 and subsequent years, we propose to apply section 1833(t)(14)(A)(iii)(II) of the Act to all separately payable drugs and biologicals, including SCODs. Although we do not distinguish SCODs in this discussion, we note that we are required to apply section 1833(t)(14)(A)(iii)(II) of the Act to SCODs, but we also are applying this provision to other separately payable drugs and biologicals, consistent with our history of using the same payment methodology for all separately payable drugs and biologicals.

For a detailed discussion of our OPSS drug payment policies from CY 2006 to CY 2012, we refer readers to the CY 2013 OPSS/ASC final rule with comment period (77 FR 68383

¹²¹ Medicare Payment Advisory Committee. June 2005 Report to the Congress. Chapter 6: Payment for pharmacy handling costs in hospital outpatient departments. Available at: http://www.medpac.gov/docs/default-source/reports/June05_ch6.pdf?sfvrsn=0.

through 68385). In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68386 through 68389), we first adopted the statutory default policy to pay for separately payable drugs and biologicals at ASP+6 percent based on section 1833(t)(14)(A)(iii)(II) of the Act. We have continued this policy of paying for separately payable drugs and biologicals at the statutory default for CYs 2014 through 2022.

b. CY 2023 Proposed Payment Policy

For CY 2023 and subsequent years, we propose to continue our payment policy that has been in effect since CY 2013 to pay for separately payable drugs and biologicals, with the exception of 340B-acquired drugs, at ASP+6 percent in accordance with section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default). We formally propose to pay for separately payable nonpass-through drugs acquired with a 340B discount at a rate of ASP minus 22.5 percent (as described in section V.B.6 of this proposed rule). . We refer readers to section V.B.6. for a full discussion of our proposed CY 2023 payment policy for 340B drugs.

In the case of a drug or biological during an initial sales period in which data on the prices for sales of the drug or biological are not sufficiently available from the manufacturer, section 1847A(c)(4) of the Act permits the Secretary to make payments that are based on WAC. Under section 1833(t)(14)(A)(iii)(II) of the Act, the amount of payment for a separately payable drug equals the average price for the drug for the year established under, among other authorities, section 1847A of the Act. As explained in greater detail in the CY 2019 PFS final rule, under section 1847A(c)(4) of the Act, although payments may be based on WAC, unlike section 1847A(b) of the Act (which specifies that payments using ASP or WAC must be made with a 6 percent add-on), section 1847A(c)(4) of the Act does not require that a particular add-on amount be applied to WAC-based pricing for this initial period when ASP data are not available. Consistent with section 1847A(c)(4) of the Act, in the CY 2019 PFS final rule (83 FR 59661 to 59666), we finalized a policy that, effective January 1, 2019, WAC-based payments for Part B drugs made under section 1847A(c)(4) of the Act will utilize a 3-percent add-on in place of the

6-percent add-on that was being used according to our policy in effect as of CY 2018. For the CY 2019 OPPS, we followed the same policy finalized in the CY 2019 PFS final rule (83 FR 59661 to 59666). For CY 2020 and subsequent years, we adopted a policy to utilize a 3-percent add-on instead of a 6-percent add-on for drugs that are paid based on WAC under section 1847A(c)(4) of the Act pursuant to our authority under section 1833(t)(14)(A)(iii)(II) (84 FR 61318 and 85 FR 86039). For CY 2023 and subsequent years, we propose to continue to utilize a 3-percent add-on instead of a 6-percent add-on for drugs that are paid based on WAC pursuant to our authority under section 1833(t)(14)(A)(iii)(II) of the Act, which provides, in part, that the amount of payment for a SCOD is the average price of the drug in the year established under section 1847A of the Act. We also propose to apply this provision to non-SCOD separately payable drugs. Because we propose to establish the average price for a drug paid based on WAC under section 1847A of the Act as WAC+3 percent instead of WAC+6 percent, we believe it is appropriate to price separately payable drugs paid based on WAC at the same amount under the OPPS. We propose, if finalized, our proposal to pay for drugs or biologicals at WAC+3 percent, rather than WAC+6 percent, would apply whenever WAC-based pricing is used for a drug or biological under 1847A(c)(4). For drugs and biologicals that would otherwise be subject to a payment reduction because they were acquired under the 340B Program, we formally propose that the payment amount for these drugs (in this case, as a rate of WAC minus 22.5 percent) would continue to apply. We refer readers to the CY 2019 PFS final rule (83 FR 59661 to 59666) for additional background on this policy. We also refer readers to section V.B.6. for a full discussion of our proposed CY 2023 payment policy for 340B drugs.

Consistent with our current policy, we propose for CY 2023 and subsequent years that payments for separately payable drugs and biologicals would be included in the budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act. We also propose that the budget neutral weight scalar would not be applied in determining payments for these separately payable drugs and biologicals.

We note that separately payable drug and biological payment rates listed in Addenda A and B to this proposed rule (available via the Internet on the CMS website), which illustrate the proposed CY 2023 payment of ASP+6 percent for separately payable nonpass-through drugs and biologicals and ASP+6 percent for pass-through drugs and biologicals, reflect either ASP information that is the basis for calculating payment rates for drugs and biologicals in the physician's office setting effective April 1, 2022, or WAC, AWP, or mean unit cost from CY 2021 claims data and updated cost report information available for this proposed rule. In general, these published payment rates are not the same as the actual January 2023 payment rates. This is because payment rates for drugs and biologicals with ASP information for January 2023 will be determined through the standard quarterly process where ASP data submitted by manufacturers for the third quarter of CY 2022 (July 1, 2022, through September 30, 2022) will be used to set the payment rates that are released for the quarter beginning in January 2023 in December 2022. In addition, payment rates for drugs and biologicals in Addenda A and B to this proposed rule, for which there was no ASP information available for April 2022, are based on mean unit cost in the available CY 2021 claims data. If ASP information becomes available for payment for the quarter beginning in January 2023, we will price payment for these drugs and biologicals based on their newly available ASP information. Finally, there may be drugs and biologicals that have ASP information available for this proposed rule (reflecting April 2022 ASP data) that do not have ASP information available for the quarter beginning in January 2023. These drugs and biologicals would then be paid based on mean unit cost data derived from CY 2021 hospital claims. Therefore, the proposed payment rates listed in Addenda A and B to this proposed rule are not for January 2023 payment purposes and are only illustrative of the CY 2023 OPPS payment methodology using the most recently available information at the time of issuance of this proposed rule.

c. Biosimilar Biological Products

For CY 2016 and CY 2017, we finalized a policy to pay for biosimilar biological products based on the payment allowance of the product as determined under section 1847A of the Act and to subject nonpass-through biosimilar biological products to our annual threshold-packaged policy (for CY 2016, 80 FR 70445 through 70446; and for CY 2017, 81 FR 79674). In the CY 2018 OPPI/ASC final rule with comment period (82 FR 59351), we finalized a policy to implement separate HCPCS codes for biosimilar biological products that was based on the policy established in the CY 2018 PFS final rule. The policy we established allowed all biosimilar biological products to be eligible for pass-through payment and not just the first biosimilar biological product for a reference product. In addition, in CY 2018, we adopted a policy that biosimilars without pass-through payment status that were acquired under the 340B Program would be paid the ASP of the biosimilar minus 22.5 percent of the reference product's ASP (82 FR 59367).

As noted in the CY 2019 OPPI/ASC proposed rule (83 FR 37123), several stakeholders raised concerns to us that the payment policy for biosimilars acquired under the 340B Program could unfairly lower the OPPI payment for biosimilars not on pass-through payment status because the payment reduction would be based on the reference product's ASP, which would generally be expected to be priced higher than the biosimilar, thus resulting in a more significant reduction in payment than if the 22.5 percent was calculated based on the biosimilar's ASP. We agreed with stakeholders that the current payment policy could unfairly lower the price of biosimilars without pass-through payment status that are acquired under the 340B Program. Accordingly, in the CY 2019 OPPI/ASC final rule (83 FR 58977), we implemented a policy that for CY 2019 and subsequent years, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act, we pay nonpass-through biosimilars acquired under the 340B Program at ASP minus 22.5

percent of the biosimilar's ASP instead of the biosimilar's ASP minus 22.5 percent of the reference product's ASP.

For CY 2023 and subsequent years, we propose to continue our policy to make all biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product for a reference product. We also formally propose to continue our current policy of paying for nonpass-through biosimilars acquired under the 340B program at the biosimilar's ASP minus 22.5 percent of the biosimilar's ASP instead of the biosimilar's ASP minus 22.5 percent of the reference product's ASP, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act. We refer readers to section V.B.6. for a full discussion of our proposed CY 2023 payment policy for 340B drugs.

3. Proposed Payment Policy for Therapeutic Radiopharmaceuticals

For CY 2023 and subsequent years, we propose to continue the payment policy for therapeutic radiopharmaceuticals that began in CY 2010. We pay for separately payable therapeutic radiopharmaceuticals under the ASP methodology adopted for separately payable drugs and biologicals. If ASP information is unavailable for a therapeutic radiopharmaceutical, we base therapeutic radiopharmaceutical payment on mean unit cost data derived from hospital claims. We believe that the rationale outlined in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524 through 60525) for applying the principles of separately payable drug pricing to therapeutic radiopharmaceuticals continues to be appropriate for nonpass-through, separately payable therapeutic radiopharmaceuticals in CY 2023. Therefore, we propose for CY 2023 and subsequent years to pay all nonpass-through, separately payable therapeutic radiopharmaceuticals at ASP+6 percent, based on the statutory default described in section 1833(t)(14)(A)(iii)(II) of the Act. For a full discussion of ASP-based payment for therapeutic radiopharmaceuticals, we refer readers to the CY 2010 OPPS/ASC final rule with comment period (74 FR 60520 through 60521). For CY 2023 and subsequent years, we also propose to rely on the most recently available mean unit cost data derived from hospital claims

data for payment rates for therapeutic radiopharmaceuticals for which ASP data are unavailable and to update the payment rates for separately payable therapeutic radiopharmaceuticals according to our usual process for updating the payment rates for separately payable drugs and biologicals on a quarterly basis if updated ASP information is unavailable. For a complete history of the OPPS payment policy for therapeutic radiopharmaceuticals, we refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65811), the CY 2006 OPPS final rule with comment period (70 FR 68655), and the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524).

The proposed CY 2023 payment rates for nonpass-through, separately payable therapeutic radiopharmaceuticals are included in Addenda A and B of this proposed rule (which are available via the Internet on the CMS website).

4. Proposed Payment for Blood Clotting Factors

For CY 2022, we provided payment for blood clotting factors under the same methodology as other nonpass-through separately payable drugs and biologicals under the OPPS and continued paying an updated furnishing fee (86 FR 63643). That is, for CY 2022, we provided payment for blood clotting factors under the OPPS at ASP+6 percent, plus an additional payment for the furnishing fee. We note that when blood clotting factors are provided in physicians' offices under Medicare Part B and in other Medicare settings, a furnishing fee is also applied to the payment. The CY 2022 updated furnishing fee was \$0.239 per unit.

For CY 2023 and subsequent years, we propose to pay for blood clotting factors at ASP+6 percent, consistent with our proposed payment policy for other nonpass-through, separately payable drugs and biologicals, and to continue our policy for payment of the furnishing fee using an updated amount. Our policy to pay a furnishing fee for blood clotting factors under the OPPS is consistent with the methodology applied in the physician's office and in the inpatient hospital setting. These methodologies were first articulated in the CY 2006 OPPS final rule with comment period (70 FR 68661) and later discussed in the CY 2008

OPPS/ASC final rule with comment period (72 FR 66765). The proposed furnishing fee update is based on the percentage increase in the Consumer Price Index (CPI) for medical care for the 12-month period ending with June of the previous year. Because the Bureau of Labor Statistics releases the applicable CPI data after the PFS and OPPS/ASC proposed rules are published, we are not able to include the actual updated furnishing fee in the proposed rules. Therefore, in accordance with our policy, as finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765), we proposed to announce the actual figure for the percent change in the applicable CPI and the updated furnishing fee calculated based on that figure through applicable program instructions and posting on our website at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html>.

We propose to provide payment for blood clotting factors under the same methodology as other separately payable drugs and biologicals under the OPPS and to continue payment of an updated furnishing fee. We will announce the actual figure of the percent change in the applicable CPI and the updated furnishing fee calculation based on that figure through the applicable program instructions and posting on the CMS website.

5. Proposed Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals with HCPCS Codes but Without OPPS Hospital Claims Data

For CY 2023 and subsequent years, we propose to continue to use the same payment policy as in CY 2022 for nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data. For a detailed discussion of the payment policy and methodology, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70442 through 70443). The proposed CY 2023 payment status of each of the nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data is listed in Addendum B to this proposed rule, which is available via the Internet on the CMS website.

6. OPPS Payment Methodology for 340B Purchased Drugs

a. Overview

Under the OPPTS, we generally set payment rates for separately payable drugs and biologicals under section 1833(t)(14)(A). Section 1833(t)(14)(A)(iii)(II) provides that, if hospital acquisition cost data is not available, the payment amount is the average price for the drug in a year established under section 1842(o), which cross-references section 1847A, which generally sets a default rate of ASP+6 percent for certain drugs. The provision also provides that the average price for the drug in the year as established under section 1847A is calculated and adjusted by the Secretary as necessary for purposes of paragraph (14). As described below, beginning in CY 2018, the Secretary adjusted the 340B drug payment rate to ASP minus 22.5 percent to approximate a minimum average discount for 340B drugs, which was based on findings of the GAO and MedPAC that hospitals were acquiring drugs at a significant discount under HRSA's 340B Drug Pricing Program.

This policy has been the subject of significant litigation, recently culminating in the Supreme Court's decision in *American Hospital Association v. Becerra*, No. 20-1114, 2022 WL 2135490 (June 15, 2022). Originally, in December 2018, the United States District Court for the District of Columbia (the "District Court") concluded that the Secretary lacks the authority to bring the default rate in line with average acquisition cost unless the Secretary obtains survey data from hospitals. The agency then appealed to the United States Court of Appeals for the District of Columbia Circuit (hereinafter referred to as "the D.C. Circuit"), and on July 31, 2020, the court entered an opinion reversing the District Court's judgment in this matter. Plaintiffs then petitioned the United States Supreme Court for a writ of certiorari, which was granted on July 2, 2021.¹²²

On June 15, 2022, the Supreme Court reversed the decision of the D.C. Circuit, holding that HHS may not vary payment rates for drugs and biologicals among *groups of hospitals* under section 1833(t)(14)(A)(iii)(II) in the absence of having conducted a survey of hospitals'

¹²² https://www.supremecourt.gov/orders/courtorders/070221zor_4gc5.pdf

acquisition costs under subparagraph (t)(14)(A)(iii)(I). While the Supreme Court's decision concerned payment rates for CYs 2018 and 2019, it obviously has implications for CY 2023 payment rates. However, given the timing of the Supreme Court's decision, we lacked the necessary time to incorporate the adjustments to the proposed payment rates and budget neutrality calculations to account for that decision before issuing this proposed rule, as explained further below. For that reason alone, the payment rates, tables, and addenda in this proposed rule reflect a payment rate of ASP minus 22.5 percent for drugs and biologicals acquired through the 340B program for CY 2023, consistent with our prior policy. However, we are also providing 340B Alternate supporting files, which provide information regarding the effects of removing the 340B program payment policy for CY 2023. We fully anticipate applying a rate of ASP+6 percent to such drugs and biologicals in the final rule for CY 2023, in light of the Supreme Court's recent decision. We are still evaluating how to apply the Supreme Court's recent decision to prior cost years.

Each year since 2018, we have continued our policy of paying for drugs and biologicals acquired through the 340B Program at ASP minus 22.5 percent. When we were developing this proposed rule, we intended to propose to continue our 340B policy, which was upheld by the D.C. Circuit Court of Appeals. That is, the rates that we previously developed, the tables, and the addenda that are part of this proposed rule build on the policy that had been in effect since 2018, which paid for drugs and biologicals at one rate if they were acquired through the 340B program (ASP minus 22.5 percent), and at another rate if they were not acquired through the 340B program (ASP+6 percent).

Development of the annual OPPI proposed rule begins several months before publication. This process includes formulating proposed policies and calculating proposed rates, which then must be adjusted to maintain budget neutrality. In particular, section 1833(t)(9)(B) requires that if the Secretary makes adjustments under subparagraph (A) of that section to the groups, the relative payment weights, or the wage or other adjustments, those adjustments for the

year may not cause the estimated amount of expenditures under this part for the year to increase or decrease from the estimated amount of expenditures that would have been made absent those adjustments. When the Supreme Court's decision was issued on June 15, 2022, we had already developed the policies we intended to include in the proposed rule and calculated the payment rates, which included application of an adjustment to maintain budget neutrality. There was not sufficient time remaining in the proposed rule development process for us to change the policy and accompanying rates in response to the Supreme Court's decision. The OPPS is a calendar year payment system and to ensure OPPS payment rates and policies are effective on January 1, 2023, we must issue the final rule with comment period in early November to allow for the 60-day delayed effective date that the Congressional Review Act (CRA) (5 U.S.C. 801(a)(3)) requires for major rules. We generally attempt to issue the annual OPPS/ASC proposed rule by early July to ensure that there is sufficient time to allow for the 60-day public comment period required by section 1871(b)(1) of the Act, followed by review of public comments and development of the final rule in time for the early November issuance date. If we were to change the policy and accompanying rates in response to the Supreme Court's decision, the proposed rule would be substantially delayed, which would jeopardize our ability to develop the final rule in time to meet the early November deadline required to adhere to the CRA's 60-day delayed effective date requirement. Therefore, the rates, tables, and addenda in this proposed rule reflect the proposal to pay for drugs differently if they were acquired through the 340B program, namely at ASP minus 22.5 percent, with the anticipated savings redistributed to all other items and services in a budget neutral manner. If interested parties or members of the public wish to comment on the propriety of maintaining differential payment for 340B-acquired drugs in the future, or other aspects of these as-published rates, we will consider such comments, subject to the constraints of the Supreme Court's recent decision.

That said, as we noted earlier, in light of the Supreme Court's decision in *American Hospital Association*, we fully anticipate reverting to our prior policy of paying ASP+6 percent,

regardless of whether a drug was acquired through the 340B program. We advise readers that a reversion to that policy will have an effect on the payment rates for other items and services due to the budget neutral nature of the OPSS system. To maintain OPSS budget neutrality under our anticipated final policy where non-pass-through separately payable OPSS drugs purchased under the 340B program are paid at ASP+6 percent in CY 2023, we would need to determine the change in estimated OPSS spending associated with the alternative policy. Based on separately paid line items with the “JG” modifier in the CY 2021 claims available for OPSS ratesetting, which represent all drug lines for which the 340B program payment policy applied, the estimated payment differential would be an increase of approximately \$1.96 billion in OPSS drug payments. To ensure budget neutrality under the OPSS after applying this alternative payment methodology for drugs and biologicals purchased under the 340B Program, we would apply this offset of approximately \$1.96 billion to decrease the OPSS conversion factor, which would result in a budget neutrality adjustment of 0.9596 to the OPSS conversion factor, for a revised conversion factor of \$83.279. This is a similar application of OPSS budget neutrality as originally applied to the OPSS 340B program payment policy described in the CY 2018 OPSS final rule (82 FR 59258, 82 FR 59482 through 59484). In the CY 2018 OPSS final rule, this budget neutrality adjustment increased the conversion factor to budget neutralize the decreased spending for drugs acquired through the 340B program in CY 2018. Under our anticipated final policy, we would apply that same calculation but we would decrease the conversion factor to budget neutralize the increased spending associated with payments for drugs acquired through the 340B program that would result from increasing the rate of ASP minus 22.5 percent to ASP+6 percent. We note that the amount of this adjustment would potentially change in the final rule due to updated data, potential modifications to the estimate methodology, and other factors. A table detailing the impact on hospital outpatient payment rates of removing the payment differential for 340B drugs and the corresponding budget neutrality adjustment for CY 2023 is included in the 340B Alternative supporting files.

b. Payment for 340B Drugs and Biologicals in CYs 2018 through 2022

For full descriptions of our OPPS payment policy for drugs and biologicals acquired under the 340B program, we refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59353 through 59371); the CY 2019 OPPS/ASC final rule with comment period (83 FR 59015 through 59022); the CY 2021 OPPS/ASC final rule with comment period (85 FR 86042 through 86055); and the CY 2022 OPPS/ASC final rule with comment period (86 FR 63640 through 63649).

Our policies for 340B-acquired drugs have been the subject of ongoing litigation, the procedural history of which is generally described above. On December 27, 2018, in the case of *American Hospital Association, et al. v. Azar, et al.*, the district court concluded in the context of reimbursement requests for CY 2018 that the Secretary exceeded his statutory authority by adjusting the Medicare payment rates for drugs acquired under the 340B Program to ASP minus 22.5 percent for that year.

On July 10, 2019, the district court entered final judgment. The agency appealed to the D.C. Circuit, and on July 31, 2020, the court entered an opinion reversing the district court's judgment in this matter. In January of 2021, appellees petitioned the United States Supreme Court for a writ of certiorari. On July 2, 2021, the Supreme Court granted the petition and heard oral arguments in November 2021. And, as noted above, the Supreme Court reversed the decision of the D.C. Circuit.

Before the D.C. Circuit upheld our authority to pay ASP minus 22.5 percent for 340B drugs, we stated in the CY 2020 OPPS/ASC final rule with comment period that we were taking the steps necessary to craft an appropriate remedy in the event of an unfavorable decision on appeal. Notably, after the CY 2020 OPPS/ASC proposed rule was issued, we announced in the **Federal Register** (84 FR 51590) our intent to conduct a 340B hospital survey to collect drug acquisition cost data for certain quarters in CY 2018 and 2019. We stated that such survey data may be used in setting the Medicare payment amount for drugs acquired by 340B hospitals for

years going forward, and also may be used to devise a remedy for prior years if the district court's ruling was upheld on appeal. The district court itself acknowledged that CMS may base the Medicare payment amount on average acquisition cost when survey data are available.¹²³ No 340B hospital disputed in the rulemakings for CY 2018 and 2019 that the ASP minus 22.5 percent formula was a conservative adjustment that represented the minimum discount that hospitals receive for drugs acquired through the 340B program, which is significant because 340B hospitals have internal data regarding their own drug acquisition costs. We stated in the CY 2020 OPPI/ASC final rule with comment period that we thus anticipated that survey data collected for CY 2018 and 2019 would confirm that the ASP minus 22.5 percent rate is a conservative amount that overcompensates covered entity hospitals for drugs acquired under the 340B program. We also explained that a remedy that relies on such survey data could avoid the complexities referenced in the district court's opinion. For a complete discussion of the Hospital Acquisition Cost Survey for 340B-Acquired Specified Covered Outpatient Drugs, we refer readers to the CY 2021 OPPI/ASC proposed rule (85 FR 48882 through 48891) and the CY 2021 OPPI/ASC final rule with comment period (85 FR 86042 through 86055). We proposed a net payment rate for 340B drugs of ASP minus 28.7 percent (minus 34.7 percent plus 6 percent) based on survey data, and also proposed in the alternative that the agency could continue its current policy of paying ASP minus 22.5 percent for CY 2021. On July 31, 2020, the D.C. Circuit reversed the decision of the district court, holding that this interpretation of the statute was reasonable.

During CY 2021 rulemaking, based on feedback from interested parties, we stated that we believed maintaining the policy of paying ASP minus 22.5 percent for 340B drugs was appropriate to maintain consistent and reliable payment for these drugs to give hospitals increased certainty as to payments for these drugs. For CY 2022, we continued this 340B policy

¹²³ See *American Hosp. Assoc. v. Azar*, 348 F. Supp. 3d 62, 82 (D.D.C. 2018).

without modification as described in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63648).

We are still evaluating how to apply the Supreme Court's recent decision to cost years 2018-2022. In that decision, the Court summarized the parties' arguments regarding budget neutrality and stated that, "[a]t this stage, we need not address potential remedies." We are additionally interested in public comments on the best way to craft any proposed, potential remedies affecting calendar years 2018-2022 given that the Court did not resolve that issue.

c. CY 2023 Proposed 340B Drug Payment Policy

As discussed above, given the timing of the Supreme Court's decision in *American Hospital Association v. Becerra*, we lacked the necessary time to account for that decision before issuing this proposed rule. For that reason alone, for CY 2023, we formally propose at this time to continue our current policy of paying ASP minus 22.5 percent for 340B-acquired drugs and biologicals, including when furnished in nonexcepted off-campus PBDs paid under the PFS. But again, in light of the Supreme Court's decision, we fully anticipate adopting, in the final rule, a policy of paying ASP+6 percent for 340B-acquired drugs and biologicals. This formal proposal is in accordance with the policy choices and calculations that CMS made in the months leading up to publication of this proposed rule before the Supreme Court issued its decision in *American Hospital Association v. Becerra*, No. 20-1114, 2022 WL 2135490 (June 15, 2022). We propose, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act, to pay for separately payable Medicare Part B drugs and biologicals (assigned status indicator "K"), other than vaccines and drugs on pass-through status, that are acquired through the 340B Program at ASP minus 22.5 percent when billed by a hospital paid under the OPPS that is not excepted from the payment adjustment. We formally propose to continue our current policy for calculating payment for 340B-acquired biosimilars, which is discussed in section V.B.2.c. of the CY 2019 OPPS/ASC final rule with comment period, and would continue the policy we finalized in CY 2019 to pay

ASP minus 22.5 percent for 340B-acquired drugs and biologicals furnished in nonexcepted off-campus PBDs paid under the PFS.

We also formally propose to continue the 340B payment adjustment for WAC-priced drugs, which is WAC minus 22.5 percent. The 340B-acquired drugs that are priced using AWP would continue to be paid an adjusted amount of 69.46 percent of AWP. Additionally, we propose to continue to exempt rural sole community hospitals (as described under the regulations at § 412.92 and designated as rural for Medicare purposes), children's hospitals, and PPS-exempt cancer hospitals from the 340B payment adjustment.

We also formally propose continuing to require hospitals to use modifiers to identify 340B-acquired drugs. We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59353 through 59370) for a full discussion and rationale for the CY 2018 policies and the requirements for use of modifiers "JG" and "TB".

Again, we note that, in light of the Supreme Court's recent decision in *American Hospital Association*, we fully anticipate reverting to our prior policy of paying for drugs at ASP+6 percent, regardless of whether they were acquired through the 340B program for CY 2023. We also fully expect that when we revert to paying for drugs acquired through the 340B program at ASP+6 percent, we will budget neutralize that increase consistent with the OPPS statute and our longstanding policy by making a corresponding decrease to the conversion factor to account for the increase in the payment rates for these drugs. As set forth above, to ensure budget neutrality under the OPPS, after applying this alternative payment methodology for drugs and biologicals purchased under the 340B Program, we currently estimate that we would apply an offset of approximately \$1.96 billion to decrease the OPPS conversion factor, which would result in a budget neutrality adjustment of 0.9596 to the OPPS conversion factor, for a revised conversion factor of \$83.279.

Public comments on the budget neutrality adjustment are welcome and will be carefully considered. For a more detailed discussion of the budget neutralizing effects of reverting to this

prior policy of paying for all drugs (whether 340B-acquired or not) at ASP+6 percent, please see the 340B Alternative supporting files, which include an alternative impact table, the calculation of a 340B Alternative conversion factor, the budget neutrality factors associated with the 340B Alternative policy, and Addenda A, B, and C, all of which provide information regarding the effects of removing the 340B program payment policy for CY 2023.

7. High Cost/Low Cost Threshold for Packaged Skin Substitutes

a. Background

In the CY 2014 OPPTS/ASC final rule with comment period (78 FR 74938), we unconditionally packaged skin substitute products into their associated surgical procedures as part of a broader policy to package all drugs and biologicals that function as supplies when used in a surgical procedure. As part of the policy to package skin substitutes, we also finalized a methodology that divides the skin substitutes into a high cost group and a low cost group, in order to ensure adequate resource homogeneity among APC assignments for the skin substitute application procedures (78 FR 74933). In the CY 2015 OPPTS/ASC final rule with comment period (79 FR 66886), we stated that skin substitutes are best characterized as either surgical supplies or devices because of their required surgical application and because they share significant clinical similarity with other surgical devices and supplies.

Skin substitutes assigned to the high cost group are described by HCPCS codes 15271 through 15278. Skin substitutes assigned to the low cost group are described by HCPCS codes C5271 through C5278. Geometric mean costs for the various procedures are calculated using only claims for the skin substitutes that are assigned to each group. Specifically, claims billed with HCPCS code 15271, 15273, 15275, or 15277 are used to calculate the geometric mean costs for procedures assigned to the high cost group, and claims billed with HCPCS code C5271, C5273, C5275, or C5277 are used to calculate the geometric mean costs for procedures assigned to the low cost group (78 FR 74935).

Each of the HCPCS codes described earlier are assigned to one of the following three skin procedure APCs according to the geometric mean cost for the code: APC 5053 (Level 3 Skin Procedures): HCPCS codes C5271, C5275, and C5277; APC 5054 (Level 4 Skin Procedures): HCPCS codes C5273, 15271, 15275, and 15277; or APC 5055 (Level 5 Skin Procedures): HCPCS code 15273. In CY 2022, the payment rate for APC 5053 (Level 3 Skin Procedures) was \$596.39, the payment rate for APC 5054 (Level 4 Skin Procedures) was \$1,774.73, and the payment rate for APC 5055 (Level 5 Skin Procedures) was \$3,326.39. This information is also available in Addenda A and B of the CY 2022 final rule with comment period, as issued with the final rule correction notice (87 FR 2058) (the correction notice and corrected Addenda A and B are available via the Internet on the CMS website).

We have continued the high cost/low cost categories policy since CY 2014, and we propose to continue it for CY 2023. Under the current policy, skin substitutes in the high cost category are reported with the skin substitute application CPT codes, and skin substitutes in the low cost category are reported with the analogous skin substitute HCPCS C-codes. For a discussion of the CY 2014 and CY 2015 methodologies for assigning skin substitutes to either the high cost group or the low cost group, we refer readers to the CY 2014 OPPI/ASC final rule with comment period (78 FR 74932 through 74935) and the CY 2015 OPPI/ASC final rule with comment period (79 FR 66882 through 66885).

For a discussion of the high cost/low cost methodology that was adopted in CY 2016 and has been in effect since then, we refer readers to the CY 2016 OPPI/ASC final rule with comment period (80 FR 70434 through 70435). Beginning in CY 2016 and in subsequent years, we adopted a policy where we determined the high cost/low cost status for each skin substitute product based on either a product's geometric mean unit cost (MUC) exceeding the geometric MUC threshold or the product's per day cost (PDC) (the total units of a skin substitute multiplied by the mean unit cost and divided by the total number of days) exceeding the PDC threshold. We assigned each skin substitute that exceeded either the MUC threshold or the PDC threshold

to the high cost group. In addition, we assigned any skin substitute with a MUC or a PDC that does not exceed either the MUC threshold or the PDC threshold to the low cost group (85 FR 86059).

However, some skin substitute manufacturers have raised concerns about significant fluctuation in both the MUC threshold and the PDC threshold from year to year using the methodology developed in CY 2016. The fluctuation in the thresholds may result in the reassignment of several skin substitutes from the high cost group to the low cost group which, under current payment rates, can be a difference of over \$1,000 in the payment amount for the same procedure. In addition, these stakeholders were concerned that the inclusion of cost data from skin substitutes with pass-through payment status in the MUC and PDC calculations would artificially inflate the thresholds. Skin substitute stakeholders requested that CMS consider alternatives to the current methodology used to calculate the MUC and PDC thresholds and also requested that CMS consider whether it might be appropriate to establish a new cost group in between the low cost group and the high cost group to allow for assignment of moderately priced skin substitutes to a newly created middle group.

We share the goal of promoting payment stability for skin substitute products and their related procedures as price stability allows hospitals using such products to more easily anticipate future payments associated with these products. We have attempted to limit year-to-year shifts for skin substitute products between the high cost and low cost groups through multiple initiatives implemented since CY 2014, including: establishing separate skin substitute application procedure codes for low-cost skin substitutes (78 FR 74935); using a skin substitute's MUC calculated from outpatient hospital claims data instead of an average of ASP+6 percent as the primary methodology to assign products to the high cost or low cost group (79 FR 66883); and establishing the PDC threshold as an alternate methodology to assign a skin substitute to the high cost group (80 FR 70434 through 70435).

To allow additional time to evaluate concerns and suggestions from stakeholders about the volatility of the MUC and PDC thresholds, in the CY 2018 OPPTS/ASC proposed rule (82 FR 33627), we proposed that a skin substitute that was assigned to the high cost group for CY 2017 would be assigned to the high cost group for CY 2018, even if it did not exceed the CY 2018 MUC or PDC thresholds. We finalized this policy in the CY 2018 OPPTS/ASC final rule with comment period (82 FR 59347). For more detailed information and discussion regarding the goals of this policy and the subsequent comment solicitations in CY 2019 and CY 2020 regarding possible alternative payment methodologies for graft skin substitute products, please refer to the CY 2018 OPPTS/ASC final rule with comment period (82 FR 59347); CY 2019 OPPTS/ASC final rule with comment period (83 FR 58967 to 58968); and the CY 2020 OPPTS/ASC final rule with comment period (84 FR 61328 to 61331).

b. Proposals for Packaged Skin Substitutes for CY 2023

For CY 2023, consistent with our policy since CY 2016, we propose to continue to determine the high cost/low cost status for each skin substitute product based on either a product's geometric MUC exceeding the geometric MUC threshold or the product's PDC (the total units of a skin substitute multiplied by the MUC and divided by the total number of days) exceeding the PDC threshold. Consistent with the methodology as established in the CY 2014 OPPTS/ASC through CY 2018 OPPTS/ASC final rules with comment period, we analyzed CY 2019 claims data to calculate the MUC threshold (a weighted average of all skin substitutes' MUCs) and the PDC threshold (a weighted average of all skin substitutes' PDCs). The proposed CY 2023 MUC threshold is \$47 per cm² (rounded to the nearest \$1) and the proposed CY 2023 PDC threshold is \$837 (rounded to the nearest \$1). We want to clarify that the availability of an HCPCS code for a particular human cell, tissue, or cellular or tissue-based product (HCT/P) does not mean that that product is appropriately regulated solely under section 361 of the PHS Act and the FDA regulations in 21 CFR part 1271. Manufacturers of HCT/Ps should consult with the FDA Tissue Reference Group (TRG) or obtain a determination through a Request for

Designation (RFD) on whether their HCT/Ps are appropriately regulated solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.

For CY 2023, as we did for CY 2022, we propose to assign each skin substitute that exceeds either the MUC threshold or the PDC threshold to the high cost group. In addition, we propose to assign any skin substitute with a MUC or a PDC that does not exceed either the MUC threshold or the PDC threshold to the low cost group except that we propose that any skin substitute product that was assigned to the high cost group in CY 2022 would be assigned to the high cost group for CY 2023, regardless of whether it exceeds or falls below the CY 2023 MUC or PDC threshold. This policy was established in the CY 2018 OPPI/ASC final rule with comment period (82 FR 59346 through 59348).

For CY 2023, we propose to continue to assign skin substitutes with pass-through payment status to the high cost category. We propose to assign skin substitutes with pricing information but without claims data to calculate a geometric MUC or PDC to either the high cost or low cost category based on the product's ASP+6 percent payment rate as compared to the MUC threshold. If ASP is not available, we propose to use WAC+3 percent to assign a product to either the high cost or low cost category. Finally, if neither ASP nor WAC is available, we propose to use 95 percent of AWP to assign a skin substitute to either the high cost or low cost category. We propose to continue to use WAC+3 percent instead of WAC+6 percent to conform to our proposed policy described in section V.B.2.b of this proposed rule to establish a payment rate of WAC+3 percent for separately payable drugs and biologicals that do not have ASP data available. New skin substitutes without pricing information would be assigned to the low cost category until pricing information is available to compare to the CY 2023 MUC and PDC thresholds. For a discussion of our existing policy under which we assign skin substitutes without pricing information to the low cost category until pricing information is available, we refer readers to the CY 2016 OPPI/ASC final rule with comment period (80 FR 70436).

In the CY 2023 PFS proposed rule, which will be included in the July 29, 2022 **Federal Register**, there is a proposal to treat all skin substitute products consistently across healthcare settings as incident-to supplies described under section 1861(s)(2) of the Act. If this proposed policy is finalized, manufacturers would not report ASPs for skin substitute products starting in CY 2023; and we would no longer be able to use ASP+6 percent pricing for a graft skin substitute product to determine whether the product should be assigned to the high cost group or the low cost group. However, manufacturers would continue to report WAC and AWP pricing information for skin substitute products through pricing compendia. Having WAC and AWP pricing will allow us to continue to use our alternative process to assign graft skin substitute products to the high cost group when cost data for a product is not available.

Table 44 includes the final CY 2023 cost category assignment for each skin substitute product.

TABLE 44: PROPOSED SKIN SUBSTITUTE ASSIGNMENTS TO HIGH COST AND LOW COST GROUPS FOR CY 2023

CY 2023 HCPCS Code	CY 2023 Short Descriptor	CY 2022 High/Low Cost Assignment	Proposed CY 2023 High/Low Cost Assignment
A2001	Innovamatrix ac, per sq cm	N/A	Low
A2002	Mirragen adv wnd mat per sq	N/A	Low
A2005	Microlyte matrix, per sq cm	N/A	Low
A2006	Novosorb synpath per sq cm	N/A	Low
A2007	Restrata, per sq cm	N/A	High
A2008	Theragenesis, per sq cm	N/A	Low
A2009	Symphony, per sq cm	N/A	Low
A2010	Apis, per square centimeter	N/A	Low
A2011	Supra sdrm, per sq cm	N/A	Low
A2012	Suprathel, per sq cm	N/A	Low
A2013	Innovamatrix fs, per sq cm	N/A	Low
A4100	Skin sub fda clrd as dev nos	N/A	Low
C9363	Integra meshed bil wound mat	High	High
Q4100	Skin substitute, nos	Low	Low
Q4101	Apligraf	High	High
Q4102	Oasis wound matrix	Low	Low
Q4103	Oasis burn matrix	High	High*
Q4104	Integra bmwd	High	High
Q4105	Integra drt or omnigraft	High	High
Q4106	Dermagraft	High	High
Q4107	Graftjacket	High	High

CY 2023 HCPCS Code	CY 2023 Short Descriptor	CY 2022 High/Low Cost Assignment	Proposed CY 2023 High/Low Cost Assignment
Q4108	Integra matrix	High	High
Q4110	Primatrix	High	High
Q4111	Gammagraft	Low	Low
Q4115	Alloskin	Low	Low
Q4116	Alloderm	High	High
Q4117	Hyalomatrix	Low	Low
Q4121	Theraskin	High	High*
Q4122	Dermacell	High	High
Q4123	Alloskin	High	High
Q4124	Oasis tri-layer wound matrix	Low	Low
Q4126	Memoderm/derma/tranz/integup	High	High
Q4127	Talymed	High	High*
Q4128	Flexhd/allopatchhd/matrixhd	High	High
Q4132	Grafix core, grafixpl core	High	High
Q4133	Grafix stravix prime pl sqcm	High	High
Q4134	Hmatrix	Low	High
Q4135	Mediskin	Low	Low
Q4136	Ezderm	Low	Low
Q4137	Amnioexcel biodexcel, 1 sq cm	High	High
Q4138	Biodfence dryflex, 1cm	High	High
Q4140	Biodfence 1cm	High	High
Q4141	Alloskin ac, 1cm	High	High*
Q4143	Repriza, 1cm	High	High
Q4146	Tensix, 1cm	High	High
Q4147	Architect ecm px fx 1 sq cm	High	High
Q4148	Neox rt or clarix cord	High	High
Q4150	Allowrap ds or dry 1 sq cm	High	High
Q4151	Amnioband, guardian 1 sq cm	High	High
Q4152	Dermapure 1 square cm	High	High*
Q4153	Dermavest, plurivest sq cm	High	High
Q4154	Biovance 1 square cm	High	High
Q4156	Neox 100 or clarix 100	High	High
Q4157	Revitalon 1 square cm	High	High
Q4158	Kerecis omega3, per sq cm	High	High
Q4159	Affinity 1 square cm	High	High
Q4160	Nushield 1 square cm	High	High
Q4161	Bio-connekt per square cm	High	High
Q4163	Woundex, bioskin, per sq cm	High	High
Q4164	Helicoll, per square cm	High	High
Q4165	Keramatrix, per square cm	Low	Low
Q4166	Cytal, per square centimeter	Low	Low
Q4167	Truskin, per square centimeter	Low	High*
Q4169	Artacent wound, per sq cm	High	High
Q4170	Cygnus, per sq cm	Low	High
Q4173	Palingen or palingen xplus	High	High*
Q4175	Miroderm, per square cm	High	High

CY 2023 HCPCS Code	CY 2023 Short Descriptor	CY 2022 High/Low Cost Assignment	Proposed CY 2023 High/Low Cost Assignment
Q4176	Neopatch, per sq centimeter	High	High
Q4178	Floweramniopatch, per sq cm	High	High
Q4179	Flowerderm, per sq cm	High	High
Q4180	Revita, per sq cm	High	High
Q4181	Amnio wound, per square cm	High	High
Q4182	Transcyte, per sq centimeter	High	High*
Q4183	Surgigraft, 1 sq cm	High	High
Q4184	Cellesta or duo per sq cm	High	High
Q4186	Epifix 1 sq cm	High	High
Q4187	Epicord 1 sq cm	High	High
Q4188	Amnioarmor 1 sq cm	High	High
Q4190	Artacent ac 1 sq cm	High	High*
Q4191	Restorigin 1 sq cm	Low	High
Q4193	Coll-e-derm 1 sq cm	High	High
Q4194	Novachor 1 sq cm	High	High
Q4195	Puraply 1 sq cm	High	High
Q4196	Puraply am 1 sq cm	High	High
Q4197	Puraply xt 1 sq cm	High	High
Q4198	Genesis amnio membrane 1 sq cm	High	High
Q4199	Cygnus matrix, per sq cm	N/A	High
Q4200	Skin te 1 sq cm	High	High
Q4201	Matrion 1 sq cm	High	High
Q4203	Derma-gide, 1 sq cm	High	High
Q4204	Xwrap 1 sq cm	Low	Low
Q4205	Membrane graft or wrap sq cm	High	High
Q4208	Novafix per sq cm	High	High*
Q4209	Surgraft per sq cm	High	High*
Q4210	Axolotl graf dualgraf sq cm	Low	High
Q4211	Amnion bio or axobio sq cm	High	High
Q4214	Cellesta cord per sq cm	Low	Low
Q4216	Artacent cord per sq cm	Low	Low
Q4217	Woundfix biowound plus xplus	Low	Low
Q4218	Surgicord per sq cm	Low	Low
Q4219	Surgigraft dual per sq cm	High	High*
Q4220	Bellacell HD, Surederm sq cm	Low	Low
Q4221	Amniowrap2 per sq cm	Low	Low
Q4222	Progenamatrix, per sq cm	High	High*
Q4224	Hhf10-p per sq cm	N/A	Low
Q4225	Amniobind, per sq cm	N/A	Low
Q4226	Myown harv prep proc sq cm	High	High
Q4227	Amniocore per sq cm	High	High
Q4228	Bionextpatch, per sq cm	Low	Low
Q4229	Cogenex amnio memb per sq cm	Low	Low
Q4232	Corplex, per sq cm	High	High
Q4234	Xcellerate, per sq cm	High	High

CY 2023 HCPCS Code	CY 2023 Short Descriptor	CY 2022 High/Low Cost Assignment	Proposed CY 2023 High/Low Cost Assignment
Q4235	Amniorepair or altiPLY sq cm	Low	High
Q4236	Carepatch per sq cm	Low	Low
Q4237	cryo-cord, per sq cm	High	High
Q4238	Derm-maxx, per sq cm	High	High
Q4239	Amnio-maxx or lite per sq cm	High	High
Q4247	Amniotext patch, per sq cm	Low	Low
Q4248	Dermacyte Amn mem allo sq cm	Low	Low
Q4249	AmniPLY, per sq cm	Low	High
Q4250	AmnioAMP-MP per sq cm	Low	Low
Q4254	Novafix dl per sq cm	Low	High
Q4255	Reguard, topical use per sq	Low	Low
Q4256	Mlg complet, per sq cm	Low	Low
Q4257	Relese, per sq cm	Low	Low
Q4258	Enverse, per sq cm	Low	Low

* These products do not exceed either the proposed MUC or PDC threshold for CY 2023, but are assigned to the high cost group because they were assigned to the high cost group in CY 2022.

c. Proposed Retirement of HCPCS Code C1849 (Skin substitute, synthetic, resorbable, by per square centimeter)

In the CY 2021 OPSS/ASC final rule with comment period (85 FR 86064 to 86067), we revised our description of skin substitutes to include synthetic products, in addition to biological products. We also established HCPCS code C1849 to facilitate payment for synthetic graft skin substitute products in the outpatient hospital setting. HCPCS code C1849 was established in response to the need to pay for graft skin substitute application services performed with synthetic graft skin substitute products in the OPSS in a manner comparable to how we pay for graft skin substitute application services performed with biological graft skin substitute products, and was designed to describe any synthetic graft skin substitute product. We did not anticipate creating product specific HCPCS codes for synthetic graft skin substitute products.

We assigned HCPCS code C1849 to the high cost skin substitute group based on our alternative methodology to assign products with WAC or AWP pricing that exceeds the MUC threshold to the high cost skin substitute group (85 FR 86066). When the CY 2021 OPSS/ASC final rule with comment period was issued, we were aware of one synthetic graft skin substitute

product described by HCPCS code C1849. The manufacturer provided WAC pricing data that showed the cost of the product was above the MUC threshold for graft skin substitute products and therefore we determined that HCPCS code C1849 should be assigned to the high cost skin substitute group. We noted that, as more synthetic graft skin substitute products are identified as being described by HCPCS code C1849, we would use their pricing data to calculate an average price for the products described by HCPCS code C1849 to determine whether HCPCS code C1849 should be assigned to the high cost or low cost skin substitute group. In the CY 2022 OPPS/ASC final rule with comment period, we stated that we had identified multiple synthetic skin substitute products that could be described by HCPCS code C1849. The average of the WAC pricing data for these products exceeded the MUC threshold (86 FR 63563). Therefore, we assigned HCPCS code C1849 to the high cost skin substitute group in CY 2022 (86 FR 63652).

While we created a single synthetic skin substitute HCPCS code for use under the OPPS beginning in CY 2021, for the physician office setting we established product-specific HCPCS codes for several graft skin substitute products that were described as synthetic skin substitute products in CY 2022 (86 FR 65119 through 65123). Because we anticipated that any graft skin substitute product assigned to the HCPCS A2XXX code series would be a synthetic product that also would be described by HCPCS code C1849 under the OPPS, we decided that graft skin substitute products assigned to the HCPCS A2XXX series would not be payable under the OPPS. Although we would pay for these products when identified by codes in the HCPCS A2XXX series in the physician office setting, it was not necessary to also make these codes payable under the OPPS because we had established HCPCS code C1849 to report the use of synthetic graft skin substitute products with graft skin substitute procedures for payment under the OPPS.

Starting in January 2022, however, all new skin substitute products with an FDA 510(k) clearance received product-specific A-codes in the HCPCS A2XXX series. FDA 510(k)-cleared

skin substitute products include both biological products that are not human cell, tissue, or cellular or tissue-based products (HCT/Ps) as well as synthetic products. The use of product-specific A-codes to identify all FDA 510(k) skin substitute products meant that several of the graft skin substitute products assigned product-specific codes in the A2XXX series starting January 1, 2022 were biological graft skin substitutes with an FDA 510(k) clearance. While graft synthetic skin substitute products are described by HCPCS code C1849, FDA 510(k)-cleared biological products are not. However, for OPSS purposes, all graft skin substitute products with product-specific A-codes were assigned status indicator A under the OPSS (Not paid under the OPSS. Paid by [Medicare Administrative Contractors] under a fee schedule or payment system other than the OPSS). Previously, biological skin substitute products with an FDA 510(k) clearance were assigned product-specific Q-codes, which are bundled into payment with the associated procedure under the OPSS. However, starting in January 2022, skin substitute products with a FDA 510(k) clearance were no longer being assigned product-specific Q-codes.

Because some of the codes in the HCPCS A2XXX series identify biological skin substitute products that need to be payable under the OPSS, and because we cannot make only certain codes in the HCPCS A-code series payable and not others, we made the HCPCS A2XXX series payable under the OPSS earlier this year. Effective April 1, 2022, in the “April 2022 Update of the Hospital Outpatient Prospective Payment System (OPSS) – Change Request 12666” (<https://www.cms.gov/files/document/r11305cp.pdf>), we changed the status indicator of all skin substitute products described in the HCPCS A2XXX series, including synthetic graft skin substitutes, to “N” (Paid under OPSS; payment is packaged into payment for other services). This change allowed packaged payment under the OPSS to be made for these products when furnished with skin substitute application procedures in the hospital outpatient department setting. We also assigned unclassified skin substitute products described by HCPCS code A4100 (Skin substitute, fda cleared as a device, not otherwise specified) status indicator “N” in this Change Request and provided that payment for products identified with this code is packaged

under the OPPS. HCPCS code A4100 is used to describe skin substitute products with FDA 510(k) clearance that do not have a product-specific HCPCS code, which includes unclassified synthetic graft skin substitutes. Graft skin substitute products with product-specific codes in the HCPCS A2XXX series or that are described by HCPCS code A4100 are subject to the same policies as other graft skin substitute products as described by section V.B.7.b of the CY 2022 OPPS/ASC final rule with comment (86 FR 63650 through 63658).

Because we now make payment under the OPPS for product-specific HCPCS A-codes for synthetic graft skin substitute products and for unclassified synthetic graft skin substitute products and other unclassified FDA 510(k)-cleared products identified by HCPCS code A4100, HCPCS code C1849 is no longer necessary to bill for these products when they are used in the hospital outpatient department with graft skin substitute application procedures. In addition to being unnecessary, we are also concerned that the continued existence of HCPCS code C1849 may lead to confusion among providers regarding which HCPCS code to report on a claim if it is not retired, as there are currently two codes that can be reported in the hospital outpatient department setting when a synthetic graft skin substitute product is used: HCPCS code C1849, which can be used for any synthetic skin substitute, or the code in the HCPCS A2XXX series that describes the specific synthetic graft skin substitute product. For these reasons, we believe it is important to retire HCPCS code C1849.

Nonetheless, we do not simply want to retire this code without making accompanying proposals to ensure that synthetic graft skin substitute products that either currently have a product-specific HCPCS code or may receive a product-specific HCPCS code in the future and are currently assigned to the high cost skin substitute group continue to be assigned to the high cost skin substitute group after the retirement of HCPCS code C1849. Most synthetic graft skin substitute products have less than 2 years of claims data and would not have cost data for us to review to determine if the products could be assigned to the high cost group. If the product manufacturers do not send WAC pricing data to us, the products would have to be assigned to

the low cost group because of a lack of cost information. Submitting WAC pricing to have a skin substitute assigned to the high cost group is voluntary for manufacturers. Establishing a policy to continue to assign synthetic graft skin substitute products that are currently described by HCPCS code C1849 or would be described by HCPCS code C1849 to the high cost skin substitute group would allow manufacturers and providers to better forecast payment for synthetic graft skin substitute products, and protect them from unanticipated payment reductions. This proposal is consistent with our proposed policy in section V.B.7.b in this proposed rule that any skin substitute product that was assigned to the high cost group in CY 2022 would be continue to be assigned to the high cost group for CY 2023, regardless of whether it exceeds or falls below the CY 2023 MUC or PDC threshold, which has been our standard practice since CY 2018. Both of these proposals promote price stability for both manufacturers and providers and eliminate the risk that a skin substitute product that is currently assigned to the high cost skin substitute group would be reassigned to the low cost skin substitute group.

In summary, for CY 2023, we propose to delete HCPCS code C1849 (Skin substitute, synthetic, resorbable, by per square centimeter). We also propose that any graft skin substitute product that is currently assigned a product-specific code in the HCPCS A2XXX series and is appropriately described by HCPCS code C1849 or is assigned a product-specific code in the HCPCS A2XXX series in the future and is appropriately described by HCPCS code C1849 be assigned to the high cost skin substitute group. We want to ensure synthetic graft skin substitute products continue to remain in the high cost skin substitute group throughout CY 2023 and do not risk reassignment to the low cost group during the transition from using HCPCS code C1849 to a product-specific A-codes even if cost and pricing data are not available for these products. We believe this policy would promote payment stability for providers and other stakeholders when using synthetic graft skin substitute products consistent with our long-standing policy that keeps graft skin substitute products in the high cost group for subsequent years once a product is assigned to the high cost group for a given year.

We also propose that HCPCS code A4100 (Skin substitute, fda cleared as a device, not otherwise specified) be assigned to the low cost skin substitute group, which is consistent with our existing payment policy that unclassified graft skin substitute products be assigned to the low cost skin substitute group. We look forward to comments on these proposals.

d. Key Objectives/Roadmap for consistent treatment of skin substitutes

We believe outlining our HCPCS Level II coding and payment policy objectives in this proposed rule will be beneficial for interested parties, as we work to create a consistent approach for treatment of the suite of products we have referred to as skin substitutes. We have a number of objectives related to refining Medicare policies in this area, including: 1) ensuring a consistent payment approach for skin substitute products across the physician office and hospital outpatient department setting; 2) ensuring that all skin substitute products are assigned an appropriate HCPCS code; 3) using a uniform benefit category across products within the physician office setting, regardless of whether the product is synthetic or comprised of human or animal based material, so we can incorporate payment methodologies that are more consistent; and 4) maintaining clarity for interested parties on CMS skin substitutes policies and procedures.

Interested parties have asked CMS to address what they have described as inconsistencies in our payment and coding policies, indicating that treating clinically similar products (for example, animal-based and synthetic skin products) differently for purposes of payment is confusing and problematic for healthcare providers and patients. These concerns exist specifically within the physician office setting; however, interested parties have also indicated that further alignment of our policies across the physician office and hospital outpatient department settings would reduce confusion.

Interested parties have suggested that all skin substitutes, regardless of the inclusion of human, animal, or synthetic material in the product, should be treated as drugs and biological products. Furthermore, they believe all skin substitute products should receive product-specific “Q” codes and receive separate payment under the ASP+6 methodology. They have expressed

confusion regarding our assignment of HCPCS Level II “A” codes to the 10 skin substitute products in accordance with the policy finalized in the CY 2022 PFS final rule, which we typically assign to identify ambulance services and medical supplies, instead of “Q” codes, which we typically assign to identify drugs, biologicals, and medical equipment or services not identified by national HCPCS Level II codes. They have indicated that the use of “A” HCPCS codes has caused confusion, not only for interested parties, but also for the A/B MACs, who the interested parties assert, have inconsistently processed submitted claims, in part because they are assigned HCPCS “A” codes that are treated as supplies, which are subject to contractor pricing under the PFS. Additionally, interested parties have expressed concern that physicians and other practitioners are hesitant to use the products associated with “A” codes because they are unsure if they will be paid appropriately for using those products. When considering potential changes to policies involving skin substitutes, we believe it would be appropriate to take a phased approach over the next 1 to 5 years, that allows CMS sufficient time to consider input from interested parties on coding and policy changes primarily through our rulemaking process, and to account for FDA’s regulation of these products, with the goal of avoiding unintended impacts on access to medically necessary care involving the use of these products.

We welcome comment on our policy objectives for creating a consistent approach for treatment of the suite of products we have referred to as skin substitutes. Additionally, we welcome feedback on our phased approach and associated timeline. To achieve our objective of creating a consistent approach for paying for skin substitutes across the physician office and hospital outpatient department setting, we are including similar proposed changes in the CY 2023 PFS proposed rule, which will be issued near the time this proposed rule is issued.

e. Changing the Terminology of Skin Substitutes

As we work to clarify our policies for these products, we believe that the existing terminology of “skin substitutes” is problematic as it is an overly broad misnomer. In the CY 2021 OPPS/ASC final rule with comment period, we revised our description of skin

substitutes to refer to a category of biological and synthetic products that are most commonly used in outpatient settings for the treatment of diabetic foot ulcers and venous leg ulcers (85 FR 80605). We noted that skin substitute products are not a substitute for a skin graft as they do not actually function like human skin that is grafted onto a wound. Instead, these products are applied to wounds to aid wound healing and through various mechanisms of action they stimulate the host to regenerate lost tissue. We also clarified that our definition of skin substitutes does not include bandages or standard dressings, and that within the hospital outpatient department, these items cannot be assigned to either the high cost or low-cost skin substitute groups or be reported with either CPT codes 15271 through 15278 or HCPCS codes C5271 through C5278. (85 FR 86066).

While this definition has been updated to provide clarity in that synthetic products are considered to be skin substitutes, there is still confusion with the usage of the term skin substitutes because, as noted above in the definition, these skin substitute products are technically not a substitute for skin, but rather, a wound covering that is used to promote healing. We have used the term “skin substitutes” to describe the suite of products that are currently referred to as skin substitutes. Additionally, the term “skin substitutes” is used within the Current Procedural Terminology (CPT®) code series 15271-8 as maintained by American Medical Association. Also, skin substitute products are generally regulated by the FDA as medical devices under section 510(k) of the Federal Food, Drug and Cosmetic (FD&C) Act and implementing regulations per 21 CFR part 807, or as HCT/Ps solely under section 361 of the PHS Act and the FDA regulations in 21 CFR part 1271.

We believe that improving how we reference these products by using a more accurate and meaningful term will help address confusion among interested parties about how we describe these products, and further, how we pay for them. We propose to replace the term “skin substitutes” with the term “wound care management” or “wound care management products.” We believe this new term more accurately describes the suite of products that are currently

referred to as skin substitutes while providing enough specificity to not include bandages or standard dressings, which, as noted above, are not considered skin substitutes. We understand that our proposed terms contain “care management” which could be construed to implicate the care management series of AMA CPT codes (e.g., 99424-99427, 99437, 99439, 99487, 99489, 99490-99491) that are commonly used by healthcare professionals. We also understand that the use of our proposed terms with “management” in our proposed terms might be construed by some to implicate AMA CPT Evaluation or Assessment and Management (E/M) codes. We would like to clarify that the proposed terms “wound care management” and “wound care management products” would not implicate the care management series of AMA CPT codes (e.g., 99424-99427, 99437, 99439, 99487, 99489, 99490-99491), or our own G-codes that describe care management services. Nor would our proposed terms relate to the AMA CPT E/M codes. Unlike “care management” or “evaluation and management” codes and services, the proposed terms would describe a category of items or products, not a type of services. Lastly, we also considered alternate terms such as wound coverings, wound dressings, wound care products, skin coverings and cellular and/or tissue-based products for skin wounds but believe the proposed terms are more technically accurate and descriptive for how these products are used than the alternative’s considered.

We solicit feedback on our proposal to change the terminology we use for the suite of products referred to as “skin substitutes” to instead use the term “wound care management” or “wound care management products” and on the alternative terms we considered, including wound coverings, wound dressings, wound care products, skin coverings and cellular and/or tissue-based products for skin wounds. We are particularly interested in how these products are referenced in current CPT coding and would appreciate feedback from the CPT Editorial Panel and other interested parties on how to address the challenges we discuss above. We also are interested in feedback on other possible terms that could be used to more meaningfully and accurately describe the suite of products currently referred to as skin substitutes.

8. Radioisotopes Derived from Non-Highly Enriched Uranium (non-HEU) Sources

Radioisotopes are widely used in modern medical imaging, particularly for cardiac imaging and predominantly for the Medicare population. Some of the Technetium-99 (Tc-99m), the radioisotope used in the majority of such diagnostic imaging services, has been produced in legacy reactors outside of the United States using highly enriched uranium (HEU).

The United States wanted to eliminate domestic reliance on these reactors, and has been promoting the conversion of all medical radioisotope production to non-HEU sources.

Alternative methods for producing Tc-99m without HEU are technologically and economically viable, but it was expected that this change in the supply source for the radioisotope used for modern medical imaging would introduce new costs into the payment system that were not accounted for in the historical claims data.

Therefore, beginning in CY 2013, we finalized a policy to provide an additional payment of \$10 for the marginal cost for radioisotopes produced by non-HEU sources (77 FR 68323). Under this policy, hospitals report HCPCS code Q9969 (Tc-99m from non-highly enriched uranium source, full cost recovery add-on per study dose) once per dose along with any diagnostic scan or scans furnished using Tc-99m as long as the Tc-99m doses used can be certified by the hospital to be at least 95 percent derived from non-HEU sources (77 FR 68323).

We stated in the CY 2013 OPPTS/ASC final rule with comment period (77 FR 68321) that our expectation was that this additional payment would be needed for the duration of the industry's conversion to alternative methods to producing Tc-99m without HEU. We also stated that we would reassess, and propose if necessary, on an annual basis whether such an adjustment continued to be necessary and whether any changes to the adjustment were warranted (77 FR 68321). A 2016 report from the National Academies of Sciences, Engineering, and Medicine anticipated the conversion of Tc-99m production from non-HEU sources would be

completed at the end of 2019.¹²⁴ However, the Secretary of Energy issued a certification effective January 2, 2020, stating that there continued to be an insufficient global supply of molybdenum-99 (Mo-99), which is the source of Tc-99m, produced without the use of HEU available to satisfy the domestic U.S. market (85 FR 3362). The January 2, 2020, certification was to remain in effect for up to two years.

The Secretary of Energy issued a new certification regarding the supply of non-HEU-sourced Mo-99 effective January 2, 2022 (86 FR 73270). This certification stated that there is a sufficient global supply of Mo-99 produced without the use of HEU available to meet the needs of patients in the United States. The Department of Energy also expects that the last HEU reactor that produces Mo-99 for medical providers in the United States will finish its conversion to a non-HEU reactor by December 31, 2022. In CY 2019, we stated that we would reassess the non-HEU incentive payment policy once conversion to non-HEU sources is closer to completion or has been completed (83 FR 58979). There is now a sufficient supply of non-HEU-sourced Mo-99 in the United States, and by CY 2023, there will be no available supply of HEU-sourced Mo-99 in the United States. Therefore, we believe that the conversion to non-HEU sources of Tc-99m has reached a point where a reassessment of the policy is necessary.

In the OPPS, diagnostic radiopharmaceuticals are packaged into the cost of the associated diagnostic imaging procedure no matter the per day cost amount of the radiopharmaceutical. The cost of the radiopharmaceutical is included as a part of the cost of the diagnostic imaging procedure and is reported through Medicare claims data. Medicare claims data used to set payment rates under the OPPS generally is from two years prior to the payment year.

That means that the likely claims data used to set payment rates for CY 2023 (CY 2021 claims data) and CY 2024 (CY 2022 claims data) would likely contain claims for diagnostic

¹²⁴ National Academies of Sciences, Engineering, and Medicine. 2016. Molybdenum-99 for Medical Imaging. Washington, DC: The National Academies Press. Available at: <https://doi.org/10.17226/23563>.

radiopharmaceuticals that would reflect both HEU-sourced Tc-99m and non-HEU-sourced Tc-99m, rather than radiopharmaceuticals sourced solely from non-HEU Tc-99m. The cost of HEU-sourced Tc-99m is substantially lower than the cost of non-HEU-sourced Tc-99m. Therefore, providers using radiopharmaceuticals that only contain non-HEU-sourced Tc-99m might not receive a payment that is reflective of the radiopharmaceutical's current cost without the add-on payment. We believe that extending the additional \$10 add-on payment described by HCPCS code Q9969 for non-HEU-sourced Tc-99m through the end of CY 2024 would help to prevent any underpayment for non-HEU-sourced Tc-99m. Starting in CY 2025, the Medicare claims data utilized to set payment rates (likely CY 2023 claims data) will only include claims for diagnostic radiopharmaceuticals that utilized non-HEU-sourced Tc-99m, which means the data will reflect the full cost of the Tc-99m diagnostic radiopharmaceuticals that will be used by providers in CY 2025. As a result, there will no longer be a need for the additional \$10 add-on payment for CY 2025 or future years.

For CY 2023 and CY 2024, we propose to continue the additional \$10 payment to ensure providers receive sufficient payment for diagnostic radiopharmaceuticals containing Tc-99m until such time as the full cost of non-HEU-sourced Tc-99m is reflected in the Medicare claims data. We also propose that the additional \$10 payment will end after December 31, 2024, since beginning with CY 2025, the Medicare claims data used to set payment rates will reflect the full cost of non-HEU-sourced Tc-99m. We look forward to comments on our proposals.

C. Proposal in Physician Fee Schedule Proposed Rule to Require HOPDs and ASCs to Report Discarded Amounts of Certain Single-dose or Single-use Package Drugs

Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117-9, November 15, 2021) ("the Infrastructure Act") amended section 1847A of the Act to re-designate subsection (h) as subsection (i) and insert a new subsection (h), which requires manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. Section III.A. of the CY 2023 PFS proposed rule includes proposals

to implement section 90004 of the Infrastructure Act, including a proposal that hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs) would be required to report the JW modifier or any successor modifier to identify discarded amounts of refundable single-dose container or single-use package drugs that are separately payable under the OPSS or ASC payment system. Specifically, we propose in the CY 2023 PFS proposed rule that the JW modifier would be used to determine the total number of billing units of the HCPCS code (that is, the identifiable quantity associated with a HCPCS code, as established by CMS) of a refundable single-dose container or single-use package drug, if any, that were discarded for dates of service during a relevant quarter for the purpose of calculating the refund amount described in section 1847A(h)(3) of the Act. The CY 2023 PFS proposed rule also proposes to require HOPDs and ASCs to use a separate modifier, JZ, in cases where no billing units of such drugs were discarded and for which the JW modifier would be required if there were discarded amounts.

Because the CY 2023 PFS proposed rule proposes to codify certain billing requirements for HOPDs and ASCs, we want to ensure interested parties are aware of them and know to refer to that rule for a full description of the proposed policy. Interested parties should submit comments on this and any other proposals to implement Section 90004 of the Infrastructure Act in response to the CY 2023 PFS proposed rule. Public comments on these proposals will be addressed in the CY 2023 PFS final rule. We note that this same notice appears in section XIII.D.3 of this proposed rule.

VI. Proposed Estimate of OPSS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices

A. Amount of Additional Payment and Limit on Aggregate Annual Adjustment

Section 1833(t)(6)(E) of the Act limits the total projected amount of transitional pass-through payment for drugs, biologicals, and categories of devices for a given year to an “applicable percentage,” currently not to exceed 2.0 percent of total program payments estimated

to be made for all covered services under the OPPS furnished for that year. If we estimate before the beginning of the calendar year that the total amount of pass-through payments in that year would exceed the applicable percentage, section 1833(t)(6)(E)(iii) of the Act requires a uniform prospective reduction in the amount of each of the transitional pass-through payments made in that year to ensure that the limit is not exceeded. We estimate the pass-through spending to determine whether payments exceed the applicable percentage and the appropriate pro rata reduction to the conversion factor for the projected level of pass-through spending in the following year to ensure that total estimated pass-through spending for the prospective payment year is budget neutral, as required by section 1833(t)(6)(E) of the Act.

For devices, developing a proposed estimate of pass-through spending in CY 2023 entails estimating spending for two groups of items. The first group of items consists of device categories that are currently eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2023. The CY 2008 OPPS/ASC final rule with comment period (72 FR 66778) describes the methodology we have used in previous years to develop the pass-through spending estimate for known device categories continuing into the applicable update year. The second group of items consists of devices that we know are newly eligible, or project may be newly eligible, for device pass-through payment in the remaining quarters of CY 2022 or beginning in CY 2023. The sum of the proposed CY 2023 pass-through spending estimates for these two groups of device categories equals the proposed total CY 2023 pass-through spending estimate for device categories with pass-through payment status. We determined the device pass-through estimated payments for each device category based on the amount of payment as required by section 1833(t)(6)(D)(ii) of the Act, and as outlined in previous rules, including the CY 2014 OPPS/ASC final rule with comment period (78 FR 75034 through 75036). We note that, beginning in CY 2010, the pass-through evaluation process and pass-through payment methodology for implantable biologicals newly approved for pass-through payment beginning on or after January 1, 2010, that are surgically inserted or

implanted (through a surgical incision or a natural orifice) use the device pass-through process and payment methodology (74 FR 60476). As has been our past practice (76 FR 74335), in the proposed rule, we proposed to include an estimate of any implantable biologicals eligible for pass-through payment in our estimate of pass-through spending for devices. Similarly, we finalized a policy in CY 2015 that applications for pass-through payment for skin substitutes and similar products be evaluated using the medical device pass-through process and payment methodology (76 FR 66885 through 66888). Therefore, as we did beginning in CY 2015, for CY 2023, we also propose to include an estimate of any skin substitutes and similar products in our estimate of pass-through spending for devices.

For drugs and biologicals eligible for pass-through payment, section 1833(t)(6)(D)(i) of the Act establishes the pass-through payment amount as the amount by which the amount authorized under section 1842(o) of the Act (or, if the drug or biological is covered under a competitive acquisition contract under section 1847B of the Act, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and year established under such section as calculated and adjusted by the Secretary) exceeds the portion of the otherwise applicable fee schedule amount that the Secretary determines is associated with the drug or biological. Our estimate of drug and biological pass-through payment for CY 2023 for this group of items is \$622.6 million, as discussed below, because we propose that most non pass-through separately payable drugs and biologicals would be paid under the CY 2023 OPPS at ASP+6 percent with the exception of 340B-acquired separately payable drugs, which we formally propose would be paid at ASP minus 22.5 percent, and because we propose to pay for CY 2023 pass-through payment drugs and biologicals at ASP+6 percent, as we discuss in section V.A of this proposed rule. However, in light of the Supreme Court's recent decision, we fully anticipate applying a rate of ASP+6 percent to 340B drugs and biologicals in the final rule for CY 2023, in which case our estimate of drug and biological pass-through payment for CY 2023 for this group of items is \$29.9 million.

Furthermore, payment for certain drugs, specifically diagnostic radiopharmaceuticals and contrast agents without pass-through payment status, is packaged into payment for the associated procedures, and these products are not separately paid. In addition, we policy-package all non pass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, drugs and biologicals that function as supplies when used in a surgical procedure, drugs and biologicals used for anesthesia, and other categories of drugs and biologicals, as discussed in section V.B.1.c of this proposed rule. We propose that all of these policy-packaged drugs and biologicals with pass-through payment status will be paid at ASP+6 percent, like other pass-through drugs and biologicals, for CY 2023, less the policy-packaged drug APC offset amount described below. Our estimate of pass-through payment for policy-packaged drugs and biologicals with pass-through payment status approved prior to CY 2023 is not \$0. This is because the pass-through payment amount and the fee schedule amount associated with the drug or biological will not be the same, unlike for separately payable drugs and biologicals. In section V.A.6 of this proposed rule, we discuss our policy to determine if the costs of certain policy-packaged drugs or biologicals are already packaged into the existing APC structure. If we determine that a policy-packaged drug or biological approved for pass-through payment resembles predecessor drugs or biologicals already included in the costs of the APCs that are associated with the drug receiving pass-through payment, we propose to offset the amount of pass-through payment for the policy-packaged drug or biological. For these drugs or biologicals, the APC offset amount is the portion of the APC payment for the specific procedure performed with the pass-through drug or biological, which we refer to as the policy-packaged drug APC offset amount. If we determine that an offset is appropriate for a specific policy-packaged drug or biological receiving pass-through payment, we propose to reduce our estimate of pass-through payments for these drugs or biologicals by the APC offset amount.

Similar to pass-through spending estimates for devices, the first group of drugs and biologicals requiring a pass-through payment estimate consists of those products that were

recently made eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2023. The second group contains drugs and biologicals that we know are newly eligible, or project will be newly eligible, in the remaining quarters of CY 2022 or beginning in CY 2023. The sum of the CY 2023 pass-through spending estimates for these two groups of drugs and biologicals equals the total CY 2023 pass-through spending estimate for drugs and biologicals with pass-through payment status.

B. Proposed Estimate of Pass-Through Spending for CY 2023

For CY 2023, we propose to set the applicable pass-through payment percentage limit at 2.0 percent of the total projected OPSS payments for CY 2023, consistent with section 1833(t)(6)(E)(ii)(II) of the Act and our OPSS policy from CY 2004 through CY 2022 (86 FR 63659). The pass-through payment percentage limit is calculated using pass-through spending estimates for devices and for drugs and biologicals.

For the first group of devices, consisting of device categories that are currently eligible for pass-through payment and will continue to be eligible for pass-through payment in CY 2023, there are 14 active categories for CY 2023. The active categories are described by HCPCS codes C1052, C1062, C1734, C1748, C1761, C1823, C1824, C1825, C1831, C1832, C1833, C1839, C1982 and C2596. Based on the information from the device manufacturers, we estimate that HCPCS code C1052 will cost \$162,000 in pass-through expenditures in CY 2023, HCPCS C1062 will cost \$1.9 million in pass-through expenditures in CY 2023, HCPCS code C1734 will cost \$2.2 million in pass-through expenditures in CY 2023, HCPCS code C1748 will cost \$2.2 million in pass-through expenditures in CY 2023, HCPCS code C1761 will cost \$9.9 million in pass-through expenditures in CY 2023, HCPCS code C1823 will cost \$1.5 million in pass-through expenditures in CY 2023, HCPCS code C1824 will cost \$1.5 million pass-through expenditures in CY 2023, HCPCS code C1825 will cost \$749,000 in pass-through expenditures in CY 2023, HCPCS code C1831 will cost \$29,900 in pass-through expenditures in CY 2023, HCPCS code C1832 will cost \$18.4 million in pass-through expenditures in CY 2023, HCPCS

code C1833 will cost \$5.1 million in pass-through expenditures in CY 2023, HCPCS code C1839 will cost \$138,000 in pass-through expenditures in CY 2023, HCPCS code C1982 will cost \$1.2 million in pass-through expenditures in CY 2023, HCPCS code C2596 will cost \$2.8 million in pass-through expenditures in CY 2023. Therefore, we propose an estimate for the first group of devices of \$48 million.

In estimating our proposed CY 2023 pass-through spending for device categories in the second group, we included: device categories that we assumed at the time of the development of the proposed rule will be newly eligible for pass-through payment in CY 2023; additional device categories that we estimated could be approved for pass-through status after the development of this proposed rule and before January 1, 2023; and contingent projections for new device categories established in the second through fourth quarters of CY 2023. For CY 2023, we propose to use the general methodology described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66778), while also taking into account recent OPPS experience in approving new pass-through device categories. For this proposed rule, the proposed estimate of CY 2023 pass-through spending for this second group of device categories is \$101.4 million.

To estimate proposed CY 2023 pass-through spending for drugs and biologicals in the first group, specifically those drugs and biologicals recently made eligible for pass-through payment and continuing on pass-through payment status for at least one quarter in CY 2023, we propose to use the CY 2021 Medicare hospital outpatient claims data regarding their utilization, information provided in the respective pass-through applications, other historical hospital claims data, pharmaceutical industry information, and clinical information regarding these drugs and biologicals to project the CY 2023 OPPS utilization of the products.

For the known drugs and biologicals (excluding policy-packaged diagnostic radiopharmaceuticals, contrast agents, drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, and drugs and biologicals that function as supplies when used in a surgical procedure) that will be continuing on pass-through payment

status in CY 2023, we estimate the pass-through payment amount as the difference between ASP+6 percent and the payment rate for non pass-through drugs and biologicals that will be separately paid. Separately payable drugs are paid at a rate of ASP+6 percent with the exception of 340B-acquired drugs, which we formally propose to pay at ASP minus 22.5 percent. Therefore, the proposed payment rate difference between the pass-through payment amount and the non pass-through payment amount is \$592.7 million for this group of drugs. However, in light of the Supreme Court's recent decision, we fully anticipate applying a rate of ASP+6 percent to 340B drugs and biologicals in the final rule for CY 2023, in which case, the proposed payment rate difference between the pass-through payment amount and the non pass-through payment amount is \$0 for this group of drugs.

Because payment for policy-packaged drugs and biologicals is packaged if the product is not paid separately due to its pass-through payment status, we propose to include in the CY 2023 pass-through estimate the difference between payment for the policy-packaged drug or biological at ASP+6 percent (or WAC+6 percent, or 95 percent of AWP, if ASP or WAC information is not available) and the policy-packaged drug APC offset amount, if we determine that the policy-packaged drug or biological approved for pass-through payment resembles a predecessor drug or biological already included in the costs of the APCs that are associated with the drug receiving pass-through payment, which we estimate for CY 2023 for the first group of policy-packaged drugs to be \$19.9 million.

To estimate proposed CY 2023 pass-through spending for drugs and biologicals in the second group (that is, drugs and biologicals that we knew at the time of development of this proposed rule were newly eligible or recently became eligible for pass-through payment in CY 2023, additional drugs and biologicals that we estimated could be approved for pass-through status subsequent to the development of this proposed rule and before January 1, 2023, and projections for new drugs and biologicals that could be initially eligible for pass-through payment in the second through fourth quarters of CY 2023), we propose to use utilization

estimates from pass-through applicants, pharmaceutical industry data, clinical information, recent trends in the per unit ASPs of hospital outpatient drugs, and projected annual changes in service volume and intensity as our basis for making the CY 2023 pass-through payment estimate. We also propose to consider the most recent OPSS experience in approving new pass-through drugs and biologicals. Using our proposed methodology for estimating CY 2023 pass-through payments for this second group of drugs, we calculated a proposed spending estimate for this second group of drugs and biologicals of approximately \$10 million.

We estimate for this proposed rule that the amount of pass-through spending for the device categories and the drugs and biologicals that are continuing to receive pass-through payment in CY 2023 and those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2023 would be approximately \$772.0 million (approximately \$149.4 million for device categories and approximately \$622.6 million for drugs and biologicals) which represents 0.90 percent of total projected OPSS payments for CY 2023 (approximately \$86.2 billion). In light of the Supreme Court's recent decision, we fully anticipate applying a rate of ASP+6 percent to 340B drugs and biologicals in the final rule for CY 2023, in light of the Supreme Court's recent decision, in which case we would estimate for this proposed rule that the amount of pass-through spending for the device categories and the drugs and biologicals that are continuing to receive pass-through payment in CY 2023 and those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2023 would be approximately \$179.3 million (approximately \$149.4 million for device categories and approximately \$29.9 million for drugs and biologicals). This alternative would represent only 0.21 percent of total projected OPSS payments for CY 2023. Therefore, we estimate that pass-through spending in CY 2023 will not amount to 2.0 percent of total projected OPSS CY 2023 program spending.

VII. Proposed OPSS Payment for Hospital Outpatient Visits and Critical Care Services

For CY 2023, we propose to continue with our current clinic and emergency department (ED) hospital outpatient visits payment policies. For a description of these policies, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70448). We also propose to continue our payment policy for critical care services for CY 2023. For a description of this policy, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70449), and for the history of this payment policy, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75043).

In this proposed rule, we are seeking public comments on any changes to these codes that we should consider for future rulemaking cycles. We continue to encourage commenters to provide the data and analysis necessary to justify any suggested changes.

As we stated in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63663), the clinic visit payment policy applies for CY 2023 and subsequent years. More specifically, we are continuing to utilize a PFS-equivalent payment rate for the hospital outpatient clinic visit service described by HCPCS code G0463 when it is furnished by excepted off-campus provider-based departments. The PFS-equivalent rate for CY 2023 is 40 percent of the proposed OPPS payment (that is, 60 percent less than the proposed OPPS rate). Under this policy, these departments will be paid approximately 40 percent of the OPPS rate (100 percent of the OPPS rate minus the 60-percent payment reduction that is applied in CY 2023) for the clinic visit service in CY 2023. Additionally, for CY 2023 we propose that excepted off-campus provider-based departments (PBDs) (departments that bill the modifier “PO” on claim lines) of rural Sole Community Hospitals, as described under 42 CFR 412.92 and designated as rural for Medicare payment purposes, would be exempt from the clinic visit payment policy that applies a Physician Fee Schedule-equivalent payment rate for the clinic visit service, as described by HCPCS code G0463, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act. For the full discussion of this proposal we refer readers to section X of this proposed

rule. We will continue to monitor the effect of this change in Medicare payment policy, including on the volume of these types of OPD services.

VIII. Proposed Payment for Partial Hospitalization Services

A. Background

A partial hospitalization program (PHP) is an intensive outpatient program of psychiatric services provided as an alternative to inpatient psychiatric care for individuals who have an acute mental illness, which includes, but is not limited to, conditions such as depression, schizophrenia, and substance use disorders. Section 1861(ff)(1) of the Act defines partial hospitalization services as the items and services described in paragraph (2) prescribed by a physician and provided under a program described in paragraph (3) under the supervision of a physician pursuant to an individualized, written plan of treatment established and periodically reviewed by a physician (in consultation with appropriate staff participating in such program), which sets forth the physician's diagnosis, the type, amount, frequency, and duration of the items and services provided under the plan, and the goals for treatment under the plan. Section 1861(ff)(2) of the Act describes the items and services included in partial hospitalization services. Section 1861(ff)(3)(A) of the Act specifies that a PHP is a program furnished by a hospital to its outpatients or by a community mental health center (CMHC), as a distinct and organized intensive ambulatory treatment service, offering less than 24-hour-daily care, in a location other than an individual's home or inpatient or residential setting. Section 1861(ff)(3)(B) of the Act defines a CMHC for purposes of this benefit. We refer readers to sections 1833(t)(1)(B)(i), 1833(t)(2)(B), 1833(t)(2)(C), and 1833(t)(9)(A) of the Act and 42 CFR 419.21, for additional guidance regarding PHP.

In CY 2008, we began efforts to strengthen the PHP benefit through extensive data analysis, along with policy and payment changes by implementing two refinements to the methodology for computing the PHP median. For a detailed discussion on these policies, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66670 through

66676). In CY 2009, we implemented several regulatory, policy, and payment changes. For a detailed discussion on these policies, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68688 through 68697). In CY 2010, we retained the two-tier payment approach for partial hospitalization services and used only hospital-based PHP data in computing the PHP APC per diem costs, upon which PHP APC per diem payment rates are based (74 FR 60556 through 60559). In CY 2011 (75 FR 71994), we established four separate PHP APC per diem payment rates: two for CMHCs (APC 0172 and APC 0173) and two for hospital-based PHPs (APC 0175 and APC 0176) and instituted a 2-year transition period for CMHCs to the CMHC APC per diem payment rates. For a detailed discussion, we refer readers to section X.B of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71991 through 71994). In CY 2012, we determined the relative payment weights for partial hospitalization services provided by CMHCs based on data derived solely from CMHCs and the relative payment weights for partial hospitalization services provided by hospital-based PHPs based exclusively on hospital data (76 FR 74348 through 74352). In the CY 2013 OPPS/ASC final rule with comment period, we finalized our proposal to base the relative payment weights that underpin the OPPS APCs, including the four PHP APCs (APCs 0172, 0173, 0175, and 0176), on geometric mean costs rather than on the median costs. For a detailed discussion on this policy, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68406 through 68412).

In the CY 2014 OPPS/ASC proposed rule (78 FR 43621 through 43622) and CY 2015 OPPS/ASC final rule with comment period (79 FR 66902 through 66908), we continued to apply our established policies to calculate the four PHP APC per diem payment rates based on geometric mean per diem costs using the most recent claims data for each provider type. For a detailed discussion on this policy, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75047 through 75050). In the CY 2016, we described our extensive analysis of the claims and cost data and ratesetting methodology, corrected a cost inversion that

occurred in the final rule data with respect to hospital-based PHP providers and renumbered the PHP APCs. In CY 2017 OPPS/ASC final rule with comment period (81 FR 79687 through 79691), we continued to apply our established policies to calculate the PHP APC per diem payment rates based on geometric mean per diem costs and finalized a policy to combine the Level 1 and Level 2 PHP APCs for CMHCs and for hospital-based PHPs. We also implemented an eight-percent outlier cap for CMHCs to mitigate potential outlier billing vulnerabilities. For a comprehensive description of PHP payment policy, including a detailed methodology for determining PHP per diem amounts, we refer readers to the CY 2016 and CY 2017 OPPS/ASC final rules with comment period (80 FR 70453 through 70455 and 81 FR 79678 through 79680).

In the CYs 2018 and 2019 OPPS/ASC final rules with comment period (82 FR 59373 through 59381, and 83 FR 58983 through 58998, respectively), we continued to apply our established policies to calculate the PHP APC per diem payment rates based on geometric mean per diem costs, designated a portion of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHCs, and proposed updates to the PHP allowable HCPCS codes. We finalized these proposals in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61352).

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61339 through 61350), we finalized our proposal to use the calculated CY 2020 CMHC geometric mean per diem cost and the calculated CY 2020 hospital-based PHP geometric mean per diem cost, but with a cost floor equal to the CY 2019 final geometric mean per diem costs as the basis for developing the CY 2020 PHP APC per diem rates. Also, we continued to designate a portion of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS, excluding outlier payments.

In the April 30, 2020 interim final rule with comment (85 FR 27562 through 27566), effective as of March 1, 2020 and for the duration of the COVID-19 Public Health Emergency

(PHE), hospital and CMHC staff are permitted to furnish certain outpatient therapy, counseling, and educational services (including certain PHP services), incident to a physician's services, to beneficiaries in temporary expansion locations, including the beneficiary's home, so long as the location meets all conditions of participation to the extent not waived. A hospital or CMHC can furnish such services using telecommunications technology to a beneficiary in a temporary expansion location if that beneficiary is registered as an outpatient. These provisions apply only for the duration of the COVID-19 PHE.

In the CY 2021 OPSS/ASC final rule with comment period (85 FR 86073 through 86080), we continued our current methodology to utilize cost floors, as needed. Since the final calculated geometric mean per diem costs for both CMHCs and hospital-based PHPs were significantly higher than each proposed cost floor, a floor was not necessary at the time, and we did not finalize the proposed cost floors in the CY 2021 OPSS/ASC final rule with comment period.

In the CY 2022 OPSS/ASC final rule with comment period (86 FR 63665 through 63666), we explained that we observed a number of changes, likely as a result of the COVID-19 PHE, in the CY 2020 OPSS claims that we would have ordinarily used for CY 2022 ratesetting, and this included changes in the claims for partial hospitalization. We explained that significant decreases in utilization and in the number of hospital-based PHP providers who submitted CY 2020 claims led us to believe that CY 2020 data were not the best overall approximation of expected PHP services in CY 2022. Therefore, we finalized our proposal to calculate the PHP per diem costs using the year of claims consistent with the calculations that would be used for other OPSS services, by using the CY 2019 claims and the cost reports that were used for CY 2021 final rulemaking to calculate the CY 2022 PHP per diem costs. In addition, for CY 2022 and subsequent years, we finalized our proposal to use cost and charge data from the Hospital Cost Report Information System (HCRIS) as the source for the CMHC cost-to-charge ratios (CCRs), instead of using the Outpatient Provider Specific File (OPSF) (86 FR 63666).

B. Proposed PHP APC Update for CY 2023

1. Proposed PHP APC Geometric Mean Per Diem Costs

For CY 2023 only, we propose to calculate the CMHC and hospital-based PHP geometric mean per diem costs in accordance with our existing methodology, except that while we propose to use the latest available CY 2021 claims data, we propose to continue to use the cost data that was available for the CY 2021 rulemaking, which is the same cost data used for the CY 2022 rulemaking (86 FR 63665 through 63666). This proposal is consistent with the overall proposed use of cost data for the OPSS, which is discussed in section X.D of this proposed rule.

Following this proposed methodology, we propose to use the geometric mean per diem cost of \$131.71 for CMHCs as the basis for developing the CY 2023 CMHC APC per diem rate, and to use the geometric mean per diem cost of \$264.06 as the basis for developing the CY 2023 hospital-based APC per diem rate. In addition, as discussed in the following sections, we propose not to include data from certain nonstandard cost center lines in the OPSS ratesetting database construction for CY 2023; however, we are requesting information from the public about these data for use in future ratesetting. Lastly, in accordance with our longstanding policy, we propose to continue to use CMHC APC 5853 (Partial Hospitalization (three or More Services Per Day)) and hospital-based PHP APC 5863 (Partial Hospitalization (three or More Services Per Day)). These proposals are discussed in more detail in the following sections.

2. Development of the PHP APC Geometric Mean Per Diem Costs

In preparation for CY 2023, we followed the PHP ratesetting methodology described in section VIII.B.2 of the CY 2016 OPSS/ASC final rule with comment period (80 FR 70462 through 70466) to calculate the PHP APCs' geometric mean per diem costs and payment rates for APCs 5853 and 5863, incorporating the modifications made in the CY 2017 OPSS/ASC final rule with comment period (81 FR 79680 through 79687) and the CY 2022 OPSS/ASC final rule with comment period (86 FR 63665 through 63666). As discussed in section VIII.B.1 of the CY 2017 OPSS/ASC final rule with comment period (81 FR 79680 through 79687), the

geometric mean per diem cost for hospital-based PHP APC 5863 is based upon actual hospital-based PHP claims and costs for PHP service days providing three or more services. Similarly, the geometric mean per diem cost for CMHC APC 5853 is based upon actual CMHC claims and costs for CMHC service days providing three or more services. As discussed in section VIII.B.1.a of the CY 2022 OPPI/ASC final rule with comment period (86 FR 63666 through 63668), the costs for CMHC service days are calculated using cost report information from HCRIS.

As mentioned earlier in this section of this proposed rule, we propose a change from our longstanding practice similar to what we finalized last year in light of the effects of the COVID-19 PHE. We discuss this proposal and our rationale in greater detail in the following paragraphs.

First, we considered whether the latest available CY 2021 claims would be appropriate to use for CY 2023 ratesetting. Ordinarily, the best available claims data is the data from 2 years prior to the calendar year that is the subject of rulemaking. For the CY 2023 OPPI/ASC proposed rule ratesetting, the best available claims data would typically be the 2021 calendar year outpatient claims data processed through December 31, 2021. As discussed in the CY 2022 OPPI/ASC final rule with comment period (86 FR 63665 through 63666), we noted significant decreases in the number of PHP days for both hospital-based PHPs and CMHCs. For this proposed rule, we continue to observe a decrease in the number of hospital-based PHP days in our trimmed CY 2021 claims dataset, which has approximately 18 percent fewer days than the CY 2020 dataset. Likewise, for CMHCs, we continue to observe this decrease in our trimmed CY 2021 claims dataset, which has approximately 32 percent fewer CMHC PHP days than the CY 2020 dataset did. Given the continued effects of COVID-19 observed on the Medicare claims and cost report data, coupled with the expectation for future variants, we believe that it is

reasonable to assume that there will continue to be some limited influence of COVID-19 PHE effects on the data we use for ratesetting.

Despite the continued effects of COVID-19 that we note in the PHP data, we also note that even though hospital operations do not appear to have returned to the same levels as 2019, the Medicare outpatient service volumes appear to be returning to more normal pre-pandemic levels. As discussed in section X.D of this proposed rule, based on our review of the CY 2021 outpatient claims available for ratesetting, we observed that the non-PHP outpatient service volumes are generally about halfway between those in the CY 2019 (pre-PHE) claims and CY 2020 (beginning of the PHE) claims, however, we recognize that future COVID-19 variants may have potentially varying effects and we believe it is reasonable to assume that there will continue to be some effects of COVID-19 PHE on the outpatient claims that we use for ratesetting. As a result, we believe that the more recently available CY 2021 claims data would better represent the volume and mix of claims for the CY 2023 OPPS. Accordingly, we believe it is appropriate to use CY 2021 data for purposes of CY 2023 OPPS ratesetting. Consistent with the proposal discussed in section X.D of this proposed rule, we propose to use the latest available CY 2021 claims for CY 2023 PHP ratesetting.

Next, we reviewed the cost report data from the December 2021 HCRIS data set, which we would ordinarily have used for this CY 2023 OPPS/ASC proposed ratesetting. As discussed in greater detail in section X.D of this proposed rule, we believe cost report data that overlap with CY 2020 are too influenced by the COVID-19 PHE for purposes of calculating the CY 2023 PHP payment rates. In the case of PHP, we observed a negative impact of the cost report data from the December 2021 HCRIS data set on the calculated geometric mean per diem cost for CMHCs. Specifically, we observed that the CMHC geometric mean per diem costs calculated using the latest available cost report data from the December 2021 HCRIS data set would be \$127.38, which would be a decrease from the cost floor of \$136.14 used to calculate the CY 2022 CMHC APC 5853 payment rate (86 FR 63668). Therefore, we believe that it is

appropriate to continue to use the same set of cost reports that we used in developing the CY 2021 OPSS, to mitigate the impact of that 2020-based data. We note that we will continue to review the updated cost report data as they are available.

Based on the results of this analysis, we propose to use the cost information from prior to the COVID-19 PHE – in other words, cost information that was available for the CY 2021 OPSS/ASC rulemaking, which is the same as that used last year for the CY 2022 OPSS/ASC rulemaking (86 FR 63665 through 63669). We would specifically use cost report data from the June 2020 HCRIS data set, which only includes cost report data through CY 2019.

Therefore, consistent with what we propose to do for other APCs under the OPSS as discussed in section X.D of this proposed rule, we propose to use the latest available CY 2021 claims, but use the cost information from prior to the COVID-19 PHE for calculating the CY 2023 CMHC and hospital-based PHP APC per diem costs.

Additionally, as mentioned above and discussed in greater detail in section II.A.1.c of this proposed rule, we have identified that we have historically not included cost report lines for certain nonstandard cost centers in the OPSS ratesetting database construction when hospitals have reported these nonstandard cost centers on cost report lines that do not correspond to the cost center number. We have found that hospitals are routinely reporting a number of nonstandard cost centers in this way. One such cost center is cost center 03550, which is used to report Psychiatric/Psychological Services.¹²⁵ Based on the program logic to process HCRIS data used for OPSS ratesetting, we obtain the cost center number based on the line and subscript number on which the cost center is reported. Our internal analysis of hospital cost report information found that providers are routinely reporting this cost center on cost report lines other than 35.50 (that is, line 35 subscript 50), and therefore, this nonstandard cost center and others reported this way have not been included in the OPSS ratesetting database construction. Our

¹²⁵ Chapter 40 of the Provider Reimbursement Manual (PRM), Part 2, available on the CMS website at <https://www.cms.gov/Regulations-andGuidance/Guidance/Manuals/Paper-Based-Manuals>.

internal analysis shows that including this additional data could potentially decrease the geometric mean cost of APC 5863 (Partial Hospitalizations (3 or more services) for hospital-based PHPs) by 12 percent.

While we generally view the use of additional cost data as improving our OPPS ratesetting process, we have historically not included cost report lines for certain nonstandard cost centers in the OPPS ratesetting database construction when hospitals have reported these nonstandard cost centers on cost report lines that do not correspond to the cost center number. Additionally, we are concerned about the significant changes in APC geometric mean costs that our analysis indicates would occur if we were to include such lines. We believe it is important to further investigate the accuracy of these cost report data before including such data in the ratesetting process. Further, we believe it is appropriate to gather additional information from the public as well before including them in OPPS ratesetting. Therefore, consistent with the proposal at II.A.1.c of this proposed rule for other OPPS services, we propose to not include data from nonstandard cost centers reported on lines that do not correspond to the cost center number in our PHP ratesetting for CY 2023. We are soliciting comment on whether there exist any specific concerns with regards to the accuracy of the data from these nonstandard cost center lines that we would need to consider before including them in future OPPS ratesetting.

a. CMHC Data Preparation: Data Trims, Exclusions, and CCR Adjustments

For this proposed rule, we used HCRIS as the source for the CMHC cost information as discussed in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63666) and prepared data consistent with our policies as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465). However, as discussed above, we propose to use CY 2021 claims data and the cost information from prior to the COVID-19 PHE, that is, the cost

information that was available for the CY 2021 OPPS/ASC rulemaking, for calculating the CY 2023 CMHC PHP APC per diem cost.

Prior to calculating the proposed geometric mean per diem cost for CMHC APC 5853, we prepared the data by first applying trims and data exclusions and assessing CCRs as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465), so that ratesetting is not skewed by providers with extreme data. Before any trims or exclusions were applied, there were 27 CMHCs in the PHP claims data file. Under the ± 2 standard deviation trim policy, we excluded any data from a CMHC for ratesetting purposes when the CMHC's geometric mean cost per day was more than ± 2 standard deviations from the geometric mean cost per day for all CMHCs. In applying this trim for CY 2023 ratesetting, one CMHC had a geometric mean cost per day above the trim's upper limit of \$466.01, and one CMHC had a geometric mean cost per day below the trim's lower limit of \$37.29. Therefore, we are excluding data for ratesetting from these two CMHCs.

In accordance with our PHP ratesetting methodology (80 FR 70465), we also remove service days with no wage index values, because we use the wage index data to remove the effects of geographic variation in costs prior to APC geometric mean per diem cost calculation (80 FR 70465). For this CY 2023 proposed rule ratesetting, no CMHC was missing wage index data for all of its service days and, therefore, no CMHC was excluded. We also exclude providers without any days containing 3 or more units of PHP-allowable services. One provider is excluded from ratesetting because it had no days containing 3 or more units of PHP-allowable services. In addition to our trims and data exclusions, before calculating the PHP APC geometric mean per diem costs, we also assess CCRs (80 FR 70463). Our longstanding PHP OPSS ratesetting methodology defaults any CMHC CCR that is not available or any CMHC CCR greater than one to the statewide hospital CCR associated with the provider's urban/rural designation and their State location (80 FR 70463). For this proposed rule ratesetting, there was one CMHC with a CCR greater than one, and four CMHCs with missing CCR information.

Therefore, we are defaulting the CCRs for these five CMHCs for ratesetting to the applicable statewide hospital CCR for each CMHC based on its urban/rural designation and its State location.

In summary, the application of these data preparation steps resulted in an adjusted CCR during our ratesetting process for five CMHCs having either a CCR greater than one or having no CCR. We are also excluding one CMHC because it had no days containing three or more services, and two CMHCs for failing the ± 2 standard deviation trim resulting in the inclusion of 24 CMHCs. There were 330 CMHC claims removed during data preparation steps due to the ± 2 standard deviation trim or because they either had no PHP-allowable codes or had zero payment days, leaving 3,134 CMHC claims in our CY 2023 proposed ratesetting modeling. After applying all of the previously listed trims, exclusions, and adjustments, we followed the methodology described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70464 through 70465) and modified in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79687 through 79688, and 79691), using the CMHC CCRs calculated based on the cost information from HCRIS as discussed in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63666), to calculate the CMHC APC geometric mean per diem cost.¹²⁶ The calculated CY 2023 geometric mean per diem cost for all CMHCs for providing 3 or more services per day (CMHC APC 5853) is \$131.71, an increase from \$129.93 calculated last year for CY 2022 ratesetting (86 FR 63667).

¹²⁶ Each revenue code on the CMHC claim must have a HCPCS code and charge associated with it. We multiply each claim service line's charges by the CMHC's overall CCR (or statewide CCR, where the overall CCR was greater than 1 or was missing) to estimate CMHC costs. Only the claims service lines containing PHP allowable HCPCS codes and PHP allowable revenue codes from the CMHC claims remaining after trimming are retained for CMHC cost determination. The costs, payments, and service units for all service lines occurring on the same service date, by the same provider, and for the same beneficiary are summed. CMHC service days must have three or more services provided to be assigned to CMHC APC 5853. The final geometric mean per diem cost for CMHC APC 5853 is calculated by taking the n th root of the product of n numbers, for days where three or more services were provided. CMHC service days with costs ± 3 standard deviations from the geometric mean costs within APC 5853 are deleted and removed from modeling. The remaining PHP service days are used to calculate the final geometric mean per diem cost for each PHP APC by taking the n th root of the product of n numbers for days where three or more services were provided.

b. Hospital-Based PHP Data Preparation: Data Trims and Exclusions

For this proposed rule, we prepared data consistent with our policies as described in the CY 2016 OPPTS/ASC final rule with comment period (80 FR 70463 through 70465) for hospital-based PHP providers, which is similar to that used for CMHCs. However, as discussed above, we propose to use CY 2021 claims data and the cost information from prior to the COVID-19 PHE, that is, the cost information that was available for the CY 2021 OPPTS/ASC rulemaking, for calculating the CY 2023 hospital-based PHP APC per diem cost. The CY 2021 PHP claims included data for 334 hospital-based PHP providers for our calculations in this CY 2023 OPPTS/ASC proposed rule.

Consistent with our policies, as stated in the CY 2016 OPPTS/ASC final rule with comment period (80 FR 70463 through 70465), we prepared the data by applying trims and data exclusions. We applied a trim on hospital service days for hospital-based PHP providers with a CCR greater than 5 at the cost center level. To be clear, the CCR greater than 5 trim is a service day-level trim in contrast to the CMHC ± 2 standard deviation trim, which is a provider-level trim. For this proposed rule ratesetting, no hospital-based PHP providers had a CCR greater than 5. Therefore, no hospital-based provider was excluded as a result of this trim. In addition, six hospital-based PHPs were removed for having no days with PHP payment. One hospital-based PHP was removed because none of their days included PHP-allowable HCPCS codes. No hospital-based PHPs were removed for missing wage index data, and a single hospital-based PHP was removed by the OPPTS ± 3 standard deviation trim on costs per day. (We refer readers to the OPPTS Claims Accounting Document, available online at

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>)¹²⁷.

¹²⁷ Click on the link labeled “CY 2023 OPPTS/ASC Notice of Proposed Rulemaking”, which can be found under the heading “Hospital Outpatient Prospective Payment System Rulemaking” and open the claims accounting document link at the bottom of the page, which is labeled “2023 NPRM OPPTS Claims Accounting (PDF)”.

Overall, we removed eight hospital-based PHP providers (6 with no PHP payment) + (1 with no PHP-allowable HCPCS codes) + (1 provider with geometric mean costs per day outside the ± 3 SD limits)], resulting in 326 (334 total – 8 excluded) hospital-based PHP providers in the data used for calculating ratesetting.

After completing these data preparation steps, we calculated the CY 2023 geometric mean per diem cost for hospital-based PHP APC 5863 by following the methodology described in the CY 2016 OPSS/ASC final rule with comment period (80 FR 70464 through 70465) and modified in the CY 2017 OPSS/ASC final rule with comment period (81 FR 79687 and 79691).¹²⁸ The calculated CY 2023 hospital-based PHP APC geometric mean per diem cost for hospital-based PHP providers that provide three or more services per service day (hospital-based PHP APC 5863) is \$264.06, which is an increase from \$253.02 calculated last year for CY 2022 ratesetting (86 FR 63668).

The proposed CY 2023 PHP geometric mean per diem costs are shown in Table 45 and are used to derive the proposed CY 2023 PHP APC per diem rates for CMHCs and hospital-based PHPs. The proposed CY 2023 PHP APC per diem rates are included in Addendum A to this proposed rule (which is available on our website at:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html>).

¹²⁸ Each revenue code on the hospital-based PHP claim must have a HCPCS code and charge associated with it. We multiply each claim service line's charges by the hospital's department-level CCR; in CY 2020 and subsequent years, that CCR is determined by using the PHP-only revenue-code-to-cost-center crosswalk. Only the claims service lines containing PHP-allowable HCPCS codes and PHP-allowable revenue codes from the hospital-based PHP claims remaining after trimming are retained for hospital-based PHP cost determination. The costs, payments, and service units for all service lines occurring on the same service date, by the same provider, and for the same beneficiary are summed. Hospital-based PHP service days must have three or more services provided to be assigned to hospital-based PHP APC 5863. The final geometric mean per diem cost for hospital-based PHP APC 5863 is calculated by taking the n th root of the product of n numbers, for days where three or more services were provided. Hospital-based PHP service days with costs ± 3 standard deviations from the geometric mean costs within APC 5863 are deleted and removed from modeling. The remaining hospital-based PHP service days are used to calculate the final geometric mean per diem cost for hospital-based PHP APC 5863.

TABLE 45: Proposed CY 2023 PHP APC Geometric Mean Per Diem Costs

CY 2023 APC	Group Title	Proposed PHP APC Geometric Mean Per Diem Costs
5853	Partial Hospitalization (three or more services per day) for CMHCs	\$131.71
5863	Partial Hospitalization (three or more services per day) for hospital-based PHPs	\$264.06

C. Outpatient Non-PHP Mental Health Services Furnished Remotely to Partial Hospitalization

Patients after the COVID-19 PHE

1. Background

As discussed in the April 30, 2020 interim final rule with comment entitled “Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency” (85 FR 27562 through 27566), effective as of March 1, 2020 and for the duration of the COVID-19 PHE, hospital and CMHC staff are permitted to furnish certain outpatient therapy, counseling, and educational services (including certain PHP services), incident to a physician’s services, to beneficiaries in temporary expansion locations, including the beneficiary’s home, so long as the location meets all conditions of participation and provider-based rules to the extent not waived. A hospital or CMHC can furnish such services using telecommunications technology to a beneficiary in a temporary expansion location if that beneficiary is registered as an outpatient. These provisions apply only for the duration of the COVID-19 PHE. In that same interim final rule (85 FR 27564), we also stated that although these services can be furnished remotely, all other PHP requirements are unchanged and still in effect, including that all services furnished under the PHP still require an order by a physician, must be supervised by a physician, must be certified by a physician, and must be furnished in accordance with coding requirements by a clinical staff member working within his or her scope of practice. We also stated that in accordance with the longstanding requirements that are detailed in the Medicare Benefit Policy

Manual, Pub 100–02, chapter 6, section 70.3, documentation in the medical record of the reason for the visit and the substance of the visit is required.

We received four comments in response to the April 30, 2020 interim final rule with comment regarding the interim final policy for PHP. One commenter, a national nonprofit organization, expressed support for this flexibility to ensure services are available safely to people with Medicare. Another commenter, a healthcare services company, encouraged CMS to ensure that temporary expansion location policies do not abruptly end at the end of the PHE, and supported a flexible transition policy to better ensure continuity of care as hospitals and communities continue to fight the spread of COVID-19 and recover from the impacts of the virus. One national insurance company voiced support for the flexibilities and noted that a major beneficial component of PHP is the structured patient engagement, which can be achieved in the absence of face-to-face interactions. This commenter stated that they believe these flexibilities are necessary to ensure that PHP beneficiaries continue to have access to the level of care they require. They further noted that for PHP patients, requiring face-to-face only interactions would place both beneficiaries and providers at risk of contracting or spreading the coronavirus, but forgoing care could put beneficiaries at risk for relapse and overdose. This commenter also expressed concern about clerical staff lacking the qualifications to provide the services described, and request further language to clarify the scope of this allowance. Another national insurance company expressed support for the use of live-two-way video interactions via remote technology for the PHP level of care when the same level of care and clinical value as an in-person interaction can be achieved during the PHE. However, this commenter expressed concern about the use of only audio communication to provide PHP services. The commenter explained that audio-only delivery of services does not allow for therapeutic groups and ongoing assessments therefore impeding the ability to achieve the clinical benefits of the programs, and cautioned that if PHP services are delivered ineffectively via audio-only communication, the patient risks relapse and inpatient readmission. We noted in the interim final rule that due to the

intensive nature of PHP we expected PHP services to be furnished using telecommunications technology involving both audio and video. However, we recognized that in some cases beneficiaries might not have access to video communication technology. In order to maintain beneficiary access to PHP services, only in the case that both audio and video are not possible could the service be furnished exclusively with audio (85 FR 27564).

In the CY 2022 OPSS/ASC proposed rule (86 FR 42187), CMS solicited comments on whether there were changes commenters believed we should make to account for shifting patterns of practice that rely on communication technology to provide mental health services to beneficiaries in their homes. We acknowledged that the widespread use of communications technology to furnish services during the PHE has illustrated acceptance within the medical community and among Medicare beneficiaries of the possibility of furnishing and receiving care through the use of that technology, and that we were interested in information on the role of hospital staff in providing care to beneficiaries remotely in their homes.

Although we did not solicit comments on extending the use of remote technology to provide partial hospitalization services to beneficiaries in their homes after the end of the COVID-19 PHE, we received several comments in response to the CY 2022 OPSS/ASC proposed rule expressing support for the flexibilities allowing PHP services to be furnished to beneficiaries in their homes via telecommunication technology during the COVID-19 PHE and encouraging CMS to maintain these flexibilities beyond the PHE or consider making these temporary policies permanent (86 FR 63750). Commenters expressed that these flexibilities, especially those allowing the use of audio-only telecommunication technology, increase access to vital mental health services amidst a persistent shortage of health care professionals and allow much greater and timelier access to mental health services, especially in rural areas and for vulnerable populations, while also helping drive reductions in the rates at which patients missed appointments. Commenters also shared research and analysis supporting the effectiveness of providing PHP services using telecommunication technology. One academic health center

discussed outcomes analysis it conducted of its PHP services and noted that its analysis did not show a decrement in clinical care for patients who received only virtual PHP services. A national association of behavioral healthcare systems shared research showing that the main differences between patients who participated in PHPs via telecommunication technology and those who attended in-person was that those who participated via telecommunication technology had greater lengths of stay and were more likely to stay in treatment until completed¹²⁹. In response to these comments and others that we received pertaining to the comment solicitation, we noted that we would consider them for future rulemaking and that CMS would continue to explore how hospital payment for virtual services could support access to care in underserved and/or rural areas.

2. Outpatient Non-PHP Mental Health Services Furnished Remotely by Hospital Staff to Beneficiaries in Their Homes after the COVID-19 PHE

As discussed in section X.A.5 of this proposed rule, we propose that payment under the OPPTS for new HCPCS codes that designate non-PHP services provided for the purposes of diagnosis, evaluation, or treatment of a mental health disorder and are furnished to beneficiaries in their homes by clinical staff of the hospital. While we are not proposing to recognize these proposed OPPTS remote services as PHP services. We are clarifying here that none of the PHP regulations would preclude a patient that is under a PHP plan of care from receiving other reasonable and medically necessary non-PHP services from a hospital if that proposal is finalized.

Additionally, we are reminding readers that section 1835(a)(2)(F) of the Act requires that in the absence of partial hospitalization services, the individual would require inpatient psychiatric care; that is, partial hospitalization services are in lieu of inpatient hospitalization. This requirement is codified in the PHP regulations at § 424.24(e)(1)(i), which requires that the

¹²⁹ <https://www.psychiatrist.com/jcp/covid-19/telehealth-treatment-patients-intensive-acute-care-psychiatric-setting-during-covid-19/>

PHP patient certification state that the individual would require inpatient psychiatric care if the partial hospitalization services were not provided. Furthermore, in accordance with § 410.43(c)(7), all PHP patients should have the cognitive and emotional ability to participate in the active treatment process and should be able to tolerate the intensity of the partial hospitalization program.

In addition, we reiterate that the physician certification and plan of care requirements at § 424.24(e)(1) and (2) require that each PHP patient must be under an individualized written plan of treatment that is periodically reviewed by a physician in consultation with appropriate staff participating in the program. This plan of treatment must set forth the physician's diagnosis; the type, amount, duration, and frequency of the services; and the treatment goals under the plan. As discussed in the CY 2009 OPPTS/ASC final rule (73 FR 68695), and §410.43(c), partial hospitalization programs are intended for patients who require a minimum of 20 hours per week of therapeutic services as evidenced in a patient's plan of care. We expect that PHP patients are receiving the amount and type of services identified in the plan of care for generally all weeks under the program stated in the plan of care rather than in the actual hours of therapeutic services a patient receives.

In accordance with these requirements, if the proposal at Section X.A.5 is finalized, we expect that a physician would update the patient's PHP plan of care to appropriately reflect any change to the type, amount, duration, or frequency of the therapeutic services planned for that patient in circumstances when a PHP patient receives non-PHP remote mental health services from a hospital outpatient department. The medical documentation should continue to support the patient's eligibility for participation in a PHP.

Lastly, we note that section 1866(e)(2) of the Act includes CMHCs as a Medicare provider of services, but only with respect to the furnishing of partial hospitalization services. As noted earlier in this section, we are not proposing to recognize the proposed OPPTS remote services as PHP services; therefore, CMHCs are not permitted to bill Medicare for any remote

mental health services furnished by clinical staff of the CMHC in an individual's home.

However, a PHP patient who typically receives PHP services at a CMHC could receive non-PHP remote mental health services from a hospital outpatient department if the proposal at section X.A.5 is finalized, or from a physician or other type of practitioner who is authorized to furnish and bill for Medicare telehealth services. As discussed in the following section of this proposed rule, we are requesting information on the need for remote mental health services by CMHC patients, as well as potential pathways CMS could consider to address this need within the current statutory framework.

3. Request for Information Regarding Remote PHP Services Furnished by Hospital Outpatient Departments and CMHCs during the COVID-19 PHE

We are interested in better understanding the use of remote mental health services for PHP patients during the COVID-19 PHE and the potential need for such services in the future among PHP patients who receive care from CMHCs and HOPDs. Specifically, we are requesting public comments on the following questions:

- How have CMHCs and HOPDs used the flexibilities allowing the provision of remote PHP services and incorporated remote PHP services into their operations during the COVID-19 PHE?
- What are the needs and circumstances in which remote PHP services have most often been used? What situations and patient populations have these flexibilities best served? How have these needs, circumstances, and patient populations differed between HOPDs and CMHCs?
- What, if any, barriers would there be to access to remote mental health services for PHP patients of a CMHC? What if any possible pathways do commenters believe might exist to minimize these barriers, while taking into consideration section 1861(ff)(3)(A) of the Act?

While we will not be responding to specific comments submitted in response to this RFI, we intend to use this input to inform future policy development. Please identify the question you

are responding to, and include as much data as possible that supports your responses. We look forward to receiving feedback on these topics.

D. Outlier Policy for CMHCs

For 2023, we propose to continue to calculate the CMHC outlier percentage, cutoff point and percentage payment amount, outlier reconciliation, outlier payment cap, and fixed dollar-threshold according to previously established policies. These topics are discussed in more detail. We refer readers to section II.G.1 of this proposed rule for our general policies for hospital outpatient outlier payments.

1. Background

As discussed in the CY 2004 OPPS final rule with comment period (68 FR 63469 through 63470), we noted a significant difference in the amount of outlier payments made to hospitals and CMHCs for PHP services. Given the difference in PHP charges between hospitals and CMHCs, we did not believe it was appropriate to make outlier payments to CMHCs using the outlier percentage target amount and threshold established for hospitals. Therefore, beginning in CY 2004, we created a separate outlier policy specific to the estimated costs and OPPS payments provided to CMHCs. We designated a portion of the estimated OPPS outlier threshold specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS each year, excluding outlier payments, and established a separate outlier threshold for CMHCs. This separate outlier threshold for CMHCs resulted in \$1.8 million in outlier payments to CMHCs in CY 2004 and \$0.5 million in outlier payments to CMHCs in CY 2005 (82 FR 59381). In contrast, in CY 2003, more than \$30 million was paid to CMHCs in outlier payments (82 FR 59381).

2. CMHC Outlier Percentage

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59267 through 59268), we described the current outlier policy for hospital outpatient payments and CMHCs. We note that we also discussed our outlier policy for CMHCs in more detail in section VIII.C of

that same final rule (82 FR 59381). We set our projected target for all OPPS aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS (82 FR 59267). This same policy was also reiterated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58996), the CY 2020 OPPS/ASC final rule with comment period (84 FR 61350), and the CY 2021 OPPS/ASC final rule with comment period (85 FR 86082).

We estimate CMHC per diem payments and outlier payments by using the most recent available utilization and charges from CMHC claims, updated CCRs, and the updated payment rate for APC 5853. For increased transparency, we are providing a more detailed explanation of the existing calculation process for determining the CMHC outlier percentages. To calculate the CMHC outlier percentage, we follow three steps:

- Step 1: We multiply the OPPS outlier threshold, which is 1.0 percent, by the total estimated OPPS Medicare payments (before outliers) for the prospective year to calculate the estimated total OPPS outlier payments:

$$(0.01 \times \text{Estimated Total OPPS Payments}) = \text{Estimated Total OPPS Outlier Payments.}$$

- Step 2: We estimate CMHC outlier payments by taking each provider's estimated costs (based on their allowable charges multiplied by the provider's CCR) minus each provider's estimated CMHC outlier multiplier threshold (we refer readers to section VIII.C.3 of the CY 2022 OPPS/ASC proposed rule). That threshold is determined by multiplying the provider's estimated paid days by 3.4 times the CMHC PHP APC payment rate. If the provider's costs exceed the threshold, we multiply that excess by 50 percent, as described in section VIII.D.3 of this proposed rule, to determine the estimated outlier payments for that provider. CMHC outlier payments are capped at 8 percent of the provider's estimated total per diem payments (including the beneficiary's copayment), as described in section VIII.D.5 of this proposed rule, so any provider's costs that exceed the CMHC outlier cap will have its payments adjusted downward. After accounting for the CMHC outlier cap, we sum all of the estimated outlier payments to determine the estimated total CMHC outlier payments.

$(\text{Each Provider's Estimated Costs} - \text{Each Provider's Estimated Multiplier Threshold}) = A$.
If A is greater than 0, then $(A \times 0.50) = \text{Estimated CMHC Outlier Payment (before cap)} = B$. If B is greater than $(0.08 \times \text{Provider's Total Estimated Per Diem Payments})$, then cap adjusted- $B = (0.08 \times \text{Provider's Total Estimated Per Diem Payments})$; otherwise, $B = B$. Sum (B or cap-adjusted B) for Each Provider = Total CMHC Outlier Payments.

- Step 3: We determine the percentage of all OPPS outlier payments that CMHCs represent by dividing the estimated CMHC outlier payments from Step 2 by the total OPPS outlier payments from Step 1: $(\text{Estimated CMHC Outlier Payments} / \text{Total OPPS Outlier Payments})$.

We propose to continue to calculate the CMHC outlier percentage according to previously established policies, and we did not propose any changes to our current methodology for calculating the CMHC outlier percentage for CY 2023. Therefore, based on our CY 2023 payment estimates, CMHCs are projected to receive 0.02 percent of total hospital outpatient payments in CY 2023, excluding outlier payments. We proposed to designate approximately less than 0.01 percent of the estimated 1.0 percent hospital outpatient outlier threshold for CMHCs. This percentage is based upon the formula given in Step 3.

3. Cutoff Point and Percentage Payment Amount

As described in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59381), our policy has been to pay CMHCs for outliers if the estimated cost of the day exceeds a cutoff point. In CY 2006, we set the cutoff point for outlier payments at 3.4 times the highest CMHC PHP APC payment rate implemented for that calendar year (70 FR 68551). For CY 2018, the highest CMHC PHP APC payment rate is the payment rate for CMHC PHP APC 5853. In addition, in CY 2002, the final OPPS outlier payment percentage for costs above the multiplier threshold was set at 50 percent (66 FR 59889). In CY 2018, we continued to apply the same 50 percent outlier payment percentage that applies to hospitals to CMHCs and continued to use the existing cutoff point (82 FR 59381). Therefore, for CY 2018, we continued to pay for partial

hospitalization services that exceeded 3.4 times the CMHC PHP APC payment rate at 50 percent of the amount of CMHC PHP APC geometric mean per diem costs over the cutoff point. For example, for CY 2018, if a CMHC's cost for partial hospitalization services paid under CMHC PHP APC 5853 exceeds 3.4 times the CY 2018 payment rate for CMHC PHP APC 5853, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.4 times the CY 2018 payment rate for CMHC PHP APC 5853 [$0.50 \times (\text{CMHC Cost} - (3.4 \times \text{APC 5853 rate}))$]. This same policy was also reiterated in the CY 2019 OPSS/ASC final rule with comment period (83 FR 58996 through 58997), CY 2020 OPSS/ASC final rule with comment period (84 FR 61351) and the CY 2021 OPSS/ASC final rule with comment period (85 FR 86082 through 86083). For CY 2023, we propose to continue to pay for partial hospitalization services that exceed 3.4 times the proposed CMHC PHP APC payment rate at 50 percent of the CMHC PHP APC geometric mean per diem costs over the cutoff point. That is, for CY 2023, if a CMHC's cost for partial hospitalization services paid under CMHC PHP APC 5853 exceeds 3.4 times the payment rate for CMHC APC 5853, the outlier payment will be calculated as [$0.50 \times (\text{CMHC Cost} - (3.4 \times \text{APC 5853 rate}))$].

4. Outlier Reconciliation

In the CY 2009 OPSS/ASC final rule with comment period (73 FR 68594 through 68599), we established an outlier reconciliation policy to address charging aberrations related to OPSS outlier payments. We addressed vulnerabilities in the OPSS outlier payment system that lead to differences between billed charges and charges included in the overall CCR, which are used to estimate cost and would apply to all hospitals and CMHCs paid under the OPSS. We initiated steps to ensure that outlier payments appropriately account for the financial risk when providing an extraordinarily costly and complex service, but are only being made for services that legitimately qualify for the additional payment.

For a comprehensive description of outlier reconciliation, we refer readers to the CY 2019 OPPTS/ASC final rules with comment period (83 FR 58874 through 58875 and 81 FR 79678 through 79680).

We propose to continue these policies for partial hospitalization services provided through PHPs for CY 2023. The current outlier reconciliation policy requires that providers whose outlier payments meet a specified threshold (currently \$500,000 for hospitals and any outlier payments for CMHCs) and whose overall ancillary CCRs change by plus or minus 10 percentage points or more, are subject to outlier reconciliation, pending approval of the CMS Central Office and Regional Office (73 FR 68596 through 68599). The policy also includes provisions related to CCRs and to calculating the time value of money for reconciled outlier payments due to or due from Medicare, as detailed in the CY 2009 OPPTS/ASC final rule with comment period and in the Medicare Claims Processing Manual (73 FR 68595 through 68599) and Medicare Claims Processing Internet Only Manual, Chapter 4, Section 10.7.2 and its subsections, available online at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf>.

5. Outlier Payment Cap

In the CY 2017 OPPTS/ASC final rule with comment period, we implemented a CMHC outlier payment cap to be applied at the provider level, such that in any given year, an individual CMHC will receive no more than a set percentage of its CMHC total per diem payments in outlier payments (81 FR 79692 through 79695). We finalized the CMHC outlier payment cap to be set at 8 percent of the CMHC's total per diem payments (81 FR 79694 through 79695). This outlier payment cap only affects CMHCs, it does not affect other provider types (that is, hospital-based PHPs), and is in addition to and separate from the current outlier policy and reconciliation policy in effect. In the CY 2020 OPPTS/ASC final rule with comment period (84 FR 61351), we finalized a proposal to continue this policy in CY 2020 and subsequent years. In the CY 2023 OPPTS/ASC proposed rule, we do not propose any changes to this policy.

6. Fixed-Dollar Threshold

In the CY 2018 OPPTS/ASC final rule with comment period (82 FR 59267 through 59268), for the hospital outpatient outlier payment policy, we set a fixed-dollar threshold in addition to an APC multiplier threshold. Fixed-dollar thresholds are typically used to drive outlier payments for very costly items or services, such as cardiac pacemaker insertions. CMHC PHP APC 5853 is the only APC for which CMHCs may receive payment under the OPPTS, and is for providing a defined set of services that are relatively low cost when compared to other OPPTS services. Because of the relatively low cost of CMHC services that are used to comprise the structure of CMHC PHP APC 5853, it is not necessary to also impose a fixed-dollar threshold on CMHCs. Therefore, in the CY 2018 OPPTS/ASC final rule with comment period, we did not set a fixed-dollar threshold for CMHC outlier payments (82 FR 59381). This same policy was also reiterated in the CY 2020 OPPTS/ASC final rule with comment period (84 FR 61351), the CY 2021 OPPTS/ASC final rule with comment period (85 FR 86083), and the CY 2022 OPPTS/ASC final rule with comment period (86 FR 63508). We propose to continue this policy for CY 2023.

IX. Proposed Services That Will Be Paid Only as Inpatient Services

A. Background

Established in rulemaking as part of the initial implementation of the OPPTS, the inpatient only (IPO) list identifies services for which Medicare will only make payment when the services are furnished in the inpatient hospital setting because of the invasive nature of the procedure, the underlying physical condition of the patient, or the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged (70 FR 68695). The IPO list was created based on the premise (rooted in the practice of medicine at that time), that Medicare should not pay for procedures furnished as outpatient services that are performed on an inpatient basis virtually all of the time for the Medicare population, for the reasons described

above, because performing these procedures on an outpatient basis would not be safe or appropriate, and therefore not reasonable and necessary under Medicare rules (63 FR 47571). Services included on the IPO list were those determined to require inpatient care, such as those that are highly invasive, result in major blood loss or temporary deficits of organ systems (such as neurological impairment or respiratory insufficiency), or otherwise require intensive or extensive postoperative care (65 FR 67826). There are some services designated as inpatient only that, given their clinical intensity, would not be expected to be performed in the hospital outpatient setting. For example, we have traditionally considered certain surgically invasive procedures on the brain, heart, and abdomen, such as craniotomies, coronary-artery bypass grafting, and laparotomies, to require inpatient care (65 FR 18456). Designation of a service as inpatient only does not preclude the service from being furnished in a hospital outpatient setting but means that Medicare will not make payment for the service if it is furnished to a Medicare beneficiary in the hospital outpatient setting (65 FR 18443). Conversely, the absence of a procedure from the list should not be interpreted as identifying that procedure as appropriately performed only in the hospital outpatient setting (70 FR 68696).

As part of the annual update process, we have historically worked with interested parties, including professional societies, hospitals, surgeons, hospital associations, and beneficiary advocacy groups, to evaluate the IPO list and to determine whether services should be added to or removed from the list. Interested parties are encouraged to request reviews for a particular code or group of codes; and we have asked that their requests include evidence that demonstrates that the procedure was performed on an outpatient basis in a safe and appropriate manner in a variety of different types of hospitals—including but not limited to—operative reports of actual cases, peer-reviewed medical literature, community medical standards and practice, physician comments, outcome data, and post-procedure care data (67 FR 66740).

We traditionally have used five longstanding criteria to determine whether a procedure should be removed from the IPO list. As noted in the CY 2012 OPPTS/ASC final rule with

comment period (76 FR 74353), we assessed whether a procedure or service met these criteria to determine whether it should be removed from the IPO list and assigned to an APC group for payment under the OPSS when provided in the hospital outpatient setting. We have explained that while we only require a service to meet one criterion to be considered for removal, satisfying only one criterion does not guarantee that the service will be removed, instead, the case for removal is strengthened with the more criteria the service meets. The criteria for assessing procedures for removal from the IPO list are the following:

1. Most outpatient departments are equipped to provide the services to the Medicare population.
2. The simplest procedure described by the code may be furnished in most outpatient departments.
3. The procedure is related to codes that we have already removed from the IPO list.
4. A determination is made that the procedure is being furnished in numerous hospitals on an outpatient basis.
5. A determination is made that the procedure can be appropriately and safely furnished in an ASC and is on the list of approved ASC services or has been proposed by us for addition to the ASC list.

In the past, we have requested that interested parties submit corresponding evidence in support of their claims that a code or group of codes met the longstanding criteria for removal from the IPO list and was safe to perform on the Medicare population in the hospital outpatient setting—including, but not limited to case reports, operative reports of actual cases, peer-reviewed medical literature, medical professional analysis, clinical criteria sets, and patient selection protocols. Our clinicians thoroughly reviewed all information submitted within the context of the established criteria and if, following this review, we determined that there was sufficient evidence to confirm that the code could be safely and appropriately performed on an outpatient basis, we assigned the service to an APC and included it as a payable procedure under

the OPSS (67 FR 66740). We determine the APC assignment for services removed from the IPO list by evaluating the clinical similarity and resource costs of the service compared to other services paid under the OPSS and review the Medicare Severity Diagnosis Related Groups (MS-DRG) rate for the service under the IPPS, though we note we would generally expect the cost to provide a service in the outpatient setting to be less than the cost to provide the service in the inpatient setting.

We stated in prior rulemaking that, over time, given advances in technology and surgical technique, we would continue to evaluate services to determine whether they should be removed from the IPO list. Our goal is to ensure that inpatient only designations are consistent with the current standards of practice. We have asserted in prior rulemaking that, insofar as advances in medical practice mitigate concerns about these procedures being performed on an outpatient basis, we would be prepared to remove procedures from the IPO list and provide for payment for them under the OPSS (65 FR 18443). Further, CMS has at times had to reclassify codes as inpatient only services with the emergence of new information.

We refer readers to the CY 2012 OPSS/ASC final rule with comment period (76 FR 74352 through 74353) for a full discussion of our historic policies for identifying services that are typically provided only in an inpatient setting and, therefore, that will not be paid by Medicare under the OPSS, as well as the criteria we have used to review the IPO list to determine whether any services should be removed.

In the CY 2021 OPSS/ASC final rule with comment period (85 FR 86084 through 86088) we finalized a policy to eliminate the IPO list over the course of 3 years (85 FR 86093). We revised our regulation at § 419.22(n) to state that, effective on January 1, 2021, the Secretary shall eliminate the list of services and procedures designated as requiring inpatient care through a 3-year transition. As part of the first phase of this elimination of the IPO list, we removed 298 codes, including 266 musculoskeletal-related services, from the list beginning in CY 2021.

In the CY 2022 OPPTS/ASC final rule with comment period, we halted the elimination of the IPO list and, after clinical review of the services removed from the IPO list in CY 2021 as part of the first phase of eliminating the IPO list using the above five criteria, we returned most services removed from the IPO list in CY 2021 back to the IPO list beginning in CY 2022 (86 FR 63671 through 63736). We also amended the regulation at § 419.22(n) to remove the reference to the elimination of the list of services and procedures designated as requiring inpatient care through a 3-year transition. We also finalized our proposal to codify the five longstanding criteria for determining whether a service or procedure should be removed from the IPO list in the regulation in a new § 419.23 (86 FR 63678).

B. Proposed Changes to the Inpatient Only (IPO) List

Using the five criteria listed above, for CY 2023, we have identified 10 services described by the following codes that we propose to remove from the IPO list for CY 2023: CPT code 16036 (Escharotomy; each additional incision (list separately in addition to code for primary procedure)); CPT code 22632 (Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; each additional interspace (list separately in addition to code for primary procedure)); CPT code 21141 (Reconstruction midface, lefort i; single piece, segment movement in any direction (eg, for long face syndrome), without bone graft); CPT code 21142 (Reconstruction midface, lefort i; 2 pieces, segment movement in any direction, without bone graft); CPT code 21143 (Reconstruction midface, lefort i; 3 or more pieces, segment movement in any direction, without bone graft); CPT code 21194 (Reconstruction of mandibular rami, horizontal, vertical, c, or l osteotomy; with bone graft (includes obtaining graft)); CPT code 21196 (Reconstruction of mandibular rami and/or body, sagittal split; with internal rigid fixation); CPT code 21347 (Open treatment of nasomaxillary complex fracture (lefort ii type); requiring multiple open approaches); CPT code 21366 (Open treatment of complicated (eg, comminuted or involving cranial nerve foramina) fracture(s) of malar area, including zygomatic arch and malar tripod;

with bone grafting (includes obtaining graft)); and CPT code 21422 (Open treatment of palatal or maxillary fracture (LeFort I type);). The services that we propose to remove from the IPO list for CY 2023 and subsequent years, including the CPT codes, long descriptors, and the proposed CY 2023 payment indicators and APC assignments are displayed in Table M1 of this proposed rule.

As noted above, we propose to remove the service described by CPT code 16036 from the IPO list for CY 2023. After reviewing the clinical characteristics of the service described by CPT code 16036, we believe that this procedure meets criteria 2 and 3 in our regulation text at §419.23(b)(2) and (3) because the simplest procedure described by the code may be performed in most outpatient departments and the service or procedure is related to codes that CMS has already removed from the IPO list. CPT code 16036 is an add-on code that is typically billed with the primary procedure described by CPT code 16035 (Escharotomy; initial incision), which was removed from the IPO list in CY 2007 OP/ASC final rule with comment period (71 FR 68156). For CY 2023, we propose to assign CPT code 16036 to status indicator “N”. We are seeking public comment on our conclusion that the service described by CPT code 16036 meets criteria 2 and 3 as well as our proposal to assign this service to status indicator “N” for CY 2023.

Additionally, we propose to remove the service described by CPT code 22632 from the IPO list for CY 2023. CPT code 22632 is an add-on code that is typically billed with the primary procedure described by CPT code 22630 (Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar), which was removed from the IPO list in CY 2021 (86 FR 63708). CPT code 22632 was previously removed from the IPO list in CY 2021 as part of the first stage of the elimination of the IPO list, but was then returned to the list for CY 2022 when the elimination of the IPO list was halted. After further in-depth clinical review of this procedure, we believe CPT code 22632 meets criteria 2 and 3 in our regulation text at §419.23(b)(2) and (3) because the simplest procedure described by the code may be performed in most outpatient

departments and it is related to CPT code 22630, which CMS has already removed from the IPO list. For CY 2023, we propose to assign CPT code 22632 to status indicator “N”. We are seeking public comment on our conclusion that the service described by CPT code 22632 meets criteria 2 and 3 as well as our proposal to assign this service to status indicator “N” for CY 2023.

As stated above, we also propose to remove the following maxillofacial procedures from the IPO list: CPT codes 21141, 21142, 21143, 21194, 21196, 21347, 21366, and 21422. These services were previously removed from the IPO list in CY 2021 as part of the first phase of the elimination of the IPO list and were added back to the IPO list when the elimination of the IPO list was halted for CY 2022. After further in-depth review of the clinical characteristics of these procedures, the claims data, and additional evidence provided by interested parties, we believe these services meet criteria 1, 2, and 3 in the regulation text at §419.23(b)(1), (2), and (3) because most outpatient departments are equipped to provide the procedures; the simplest procedures described by the codes may be performed in most outpatient departments; and the procedures are related to codes that CMS has already removed from the IPO list and we propose to remove them from the IPO list. We propose to assign these eight services to APC 5165 - Level 5 ENT Procedures and status indicator “J1”. We are seeking public comment on our conclusion that the services described by CPT codes 21141, 21142, 21143, 21194, 21196, 21347, 21366, and 21422 meet criteria 1, 2, and 3 and our proposal to assign these services to APC 5165 - Level 5 ENT Procedures and status indicator “J1”.

We propose to add eight services that were newly created by the AMA CPT Editorial Panel for CY 2023 to the IPO list. These services, which will be effective on January 1, 2023, are described by CPT codes 157X1, 228XX, 49X06, 49X10, 49X11, 49X12, 49X13, and 49X14. After clinical review of these services, we found that they require a hospital inpatient admission or stay and we propose to assign these services to status indicator “C” for CY 2023. The CPT codes, long descriptors, and the proposed CY 2023 payment indicators are displayed in Table 46.

Table 46 below contains the proposed changes to the IPO list for CY 2023. The complete list of codes describing services that are proposed to be designated as inpatient only services beginning in CY 2023 is also included as Addendum E to this proposed rule, which is available via the internet on the CMS website.

TABLE 46: PROPOSED CHANGES TO THE INPATIENT ONLY (IPO) LIST FOR CY 2023

CY 2023 CPT Code	CY 2023 Long Descriptor	Proposed Action	CY 2023 OPPS Proposed Status Indicator	CY 2023 OPPS Proposed APC Assignment
16036	Escharotomy; each additional incision (list separately in addition to code for primary procedure)	Remove from the IPO list	N	N/A
22632	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; each additional interspace (list separately in addition to code for primary procedure)	Remove from the IPO list	N	N/A
21141	Reconstruction midface, lefort i; single piece, segment movement in any direction (eg, for long face syndrome), without bone graft	Remove from the IPO list	J1	5165
21142	Reconstruction midface, lefort i; 2 pieces, segment movement in any direction, without bone graft	Remove from the IPO list	J1	5165
21143	Reconstruction midface, lefort i; 3 or more pieces, segment movement in any direction, without bone graft	Remove from the IPO list	J1	5165
21194	Reconstruction of mandibular rami, horizontal, vertical, c, or l osteotomy; with bone graft (includes obtaining graft)	Remove from the IPO list	J1	5165
21196	Reconstruction of mandibular rami and/or body, sagittal split; with internal rigid fixation	Remove from the IPO list	J1	5165

CY 2023 CPT Code	CY 2023 Long Descriptor	Proposed Action	CY 2023 OPPTS Proposed Status Indicator	CY 2023 OPPTS Proposed APC Assignment
21347	Open treatment of nasomaxillary complex fracture (lefort ii type); requiring multiple open approaches	Remove from the IPO list	J1	5165
21366	Open treatment of complicated (eg, comminuted or involving cranial nerve foramina) fracture(s) of malar area, including zygomatic arch and malar tripod; with bone grafting (includes obtaining graft)	Remove from the IPO list	J1	5165
21422	Open treatment of palatal or maxillary fracture (lefort i type);	Remove from the IPO list	J1	5165
157X1	Implantation of absorbable mesh or other prosthesis for delayed closure of defect(s) (ie, external genitalia, perineum, abdominal wall) due to soft tissue infection or trauma	Add to the IPO list	C	N/A
228XX	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); second interspace, lumbar (List separately in addition to code for primary procedure)	Add to the IPO list	C	N/A
49X06	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including placement of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, incarcerated or strangulated	Add to the IPO list	C	N/A
49X10	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis when performed, total length of defect(s); 3 cm to 10 cm, incarcerated or strangulated	Add to the IPO list	C	N/A
49X11	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent,	Add to the IPO list	C	N/A

CY 2023 CPT Code	CY 2023 Long Descriptor	Proposed Action	CY 2023 OPPS Proposed Status Indicator	CY 2023 OPPS Proposed APC Assignment
	including placement of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, reducible			
49X12	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, Cincarcerated or strangulated	Add to the IPO list	C	N/A
49X13	Repair of parastomal hernia, any approach (ie, open, laparoscopic, robotic), initial or recurrent, including placement of mesh or other prosthesis, when performed; reducible	Add to the IPO list	C	N/A
49X14	Repair of parastomal hernia, any approach (ie, open, laparoscopic, robotic), initial or recurrent, including placement of mesh or other prosthesis, when performed; incarcerated or strangulated	Add to the IPO list	C	N/A

X. Nonrecurring Policy Changes

A. Mental Health Services Furnished Remotely by Hospital Staff to Beneficiaries in Their Homes

1. Payment for Mental Health Services Furnished as Medicare Telehealth Services or by Rural Health Clinics and Federally Qualified Health Centers

Under the Physician Fee Schedule (PFS), Medicare makes payment to professionals and other suppliers for physicians' services, including certain diagnostic tests and preventive services. Section 1834(m) of the Act specifies the payment amounts and circumstances under which Medicare makes payment for a discrete set of Medicare telehealth services, all of which must ordinarily be furnished in-person, when they are instead furnished using interactive, real-time telecommunications technology. Section 1834(m)(4)(D) and (E) of the Act specify the types

of health care professionals that can furnish and be paid for Medicare telehealth services (referred to as distant site physicians and practitioners). Section 1834(m)(4)(C) also generally limits the types of settings and geographic locations where a beneficiary can receive telehealth services (referred to as originating sites) to medical care settings in rural areas.

Due to the circumstances of the COVID–19 pandemic, particularly the need to maintain physical distance to avoid exposure to the virus, we anticipated that health care practitioners would develop new approaches to providing care using various forms of technology when they are not physically present with the patient. We established several flexibilities to accommodate these changes in the delivery of care. For Medicare telehealth services, using waiver authority under section 1135(b)(8) of the Act in response to the PHE for the COVID–19 pandemic, we removed the geographic and site of service originating site restrictions in section 1834(m)(4)(C) of the Act, as well as the restrictions in section 1834(m)(4)(E) of the Act on the types of practitioners who may furnish telehealth services, for the duration of the PHE. We also used waiver authority to allow certain telehealth services to be furnished via audio-only telecommunications technology during the PHE.

Division CC, section 123 of the Consolidated Appropriations Act, 2021 (CAA, 2021), modified the circumstances under which payment is made under the PFS for mental health services furnished via telehealth technology following the PHE. Specifically, section 123 removed the geographic originating site restrictions and added the home of the individual as a permissible originating site for Medicare telehealth services when furnished for the purposes of diagnosis, evaluation, or treatment of a mental health disorder. These amendments were implemented in the CY 2022 PFS final rule (86 FR 65055 through 65059). In the CY 2022 PFS final rule we also implemented a similar policy for mental health visits furnished by staff of RHCs and FQHCs (86 FR 65207 through 65211).

2. Hospital Payment for Mental Health Services Furnished Remotely During the PHE for COVID-19

For services that are not paid under the PFS, there is no statutory provision similar to section 1834(m) that addresses payment for services furnished by hospitals or other institutional providers to beneficiaries who are not physically located in the hospital or facility. CMS does pay, however, for certain covered OPD services that do not require the beneficiary's physical presence in the hospital. In CY 2015, CMS began paying for CPT code 99490 (Chronic care management services, at least 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month, with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; comprehensive care plan established, implemented, revised, or monitored), which describes non-face-to-face care management services furnished by clinical staff under the direction of a physician or other qualified health professional over the course of a calendar month to a beneficiary who is not physically in the hospital (see Addendum B at: www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1613-FC). In CY 2019, the OPDS began making payment for certain remote monitoring services, which similarly involve a beneficiary who is not physically in the hospital but who is using a monitoring device that transmits data to hospital staff (see Addendum B at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1695-FC>).

In many cases, hospitals provide hospital outpatient mental and behavioral health services (collectively hereafter, mental health services) that are furnished by hospital-employed counselors or other licensed professionals. Examples of these services include psychoanalysis, psychotherapy, and other counseling services. For some of these types of professionals (for example, certain mental health counselors such as marriage and family therapists or licensed

professional counselors), the Medicare statute does not have a benefit category that would allow them to bill independently for their services. These services can, in many cases, be covered when furnished by providers such as hospitals and paid under the OPPTS.

As we explained in the interim final rule with comment period published on May 8, 2020, in the **Federal Register** titled “Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program” (the May 8th COVID–19 IFC) (85 FR 27550, 27563), outpatient mental health services, education, and training services require communication and interaction between the patient and the clinical staff providing the service. We stated that facility staff can effectively furnish these services using telecommunications technology and, unlike many hospital services, the clinical staff and patient are not required to be in the same location to furnish them. We further explained that blanket waivers in effect during the COVID–19 PHE allow the hospital to consider the beneficiary’s home, and any other temporary expansion location operated by the hospital during the PHE, to be a provider-based department (PBD) of the hospital, so long as the hospital can ensure the location meets all the conditions of participation, to the extent they are not waived. In light of the need for infection control and a desire for continuity of behavioral health care and treatment services, we recognized the ability of the hospital’s clinical staff to continue to deliver these services even when the beneficiary is not physically located in the hospital. Therefore, in the May 8th COVID–19 IFC (85 FR 27564), we made clear that when a hospital’s clinical staff are furnishing hospital outpatient mental health services, education, and training services to a patient in the hospital (which can include the patient’s home so long as it is provider-based to the hospital), and the patient is registered as an outpatient of the hospital, we will consider the requirements of the regulations at § 410.27(a)(1) to be met. We referred to this policy as Hospitals without Walls (HWW). We reminded readers that the physician supervision level for the vast majority of hospital outpatient therapeutic services is currently general supervision under § 410.27. This

means a service must be furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the service.

3. Comment Solicitation in the CY 2022 OPPS/ASC Rule

In the CY 2022 OPPS/ASC proposed rule (86 FR 63748 through 63750) we sought comment on the extent to which hospitals have been relying on the HWW policy to bill for mental health services furnished to beneficiaries in their homes by clinical staff of the hospital. We stated that, given that the widespread use of communications technology to furnish services during the PHE has illustrated acceptance within the medical community and among Medicare beneficiaries of the possibility of furnishing and receiving care through use of that technology, we were interested in information on the role of hospital staff in providing care to beneficiaries remotely in their homes.

We sought comment on the extent to which hospitals have been billing for mental health services provided to beneficiaries in their homes through communications technology during the PHE and whether they would anticipate continuing demand for this model of care following the conclusion of the PHE. We sought comment on whether, during the PHE, hospitals have experienced a similar increase in utilization of mental health services provided by hospital staff to beneficiaries in their homes through communications technology. We also sought comment on whether there are changes commenters believe CMS should make to account for shifting patterns of practice that rely on communications technology to provide mental health services to beneficiaries in their homes.

In response to our comment solicitation, we received approximately 60 comments that were predominantly in support of continuing OPPS payment for mental health services furnished to beneficiaries in their homes by clinical staff of the hospital through the use of communications technology as a permanent policy post-PHE. These comments stated that the expansion of virtual care broadly during the PHE has been instrumental in maintaining and expanding access to mental health services during the PHE.

4. Current Crisis in Mental Health and Substance Use Disorder

During the COVID-19 pandemic, the number of adults reporting adverse behavioral health conditions has increased sharply, with higher rates of depression, substance use, and self-reported suicidal thoughts observed in racial and ethnic minority groups.¹³⁰ According to CDC data “[d]uring August 19, 2020–February 1, 2021, the percentage of adults with symptoms of an anxiety or a depressive disorder during the past 7 days increased significantly (from 36.4% to 41.5%), as did the percentage reporting that they needed but did not receive mental health counseling or therapy during the past 4 weeks (from 9.2% to 11.7%)”.¹³¹

In addition to the mental health crisis exacerbated by the COVID-19 pandemic, the United States is currently in the midst of an ongoing opioid PHE, which was first declared on October 26, 2017 by former Acting Secretary Eric D. Hargan, and most recently renewed by Secretary Xavier Becerra on April 4, 2022, and is facing an overdose crisis as a result of rising polysubstance use, such as the co-use of opioids and psychostimulants (for example, methamphetamine, cocaine). Recent CDC estimates of overdose deaths now exceed 107,000 for the 12-month period ending in December 2021¹³², with overdose death rates surging among Black and Latino Americans.¹³³ While overdose deaths were already increasing in the months preceding the COVID-19 pandemic, the latest numbers suggest an acceleration of overdose deaths during the pandemic. Recent increases in overdose deaths have reached historic highs in this country.¹³⁴ According to information provided to CMS by interested parties, these spikes in substance use and overdose deaths reflect a combination of increasingly deadly illicit drug supplies, as well as treatment disruptions, social isolation, and other hardships imposed by the COVID-19 pandemic; but they also reflect the longstanding inadequacy of our healthcare

¹³⁰ <https://www.cdc.gov/mmwr/volumes/69/wr/mm6932a1.htm>

¹³¹ <https://www.cdc.gov/mmwr/volumes/70/wr/mm7013e2.htm>

¹³² <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>

¹³³ Drake, J., Charles, C., Bourgeois, J.W., Daniel, E.S., & Kwende, M. (January 2020). Exploring the impact of the opioid epidemic in Black and Hispanic communities in the United States. *Drug Science, Policy and Law*. doi:10.1177/2050324520940428.

¹³⁴ <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>

infrastructure when it comes to preventing and treating substance use disorders (SUD) (for example, alcohol, cannabis, stimulants and opioid SUDs). Even before the COVID-19 pandemic began, in 2019, more than 21 million Americans aged 12 or over needed treatment for a SUD in the past year, but only about 4.2 million of them received any treatment or ancillary services for it.¹³⁵

According to the Commonwealth Fund, the provision of behavioral health services via communications technology has a robust evidence base; and numerous studies have demonstrated its effectiveness across a range of modalities and mental health diagnoses (for example, depression, SUD). Clinicians furnishing tele-psychiatry services at Massachusetts General Hospital Department of Psychiatry during the PHE observed several advantages of the virtual format for furnishing psychiatric services, noting that patients with psychiatric pathologies that interfere with their ability to leave home (for example, immobilizing depression, anxiety, agoraphobia, and/or time consuming obsessive-compulsive rituals) were able to access care more consistently since eliminating the need to travel to a psychiatry clinic can increase privacy and therefore decrease stigma-related barriers to treatment. This flexibility could potentially bring care to many more patients in need, as well as enhance ease of scheduling, decrease rate of no shows, increase understanding of family and home dynamics, and protect patients and practitioners with underlying health conditions.¹³⁶

5. CY 2023 OPPS Proposal to Pay for Mental Health Services Furnished Remotely by Hospital Staff

a. Designation of Mental Health Services Furnished to Beneficiaries in Their Homes as Covered OPD Services

¹³⁵ Substance Abuse and Mental Health Services Administration. (2020). Key substance use and mental health indicators in the United States: Results from the 2019 National Survey on Drug Use and Health (HHS Publication No. PEP20-07-01-001, NSDUH Series H-55). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from <https://www.samhsa.gov/data/>

¹³⁶ <https://www.commonwealthfund.org/blog/2020/using-telehealth-meet-mental-health-needs-during-covid-19-crisis>

During the PHE for COVID-19, many beneficiaries may be receiving mental health services in their homes from a clinical staff member of a hospital or CAH using communications technology under the flexibilities we adopted to permit hospitals to furnish these services. After the PHE ends, absent changes to our regulations, the beneficiary would need to physically travel to the hospital to continue receiving these outpatient hospital services from hospital clinical staff. We are concerned that this could have a negative impact on access to care in areas where beneficiaries may only be able to access mental health services provided remotely by hospital staff and, during the PHE, have become accustomed to receiving these services in their homes. We are also concerned about potential disruptions to continuity of care in instances where beneficiaries' inability to continue receiving these mental health services in their homes would lead to loss of access to a specific practitioner with whom they have established clinical relationships. We believe that, given the current mental health crisis, the consequences of loss of access could potentially be severe. We also note that beneficiaries' ability to receive mental health services in their homes may help expand access to care for beneficiaries who prefer additional privacy for the treatment of their condition. We also believe that, given the changes in payment policy for mental health services via telehealth by physicians and practitioners under the PFS and mental health visits furnished by staff of RHCs and FQHCs, using interactive, real-time telecommunications technology, it is important to maintain consistent payment policies across settings of care so as not to create payment incentives to furnish these services in a specific setting.

Therefore, we propose to designate certain services provided for the purposes of diagnosis, evaluation, or treatment of a mental health disorder performed remotely by clinical staff of a hospital using communications technology to beneficiaries in their homes as hospital outpatient services that are among the "covered OPD services" designated by the Secretary as described in section 1833(t)(1)(B)(i) of the Act and for which payment is made under the OPPS. To effectuate payment for these services, we propose to create OPPS-specific coding to describe

these services. The proposed code descriptors specify that the beneficiary must be in their home and that there is no associated professional service billed under the PFS. We note that, consistent with the conditions of participation for hospitals at 42 CFR 482.11(c), all hospital staff performing these services must be licensed to furnish these services consistent with all applicable State laws regarding scope of practice. We also propose that the hospital clinical staff be physically located in the hospital when furnishing services remotely using communications technology for purposes of satisfying the requirements at 42 CFR 410.27(a)(1)(iii) and § 410.27(a)(1)(iv)(A), which refer to covered therapeutic outpatient hospital services incident to a physician's or nonphysician practitioner's service as being “in” a hospital outpatient department. We are seeking comment on whether requiring the hospital clinical staff to be located in the hospital when furnishing the mental health service remotely to the beneficiary in their home would be overly burdensome or disruptive to existing models of care delivery developed during the PHE, and whether we should revise the regulatory text in the provisions cited above to remove references to the practitioner being “in” the hospital outpatient department.

Please see Table 47 for the proposed codes and their descriptors.

Table 47: C-CODE NUMBERS AND PROPOSED LONG DESCRIPTORS

HCPCS Code	Proposed Long Descriptor
CXX78	Service for diagnosis, evaluation, or treatment of a mental health or substance use disorder, initial 15-29 minutes, provided remotely by hospital staff who are licensed to provide mental health services under applicable State law(s), when the patient is in their home, and there is no associated professional service
CXX79	Service for diagnosis, evaluation, or treatment of a mental health or substance use disorder, initial 30-60 minutes, provided remotely by hospital staff who are licensed to provide mental health services under applicable State law(s), when the patient is in their home, and there is no associated professional service
CXX80	Service for diagnosis, evaluation, or treatment of a mental health or substance use disorder, each additional 15 minutes, provided remotely by hospital staff who are licensed to provide mental health services under applicable State law(s), when the patient is in their home, and there is no associated professional service (List separately in addition to code for primary service)

When beneficiaries are in their homes and not physically within the hospital, we do not believe that the hospital is accruing all the costs associated with an in-person service and as such the full OPPS rate may not accurately reflect these costs. We believe that the costs associated with hospital clinical staff remotely furnishing a mental health service to a beneficiary who is in their home using communications technology more closely resembles the PFS payment amount for similar services when performed in a facility, which reflects the time and intensity of the professional work associated with performing the mental health service but does not reflect certain practice expense costs, such as clinical labor, equipment, or supplies.

Therefore, we propose to assign HCPCS codes CXX78 and CXX79 to APCs based on the PFS facility payment rates for CPT codes 96159 (Health behavior intervention, individual, face-to-face; each additional 15 minutes (List separately in addition to code for primary service)) and 96158 (Health behavior intervention, individual, face-to-face; initial 30 minutes), respectively. We believe that the APC series that is most clinically appropriate would be the Health and Behavior Services APC series. For CY 2022, CPT code 96159 has a PFS facility payment rate of around \$20 while CPT code 96158 has a PFS facility payment rate of around \$60. If we use these PFS payment rates to approximate the costs associated with furnishing CXX78 and CXX79, these codes should be placed in APC 5821 (Level 1 Health and Behavior Services) and APC 5822 (Level 2 Health and Behavior Services), respectively. As CXX80 is an add-on code, payment would be packaged; and the code would not be assigned to an APC. See Table 48 for proposed SI and APC assignments and payment rates for HCPCS codes CXX78-CXX80.

TABLE 48: PROPOSED SI, APC ASSIGNMENT AND GEOMETRIC MEAN COST FOR HCPCS CODE CXX78-CXX80

HCPCS Code	Short Descriptor	Proposed SI	Proposed Proxy Service	PFS Facility Rate	Proposed APC	APC GMC
CXX78	HOPD mntl hlt, 15-29 min	S	96159	\$19.52	5821	\$30.48

CXX79	HOPD mntl hlt, 30-60 min	S	95158	\$56.56	5822	\$77.67
CXX80	HOPD mntl hlt, ea addl	N	N/A	N/A	N/A	N/A

We are seeking comment on the designation of mental health services furnished remotely to beneficiaries in their homes as covered OPD services payable under the OPPS, and on these proposed codes, their proposed descriptors, the proposed HCPCS codes and PFS facility rates as proxies for hospital costs, and the proposed APC assignments for the proposed codes. We recognize that, while mental health services have been paid under the OPPS when furnished by hospital staff in-person to beneficiaries physically located in the hospital, the ability to provide these services remotely via communications technology when the beneficiary is at home is a new model of care delivery and that we could benefit from additional information to assist us to appropriately code and pay for these services. We invite additional information from commenters on all aspects of this proposal. We will also monitor uptake of these services for any potential fraud and/or abuse. Finally, we note this proposal would also allow these services to be billed by CAHs, even though CAHs are not paid under the OPPS.

b. Periodic In-Person Visits

Section 123(a) of the CAA, 2021 also added a new subparagraph (B) to section 1834(m)(7) of the Act to prohibit payment for a Medicare telehealth service furnished in the patient’s home for purposes of diagnosis, evaluation, or treatment of a mental health disorder unless the physician or practitioner furnishes an item or service in-person, without the use of telehealth, within six months prior to the first time the physician or practitioner furnishes a telehealth service to the beneficiary, and thereafter, at such times as the Secretary determines appropriate. In the CY 2022 PFS final rule, we finalized that, after the first mental health telehealth service in the patient’s home, there must be an in-person, non-telehealth service within 12 months of each mental health telehealth service—but also finalized a policy to allow for limited exceptions to the requirement. Specifically, if the patient and practitioner agree that the

benefits of an in-person, non-telehealth service within 12 months of the mental health telehealth service are outweighed by risks and burdens associated with an in-person service, and the basis for that decision is documented in the patient's medical record, the in-person visit requirement will not apply for that 12-month period (86 FR 65059). We finalized identical in-person visit requirements for mental health visits furnished through communications technology for RHCs and FQHCs.

In the interest of maintaining similar requirements between mental health visits furnished by RHCs and FQHCs via communications technology, mental health telehealth services service under the PFS, and mental health services furnished remotely under the OPFS, we propose to require that payment for mental health services furnished remotely to beneficiaries in their homes using telecommunications technology may only be made if the beneficiary receives an in-person service within 6 months prior to the first time the hospital clinical staff provides the mental health services remotely; and that there must be an in-person service without the use of telecommunications technology within 12 months of each mental health service furnished remotely by the hospital clinical staff. We also propose the same exceptions policy as was finalized in the CY 2022 PFS final rule, specifically, that we would permit exceptions to the requirement that there be an in-person service without the use of communications technology within 12 months of each remotely furnished mental health service when the hospital clinical staff member and beneficiary agree that the risks and burdens of an in-person service outweigh the benefits of it. Exceptions to the in-person visit requirement should involve a clear justification documented in the beneficiary's medical record including the clinician's professional judgement that the patient is clinically stable and/or that an in-person visit has the risk of worsening the person's condition, creating undue hardship on the person or their family, or would otherwise result in disengaging with care that has been effective in managing the person's illness. Hospitals must also document that the patient has a regular source of general

medical care and has the ability to obtain any needed point of care testing, including vital sign monitoring and laboratory studies.

Section 304(a) of Division P, Title III, Subtitle A of the Consolidated Appropriations Act, 2022 (Pub. L. 117-103, March 15, 2022) amended section 1834(m)(7)(B)(i) of the Act to delay the requirement that there be an in-person visit with the physician or practitioner within 6 months prior to the initial mental health telehealth service, and at subsequent intervals as determined by the Secretary, until the 152nd day after the emergency period described in section 1135(g)(1)(B) (the PHE for COVID-19) ends. In addition, Section 304 of the CAA, 2022, delayed until 152 days after the end of the PHE similar in-person visit requirements for remotely furnished mental health visits furnished by RHCs and FQHCs. In the interest of continuity across payment systems so as to not create incentives to furnish mental health services in a given setting due to a differential application of additional requirements, and to avoid any burden associated with immediate implementation of the proposed in-person visit requirements, we propose that the in-person visit requirements would not apply until the 152nd day after the PHE for COVID-19 ends.

c. Audio-only Communication Technology

Section 1834(m) of the Act outlines the requirements for PFS payment for Medicare telehealth services that are furnished via a “telecommunications system,” and specifies that, only for purposes of Medicare telehealth services furnished through a Federal telemedicine demonstration program conducted in Alaska or Hawaii, the term “telecommunications system” includes asynchronous, store-and-forward technologies. We further defined the term, “telecommunications system,” in the regulation at § 410.78(a)(3) to mean an interactive telecommunications system, which is defined as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communications between the patient and distant site physician or practitioner.

During the PHE for COVID–19, we used waiver authority under section 1135(b)(8) of the Act to temporarily waive the requirement, for certain behavioral health and/or counseling services and for audio-only evaluation and management (E/M) visits, that telehealth services must be furnished using an interactive telecommunications system that includes video communications technology. Therefore, for certain services furnished during the PHE for COVID–19, we make payment for these telehealth services when they are furnished using audio-only communications technology. In the CY 2022 PFS final rule, we stated that, given the generalized shortage of mental health care professionals¹³⁷, and the existence of areas and populations where there is limited access to broadband due to geographic or socioeconomic challenges, that we believed beneficiaries may have come to rely upon the use of audio-only communications technology in order to receive mental health services, and that a sudden discontinuation of this flexibility at the end of the PHE could have a negative impact on access to care (86 FR 65059). Due to these concerns, we modified the definition of interactive telecommunications system in § 410.78(a)(3) for services furnished for purposes of diagnosis, evaluation, or treatment of a mental health disorder to a patient in their home to include two-way, real-time audio-only communications technology in instances where the physician or practitioner furnishing the telehealth service is technically capable to use telecommunications technology that includes audio and video, but the beneficiary is not capable of, or did not consent to, use two-way, audio/video technology. We stated that we believed that this requirement will ensure that mental health services furnished via telehealth are only conducted using audio-only communications technology in instances where the use of audio-only technology is facilitating access to care that would be unlikely to occur otherwise, given the patient’s technological limitations, abilities, or preferences (86 FR 65062). We also made a conforming change for purposes of furnishing mental health visits through telecommunications technology for RHCs and FQHCs. We limited payment for audio-only services to services furnished by physicians or

¹³⁷ <https://bhw.hrsa.gov/data-research/review-health-workforceresearch>

practitioners who have the capacity to furnish two-way, audio/video telehealth services but are providing the mental health services via audio-only communications technology in instances where the beneficiary is not capable of, or does not wish to use, two-way, audio/video technology.

In order to maximize accessibility for mental health services, particularly for beneficiaries in areas with limited access to broadband infrastructure, and in the interest of policy continuity across payment systems so as to not create incentives to furnish mental health services in a given setting due to a differential application of additional requirements, we propose a similar policy for mental health services furnished remotely by hospital clinical staff to beneficiaries in their homes through communications technology. Specifically, we propose that hospital clinical staff must have the capability to furnish two-way, audio/video services but may use audio-only communications technology given an individual patient's technological limitations, abilities, or preferences.

B. Comment Solicitation on Intensive Outpatient Mental Health Treatment, including Substance Use Disorder (SUD) Treatment Furnished by Intensive Outpatient Programs (IOPs)

There are a range of services described by existing coding under the PFS and OPFS that can be billed for treatment of mental health conditions, including SUD, such as individual, group, and family psychotherapy. Over the past several years, in collaboration with interested parties and the public, we have provided additional coding and payment mechanisms for mental health care services paid under the PFS and OPFS. For example, in the CY 2020 PFS final rule (84 FR 62673), we finalized the creation of new coding and payment describing a bundled episode of care for the treatment of Opioid Use Disorder (OUD) (HCPCS codes G2086-G2088). In the CY 2021 PFS final rule, we finalized expanding the bundled payments described by

HCPCS codes G2086–G2088 to be inclusive of all SUDs (85 FR 84642 through 84643). These services are also paid under the OPSS.

Additionally, in the CY 2020 PFS final rule (84 FR 62630 through 62677), we implemented coverage requirements and established new codes describing bundled payments for episodes of care for the treatment of OUD furnished by Opioid Treatment Programs (OTPs). Medicare also covers services furnished by inpatient psychiatric facilities and partial hospitalization programs (PHP). PHP services can be furnished by a hospital outpatient department or a Medicare-certified Community Mental Health Center (CMHC). PHPs are structured to provide intensive psychiatric care through active treatment that utilizes a combination of the clinically recognized items and services described in §1861(ff) of the Social Security Act (the Act). According to the Medicare Benefit Policy Manual, Chapter 6, Section 70.3, the treatment program of a PHP closely resembles that of a highly structured, short-term hospital inpatient program and is at a level more intense than outpatient day treatment or psychosocial rehabilitation. PHPs work best as part of a community continuum of mental health services, which range from the most restrictive inpatient hospital setting to less restrictive outpatient care and support.

We understand that, in some cases, people who do not require a level of care for mental health needs that meets the standards for PHP services nonetheless require intensive services on an outpatient basis. For example, according to SAMHSA's *Advisory on Clinical Issues in Intensive Outpatient Treatment for Substance Use Disorders*, IOP programs for substance use disorders (SUDs) offer services to clients seeking primary treatment; step-down care from inpatient, residential, and withdrawal management settings; or step-up treatment from individual or group outpatient treatment. IOP treatment includes a prearranged schedule of core services (e.g., individual counseling, group therapy, family psychoeducation, and case management) for a minimum of nine hours per week for adults or six hours per week for adolescents. SAMSHA

further states that the 2019 National Survey of Substance Abuse Treatment Services reports that 46 percent of SUD treatment facilities offer IOP treatment.¹³⁸

We are seeking comment on whether these services are described by existing CPT codes paid under the OPPTS, or whether there are any gaps in coding that may be limiting access to needed levels of care for treatment of mental health disorders or SUDs, for Medicare beneficiaries. We are also interested in additional, detailed information about IOP services, such as the settings of care in which these programs typically furnish services, the range of services typically offered, the range of practitioner types that typically furnish those services, and any other relevant information, especially to the extent it would inform our ability to ensure that Medicare beneficiaries have access to this care.

C. Direct Supervision of Certain Cardiac and Pulmonary Rehabilitation Services by Interactive Communications Technology

In the interim final rule with comment period titled “Policy and Regulatory Provisions in Response to the COVID–19 Public Health Emergency” published on April 6, 2020 (the April 6th COVID–19 IFC) (85 FR 19230, 19246, 19286), we changed the regulation at 42 CFR 410.27(a)(1)(iv)(D) to provide that, during a Public Health Emergency as defined in § 400.200, the presence of the physician for purposes of the direct supervision requirement for pulmonary rehabilitation (PR), cardiac rehabilitation (CR), and intensive cardiac rehabilitation (ICR) services includes virtual presence through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider. Specifically, the required direct physician supervision can be provided through virtual presence using audio/video real-time communications technology (excluding audio-only) subject to the clinical judgment of the supervising practitioner. We further amended § 410.27(a)(1)(iv)(D) in the CY 2021 OPPTS/ASC final rule with comment period to provide that this flexibility continues until the later of the end of the calendar year in which the PHE as

¹³⁸ https://store.samhsa.gov/sites/default/files/SAMHSA_Digital_Download/pep20-02-01-021.pdf

defined in § 400.200 ends or December 31, 2021 (85 FR 86113 and 86299). In the CY 2021 OPPTS/ASC final rule with comment period we also clarified that this flexibility excluded the presence of the supervising practitioner via audio-only telecommunications technology (85 FR 86113).

In the CY 2022 PFS final rule, CMS added CPT codes 93797 (Physician or other qualified health care professional services for outpatient cardiac rehabilitation; without continuous ECG monitoring (per session)) and 93798 (Physician or other qualified health care professional services for outpatient cardiac rehabilitation; with continuous ECG monitoring (per session)) and HCPCS codes G0422 (Intensive cardiac rehabilitation; with or without continuous ecg monitoring with exercise, per session) and G0423 (Intensive cardiac rehabilitation; with or without continuous ecg monitoring; without exercise, per session) to the Medicare Telehealth Services List on a Category 3 basis (86 FR 65055). These services will not be able to be furnished as Medicare telehealth services to beneficiaries in their homes after the PHE ends because of the statutory restrictions at section 1834(m)(4)(C)(ii) of the Act on eligible originating sites. However, the inclusion of these codes on the Medicare Telehealth Services List will enable payment for these services when furnished in full using two-way, audio/video communications technology when the beneficiary is in a medical setting that can serve as a telehealth originating site and meet the geographic requirements specified in section 1834(m)(4)(C). These services will remain on the Medicare Telehealth Services List through the end of CY 2023.

In order to effectuate a similar policy under the OPPTS, where PR, CR and ICR rehabilitation services currently may be furnished during the PHE to beneficiaries in hospitals under direct supervision of a physician where the supervising practitioner is immediately available to be present via two-way, audio/video communications technology, we are seeking comment on whether we should continue to allow direct physician supervision for these services to include presence of the supervising practitioner physician via two-way, audio/video

communication technology through the end of CY 2023. We also are seeking comment on whether there are safety and/or quality of care concerns regarding adopting this policy beyond the PHE and what policies CMS could adopt to address those concerns if the policy were extended post-PHE.

D. Use of Claims Data for CY 2023 OPPTS and ASC Payment System Ratesetting Due to the PHE

As described in section I.A of this proposed rule, section 1833(t) of the Act requires the Secretary to annually review and update the payment rates for services payable under the Hospital OPPTS. Specifically, section 1833(t)(9)(A) of the Act requires the Secretary to review not less often than annually and to revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) of the Act to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors.

When updating the OPPTS payment rates and system for each rulemaking cycle, we primarily use two sources of information: the outpatient Medicare claims data and Healthcare Cost Report Information System (HCRIS) cost report data. The claims data source is the Outpatient Standard Analytic File, which includes final action Medicare outpatient claims for services furnished in a given calendar year. For the OPPTS ratesetting process, our goal is to use the best available data for ratesetting to accurately estimate the costs associated with furnishing outpatient services and set appropriate payment rates. Ordinarily, the best available claims data are the data from 2 years prior to the calendar year that is the subject of rulemaking. For the CY 2023 OPPTS/ASC proposed rule ratesetting, the best available claims data would typically be the CY 2021 calendar year outpatient claims data processed through December 31, 2021. The cost report data source is typically the Medicare hospital cost report data files from the most recently available quarterly HCRIS file as we begin the ratesetting process. The best available cost report data used in developing the OPPTS relative weights would ordinarily be from cost

reports beginning three fiscal years prior to the year that is the subject of the rulemaking. For example, under ordinary circumstances, for CY 2023 OPSS ratesetting, that would be cost report data from HCRIS extracted in December 2021, which would contain many cost reports ending in FY 2020 and 2021 based on each hospital's cost reporting period.

As discussed in the CY 2022 OPSS final rule with comment period, the standard hospital data we would have otherwise used for purposes of CY 2022 ratesetting included significant effects from the COVID-19 PHE, which led to a number of concerns with using this data for CY 2022 ratesetting (86 FR 63751 through 63754). In section X.E. of the CY 2022 OPSS/ASC proposed rule (86 FR 42188 through 42190), we noted a number of changes in the CY 2020 OPSS claims data we would ordinarily use for ratesetting, likely as a result of the PHE. These changes included overall aggregate decreases in claims volume (particularly those associated with visits); significant increases in HCPCS code Q3014 (Telehealth originating site facility fee) in the hospital outpatient claims; and increases in certain PHE-related services, such as HCPCS code C9803, which describes COVID-19 specimen collection and services assigned to APC 5801 (Ventilation Initiation and Management). As a result of the effects we observed from COVID-19 PHE-related factors in our claims and cost report data, as well as the increasing number of Medicare beneficiaries vaccinated against COVID-19, which we believed might make the CY 2022 outpatient experience closer to CY 2019 rather than CY 2020, we believed that CY 2020 data were not the best overall approximation of expected outpatient hospital services in CY 2022. Instead, we believed that CY 2019 data, as the most recent complete calendar year of data prior to the COVID-19 PHE, were a better approximation of expected CY 2022 hospital outpatient services. Therefore, in the CY 2022 OPSS/ASC final rule with comment period, we established a policy of using CY 2019 claims data and cost reports prior to

the PHE in ratesetting for the CY 2022 OPSS with certain limited exceptions, such as where CY 2019 data were not available (86 FR 63753 through 63754).

Given the effects the virus that causes COVID-19 has had on Medicare claims and cost report data the last 2 years, coupled with the expectation for future variants, we believe that it is reasonable to assume that there will continue to be some limited influence of COVID-19 PHE effects on the data we use for ratesetting. We reviewed the CY 2021 claims data available for CY 2023 OPSS ratesetting, similar to the review we conducted for CY 2022 OPSS ratesetting, to determine the degree to which the effects of the COVID-19 PHE had continued or subsided in our claims data as well as what claims and cost report data would be appropriate for CY 2023 OPSS ratesetting. In general, we continue to see limited effects of the PHE, with service volumes generally about halfway between those in the CY 2019 (pre-PHE) claims and CY 2020 (beginning of the PHE) claims. At the aggregate level, there continues to be a decrease in the overall volume of outpatient hospital claims during the PHE, with approximately 10 percent fewer claims usable for ratesetting purposes when compared to the CY 2019 outpatient claims volume. This number compares to the 20 percent reduction that we observed last year in the CY 2020 claims. Similarly, this moderate return to more normal volumes extends across claims volume and applies to a majority of the clinical APCs in the OPSS, suggesting that, while clinical and billing patterns have not quite returned to their pre-PHE levels, they are beginning to do so.

Similar to what we observed in CY 2022 OPSS ratesetting, we continue to see broad changes as a result of the PHE, including in the APCs for hospital emergency department and clinic visits. Among those APCs, the decrease in volume was approximately 20 percent, some of which may be related to changing practice patterns during the PHE. For example, we saw a significant increase in the use of the HCPCS code Q3014 (Telehealth originating site facility fee) in the hospital outpatient claims during the first year of the PHE, with approximately 35,000 services billed in the CY 2019 OPSS claims and 2.1 million services billed in the CY 2020 OPSS

claims. However, in the CY 2021 OPSS claims currently available for ratesetting, we see a slight decline in volume to about 1.6 million services, noting that we would expect slightly more claims in the final rule data. Our view is that a large part of the volume increase in CY 2020 was the result of site of service changes due to the PHE.

In other cases, we saw claims data changes associated with specific services that were furnished more frequently during the PHE. For example, we identified two notable changes in the claims data for APC 5731 (Level 1 Minor Procedures) and APC 5801 (Ventilation Initiation and Management). In the CY 2020 claims data reviewed last year, we noted a significant increase in the services provided under APC 5801, from 10,340 units provided in CY 2019 claims to 12,802 units in the CY 2020 claims. However, in the CY 2021 claims available for NPRM ratesetting, there are only approximately 8,596 units of service provided through this APC, an amount even lower than the service volume we observed in CY 2019 claims.

In the case of APC 5731, HCPCS code C9803 was made effective for services furnished on or after March 1, 2020, through the interim final rule with comment period titled “Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program” (85 FR 27602 through 27605) to describe COVID–19 specimen collection. In the CY 2021 claims data available for ratesetting for this proposed rule, there are approximately 1,367,531 single claims available for ratesetting purposes for HCPCS code C9803, which, if this code were included in ratesetting, would make up 93 percent of the claims used to set the payment rate for APC 5731 (Level 1 Minor Procedures APC). Under current policy, HCPCS code C9803 is a temporary code that was created to support increased testing solely during the COVID-19 PHE. Given that this is a temporary code only in use for the duration of the PHE, that the PHE could conclude before CY 2023, and that the large volume of services for this code in the CY 2021 claims data would dictate the payment rate for APC 5731 if we included this code in ratesetting, we do not believe including the claims data for this code in establishing CY 2023

payment rates would be appropriate. Our CY 2022 final policies on data used in ratesetting were established due to our expectation that the CY 2022 outpatient experience would be more similar to the CY 2019 claims rather than CY 2020 claims. Our proposed rule review of the data for CY 2023 OPSS ratesetting also is based on our belief of how well the claims and cost report data may relate to the CY 2023 outpatient experience. It is with similar considerations in mind and our belief that the volumes and costs associated with HCPCS code C9803 will not be reflective of the CY 2023 outpatient experience that we believe it is appropriate to exclude claims that would typically be used to model the cost of HCPCS code C9803 from ratesetting.

Based on our review of the CY 2021 outpatient claims available for ratesetting, we observed that many of the outpatient service volumes have partially returned to their pre-PHE levels. While the effects of the COVID-19 PHE remain at both the aggregate and service levels for certain services, as discussed earlier in this section and in section I.F of the FY 2023 IPPS proposed rule (87 FR 28123 through 28125), we recognize that future COVID-19 variants may have potentially varying effects. Therefore, we believe it is reasonable to assume that there will continue to be some effects of the COVID-19 PHE on the outpatient claims that we use for OPSS ratesetting, similar to the CY 2021 claims data. As a result, we propose to use the CY 2021 claims for CY 2023 OPSS ratesetting.

We propose to use cost report data for this proposed rule from the same set of cost reports we originally used in the CY 2021 OPSS/ASC final rule for ratesetting, which in most cases included cost reporting periods beginning in CY 2018. We ordinarily would have used the most updated available cost reports available in HCRIS in determining the proposed CY 2022 OPSS/APC relative weights (as discussed in greater detail in section II.E of the CY 2022 OPSS/ASC proposed rule (86 FR 42053)). As previously discussed, if we were to proceed with the standard ratesetting process of using updated cost reports, we would have used approximately 1,000 cost reports with the fiscal year ending in CY 2020, based on each hospital's cost reporting period. Under our historical process of updating cost report data, for the CY 2023 OPSS, the

majority of the cost reports in our data would have cost reporting periods that overlap parts of CY 2020. Noting that we observed significant impact at the service level when incorporating these cost reports into ratesetting and the effects on billing/clinical patterns, similar to what we observed in the CY 2020 claims when reviewing them for the CY 2022 OPPS/ASC rulemaking cycle, we believe that it is appropriate to continue to use the same set of cost reports that we used in developing the CY 2021 OPPS, so as to mitigate the impact of that 2020-based data. We note that we will continue to review the updated cost report data as they are available.

We also note that, similar to the proposed IPPS outlier policy described in section II.A.4 of the addendum to the FY 2023 IPPS proposed rule (87 FR 28868), we propose to return to our historical process of using CCRs when determining the fixed-dollar amount threshold, and to adopt the charge and CCR inflation factors developed for the FY 2023 IPPS. For more detail regarding the proposed CY 2023 OPPS outlier policy, see section II.G of this proposed rule.

As a result of our expectation that the CY 2021 claims that we would typically use will be appropriate for establishing the CY 2023 OPPS, we propose to use the CY 2021 claims for the CY 2023 OPPS/ASC ratesetting process. However, we propose to use the same set of cost reports from the June 2020 cost report extract, which contains only pre-PHE data, to remove the effect of the PHE cost report data on estimated service cost. In addition, we propose to exclude from ratesetting claims that would be used to model the estimated cost of HCPCS code C9803 in this proposed rule.

We are also considering the alternative of continuing with our standard process of using the most updated claims and cost report data available. While the CY 2021 claims used in ratesetting would be the same as under our proposal, under this alternative our cost reports would also be updated for the most recent extract we typically would use: cost report data extracted from HCRIS in December 2021, which in most cases included cost reporting periods beginning in CY 2018. To facilitate comment on the alternative proposal for CY 2023, we are making available the cost statistics and addenda utilizing the CY 2021 claims and updated cost report

data we would ordinarily have provided in conjunction with the CY 2023 OPPS/ASC proposed rule. We have provided all relevant files that would have changes calculated under this alternative approach including: the OPPS Impact File, cost statistics files, and addenda. The files specific to this alternative configuration will be identified by the word “Alternative” in the filenames, similar to our approach in the CY 2022 OPPS/ASC proposed and final rules. We note that the primary change as a result of the alternative proposed methodology would be in the scaled weights, which are displayed in the addenda. We refer the reader to the CMS website for the CY 2023 OPPS/ASC proposed rule for more information on where these supplemental files may be found.

E. Supervision by Nonphysician Practitioners of Hospital and CAH Diagnostic Services
Furnished to Outpatients

1. Background

The regulation at 42 CFR 410.32 provides the conditions of Medicare Part B payment for diagnostic tests. Section 410.32(b) provides the supervision requirements for diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests paid under the PFS. Prior to 2020, the regulation allowed only physicians as defined under Medicare law to supervise the performance of these diagnostic tests.

In the interim final rule with comment period published on May 8, 2020, in the **Federal Register** titled “Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program” (the May 8th COVID-19 IFC) (85 FR 27550, 27555 through 27556, 27620), we revised § 410.32(b)(1) to allow, for the duration of the PHE, certain nonphysician practitioners (nurse practitioners, physician assistants, clinical nurse specialists and

certified nurse midwives) to supervise the performance of diagnostic tests to the extent they were authorized to do so under their scope of practice and applicable State law.

In the CY 2021 PFS final rule (85 FR 84590 through 84492, 85026), we further revised § 410.32(b)(1) to make the revisions made by the May 8th COVID-19 IFC permanent and to add certified registered nurse anesthetists to the list of nonphysician practitioners permitted to provide supervision of diagnostic tests to the extent authorized to do so under their scope of practice and applicable State law.

As we explained in those final rules, the basis for making these revisions was to both ensure that an adequate number of health care professionals were available to support critical COVID-19-related and other diagnostic testing needs and provide needed medical care during the PHE and to implement policy consistent with section 5(a) of the President's Executive Order 13890 on "Protecting and Improving Medicare for Our Nation's Seniors" (84 FR 53573, October 8, 2019, E.O. 13890), which directed the Secretary to identify and modify Medicare regulations that contained more restrictive supervision requirements than existing scope of practice laws, or that limited healthcare professionals from practicing at the top of their license. We refer readers to the May 8th COVID-19 IFC (85 FR 27555 through 27556, 27620) and CY 2021 PFS final rule (85 FR 84590 through 84492, 85026) for a more detailed discussion of the reasoning behind our revisions to § 410.32.

Section 410.32(b)(1), titled "Basic rule," states that "...all diagnostic x-ray and other diagnostic tests covered under section 1861(s)(3) of the Act and payable under the physician fee schedule must be furnished under the appropriate level of supervision by a physician as defined in section 1861(r) of the Act or, to the extent that they are authorized to do so under their scope of practice and applicable State law, by a nurse practitioner, clinical nurse specialist, physician assistant, certified registered nurse anesthetist, or a certified nurse-midwife."

Section 410.32(b)(2) provides a list of services that are excepted from the basic rule in § 410.32(b)(1). Section 410.32(b)(3) defines the levels of supervision referenced in

§ 410.32(b)(1): general supervision (§ 410.32(b)(3)(i)); direct supervision (§ 410.32(b)(3)(ii)); and personal supervision (§ 410.32(b)(3)(iii)). Within these three definitions, only the definition for direct supervision indicates that a “supervising practitioner” other than a physician can provide the required supervision. The definitions for general and personal supervision continue to refer only to a physician providing the required level of supervision. Although the definitions of general and personal supervision do not specify that a “supervising practitioner” could furnish these levels of supervision, the above-described revisions to the “basic rule” governing supervision of diagnostic tests at § 410.32(b)(1) allow certain nonphysician practitioners to provide general and personal supervision to the extent they are authorized to do so under their scope of practice and applicable State law.

Section 410.28 provides conditions of payment for diagnostic services under Medicare Part B provided to outpatients by, or under arrangements by, hospitals and CAHs, including specific supervision requirements under § 410.28(e) for diagnostic tests in those settings. Section 410.28(e) relies upon the definitions of general, direct (for nonhospital locations) and personal supervision at § 410.32(b)(3)(i) through (iii) by cross-referencing those definitions. As noted above, the term “supervising practitioner” is absent from those definitions, although the “basic rule” at § 410.32(b)(1) allows certain nonphysician practitioners to provide general and personal supervision to the extent they are authorized to do so under their scope of practice and applicable State law. However, § 410.32(b) is explicitly limited to “all diagnostic x-ray and other diagnostic tests covered under section 1861(s)(3) of the Act and payable under the physician fee schedule,” and § 410.28(e) does not contain any such “basic rule” to clarify that nonphysician practitioners can provide general and personal supervision.

2. Proposed Revisions to 42 CFR 410.28 and § 410.27

For purposes of clarity and consistency, we propose to revise § 410.28(e) to clarify that the same nonphysician practitioners that can provide general and personal supervision of diagnostic testing services payable under the PFS under § 410.32(b) can provide supervision of

diagnostic testing services furnished to outpatients by hospitals or CAHs. Specifically, we propose to revise our existing supervision requirements at § 410.28(e) to clarify that nurse practitioners, clinical nurse specialists, physician assistants, certified registered nurse anesthetists and certified nurse midwives may provide general, direct, and personal supervision of outpatient diagnostic services to the extent that they are authorized to do so under their scope of practice and applicable State law.

We also propose to replace the cross-references at § 410.28(e) to the definitions of general, direct (for outpatient services provided at a nonhospital location), and personal supervision at § 410.32(b)(3)(i) through (iii) with the text of those definitions as newly designated paragraphs (1), (2)(i), (2)(ii), (2)(iii), and (3) so that they are now contained within § 410.28.

Similarly, since § 410.27, which provides the supervision requirements for therapeutic outpatient hospital and CAH services, also relies on the definitions of general and personal supervision at § 410.32(b)(3)(i) and (iii), we propose to replace the cross-references at § 410.27(a)(1)(iv)(A) and (B) with the text of those definitions so that they are now contained within § 410.27. Additionally, for clarity we propose to designate the existing definition of direct supervision and the proposed definition of personal supervision at § 410.27(a)(1)(iv)(B) as § 410.27(a)(1)(iv)(B)(1) and (2), respectively. Finally, since § 410.27(a)(1)(iv)(B) and (D) contain duplicate definitions for direct supervision, we propose to remove § 410.27(a)(1)(iv)(D) in its entirety and add its language regarding pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services and the virtual presence of a physician through audio/video real-time communications technology during the PHE to the newly designated § 410.27(a)(1)(iv)(B)(1).

F. Coding and Payment for Category B Investigational Device Exemption Clinical Devices and Studies

1. Medicare Coverage of Items and Services in FDA-Approved Investigational Device

Exemption Clinical Studies

Section 1862(m) of the Act (as added by section 731(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173, enacted on December 8, 2003) allows for Medicare payment of the routine costs of care furnished to Medicare beneficiaries in a Category A investigational device exemption (IDE) study. Under the general rulemaking authority under section 1871 of the Act, CMS finalized changes to the IDE regulations (42 CFR 405 Subpart B), effective January 1, 2015 (78 FR 74809). CMS added criteria for coverage of IDE studies and changed from local Medicare Administrative Contractor (MAC) review and approval of IDE studies to a centralized review and approval of IDE studies.

2. Background on Medicare Payment for FDA-Approved IDE Studies

Medicare may make payment for routine care items and services furnished in an FDA-approved Category A (Experimental) study if CMS determines that the Medicare coverage IDE study criteria in 42 CFR 405.212 are met. However, Medicare does not make payment for the Category A device, which is excluded from coverage by 1862(a) of the Act. A Category A (Experimental) device refers to a device for which “absolute risk” of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved) and the FDA is unsure whether the device type can be safe and effective.

As described in § 405.211(b), with regard to a Category B (Nonexperimental/investigational) IDE study, Medicare may make payment for the Category B device and the routine care items and services in the study if CMS determines that the Medicare coverage IDE study criteria in § 405.212 are met. A Category B (Non-experimental/investigational) device refers to a device for which the incremental risk is the primary risk in question (that is, initial questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for

example, other manufacturers have obtained FDA premarket approval or clearance for that device type (§ 405.201(b)).

3. Proposal for Coding and Payment for Category B IDE Devices and Studies

In the CY 2020 OPPI/ASC final rule with comment period (84 FR 61223 through 61224), we created a temporary HCPCS code to describe the V-Wave Interatrial Shunt Procedure, including the cost of the device, for the experimental group and the control group of the study after hearing concerns from interested parties that current coding for the V-Wave procedure would compromise the scientific validity of the study. Specifically, for that randomized, double-blinded control Category B IDE study, all participants received a right heart catheterization procedure described by CPT code 93451 (Right heart catheterization including measurement(s) of oxygen saturation and cardiac output, when performed). Participants assigned to the experimental group also received the V-Wave interatrial shunt procedure while participants assigned to the control group only received right heart catheterization. We stated that the developer of V-Wave was concerned that the current coding of these services by Medicare would reveal to the study participants whether they have received the Category B IDE device – the interatrial shunt – because an additional procedure code would be included on the claims for participants receiving the interatrial shunt. Therefore, we created a temporary HCPCS code to describe the V-Wave interatrial shunt procedure for both the experimental group and the control group in the study. Specifically, we established HCPCS code C9758 (Blinded procedure for NYHA class III/ IV heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization, trans-esophageal echocardiography (TEE)/intracardiac echocardiography (ICE), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved IDE study) to describe the service, including the cost of the device, and we assigned the service to New Technology APC 1589 (New Technology—Level 38 (\$10,001– \$15,000)).

In addition to the previously described procedure and the creation of HCPCS code C9758, CMS has created similar codes and used similar payment methodologies for other similar IDE studies. For example, the following HCPCS codes were also created and described blinded procedures, including the cost of the device, in which both the active treatment and placebo groups are described by the same HCPCS code: HCPCS code C9782 (Blinded procedure for New York Heart Association (NYHA) Class II or III heart failure, or Canadian Cardiovascular Society (CCS) Class III or IV chronic refractory angina; transcatheter intramyocardial transplantation of autologous bone marrow cells (e.g., mononuclear) or placebo control, autologous bone marrow harvesting and preparation for transplantation, left heart catheterization including ventriculography, all laboratory services, and all imaging with or without guidance (e.g., transthoracic echocardiography, ultrasound, fluoroscopy), all device(s), performed in an approved Investigational Device Exemption (IDE) study), and HCPCS code C9783 (Blinded procedure for transcatheter implantation of coronary sinus reduction device or placebo control, including vascular access and closure, right heart catheterization, venous and coronary sinus angiography, imaging guidance and supervision and interpretation when performed in an approved Investigational Device Exemption (IDE) study).

For CY 2023, we propose to make a single blended payment, and establish a new HCPCS code or revise an existing HCPCS code for devices and services in Category B IDE studies when the Medicare coverage IDE study criteria at § 405.212 are met and where CMS determines, that a new or revised code and/or payment rate is necessary to preserve the scientific validity of such a study. We intend that this proposal would preserve the scientific validity of these studies by avoiding differences in Medicare payment methods that would otherwise reveal the group (treatment or control) to which a patient has been assigned. For example, it is expected that in a typical study, those receiving the placebo may have a lesser Medicare payment due to absence of the Category B device, and therefore, the payment amount may unblind the study and compromise its scientific validity. As has occurred previously, we anticipate interested parties

will engage with us and notify us, for instance, if they have concerns that an existing HCPCS code may compromise the scientific validity of a Category B IDE study.

Therefore, we propose to create a new HCPCS code or revise an existing HCPCS code to describe a Category B IDE device and study, which would include both the treatment and control arms and related device(s), as well as routine care items and services as specified under § 405.201, if we determine it is necessary to do so to preserve the scientific validity of the study; we would assign the new or revised code a blended payment rate. We would do this where the coding would compromise the scientific validity of the study. The single blended payment rate would be dependent on the specific trial protocol and would account for the frequency with which the investigational device is used compared to placebo. For example, in a study, for which CMS determines the Medicare coverage IDE study criteria in § 405.212 are met and where there is a 1:1 assignment of the device to placebo (no device), Medicare's payment rate would prospectively average the payment for the device with the zero payment for the placebo in a 1:1 ratio. Furthermore, costs for routine care items and services, as specified under § 405.201 in the study would be included in the single blended payment.

Section 1833(t)(9)(A) of the Act requires the Secretary to review not less often than annually and revise the groups, the relative payment weights, and the wage and other adjustments to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other information and factors. Consistent with this requirement, we propose this policy to ensure we pay appropriately under the OPPS for Category B IDE devices and studies in a manner that preserves the studies' scientific validity. This proposal is similar to our standard practice of setting payment rates based on the frequency of resources used. Our proposal to create new HCPCS codes or revise existing HCPCS codes to operationalize our proposal to make a single payment for the blended cost of the device depending on the frequency with which it is used in the study, together with the study costs, is consistent with our historical practice of creating new codes for OPPS and ASC programmatic

needs. We note that, in addition to our general authority to review and revise the APC groups and the relative payment weights in section 1833(t)(9)(A) of the Act, section 1833(w) of the Act is additional authority that would support our proposal. In particular, section 1833(w) of the Act authorizes the Secretary to develop alternative methods of payment for items and services provided under clinical trials and comparative effectiveness studies sponsored or supported by an agency of the Department of Health and Human Services, as determined by the Secretary, to those that would otherwise apply under section 1833, to the extent such alternative methods are necessary to preserve the scientific validity of such trials or studies. For example, Medicare may make an alternative method of payment for items and services provided under clinical trials where masking the identity of interventions from patients and investigators is necessary to comply with the particular trial or study design. We are inviting comments on our proposal.

4. Proposed Coding and Payment for Category B IDE Studies Regulation Text Changes

We propose to codify our proposed process of utilizing a single packaged payment for Category B IDE studies, including the cost of the device and routine care items and services, in the regulation text for payment to hospitals in a new § 419.47. In particular, we propose to provide in new § 419.47(a) that CMS will create a new HCPCS code, or revise an existing HCPCS code, to describe a Category B IDE study, which would include both the treatment and control arms, related device(s) of the study, as well as routine care items and services, as specified under § 405.201, when CMS determines that the Medicare coverage IDE study criteria at § 405.212 are met, and a new or revised code is necessary to preserve the scientific validity of the IDE study. Additionally, in a new section, § 419.47(b), we propose that when we create a new HCPCS code or revise an existing HCPCS code under proposed paragraph (a), we will make a single packaged payment for the HCPCS code that includes payment for the investigational device, placebo control, and routine care items and services of a Category B IDE study, as specified under §405.201. The payment would be based on the average resources

utilized for each study participant. For example, the payment would account for the frequency with which the investigational device is used in the study population.

G. OPSS Payment for Software as a Service

1. Background on Clinical Software and OPSS Add-on Codes Policy

Rapid advances in innovative technology are having a profound effect on every facet of health care delivery. Novel and evolving technologies are introducing advances in treatment options that have the potential to increase access to care for Medicare beneficiaries, improve outcomes, and reduce overall costs to the program. In some cases, these innovative technologies are substituting for more invasive care and/or augmenting the practice of medicine.

New clinical software, which includes clinical decision support software, clinical risk modeling, and computer aided detection (CAD), are becoming increasingly available to providers. These technologies often perform data analysis of diagnostic images from patients. While many of these technologies are new, we note that clinical software, particularly CAD, has been used to aid or augment clinical decision making for decades. These technologies rely on complex algorithms or statistical predictive modeling to aid in the diagnosis or treatment of a patient's condition. We refer to these algorithm-driven services that assist practitioners in making clinical assessments, and that providers pay for either on a subscription or per-use basis, as Software as a Service (SaaS).

Starting in 2018, we began making payment for the SaaS procedure Fractional Flow Reserve Derived from Computed Tomography (FFRCT), also known by the trade name HeartFlow. HeartFlow is a noninvasive diagnostic service that allows physicians to measure coronary artery disease in a patient through the use of coronary CT scans. The HeartFlow SaaS procedure is intended for clinically stable symptomatic patients with coronary artery disease, and, in many cases, its use may eliminate the need for an invasive coronary angiogram procedure. HeartFlow uses a proprietary data analysis process performed at a central facility to develop a three-dimensional image of a patient's coronary arteries, which allows physicians to

identify the fractional flow reserve to assess whether patients should undergo further invasive testing (that is, a coronary angiogram).

For many services paid under the OPPS, payment for analytics that are performed after the main diagnostic/image procedure are packaged into the payment for the main diagnostic/image procedure (i.e., the primary service). In the CY 2018 OPPS/ASC final rule, however, we determined that it was appropriate for HeartFlow to receive a separate payment because the analytics are performed by a separate entity (that is, a HeartFlow technician who conducts computer analysis offsite) rather than the provider performing the CT scan (82 FR 52422 through 52425). We assigned CPT code 0503T, which describes the analytics performed, to New Technology APC 1516 (New Technology—Level 16 (\$1,401–\$1,500)), with a payment rate of \$1,450.50 based on pricing information provided by the developer of the SaaS procedure that indicated the price of the procedure was approximately \$1,500. In CY 2020, we utilized our low-volume payment policy to calculate HeartFlow’s arithmetic mean to assign it to New Technology APC 1511 (New Technology –Level 11 (\$901-\$1000)) with a payment rate of \$950.00 (84 FR 61220 through 61221). We continued this APC assignment in CY 2021 and CY 2022 using our equitable adjustment authority (84 FR 85941 through 85943; 86 FR 63533 through 63535). For CY 2023, we propose to move HeartFlow (HCPCS 0503T) from New Technology APC 1511 to APC 5724 (Level 4 Diagnostic Tests and Related Services), a clinical APC, as we believe we have enough data to make an appropriate clinical APC assignment for HeartFlow. We direct readers to section III.E of this proposed rule for a more detailed discussion of the proposed Heartflow clinical APC assignment.

While HeartFlow was the first SaaS procedure for which we made separate payment under the OPPS, we have since begun paying for other SaaS procedures. In CY 2021, we assigned CPT code 92229 (Imaging of retina for detection or monitoring of disease; point-of-care automated analysis and report, unilateral or bilateral), an artificial intelligence system to detect diabetic retinopathy known as IDx-DR to APC 5733 with the status indicator “S”

(85 FR 85960 to 85961). IDx-DR uses an artificial intelligence algorithm to review images of a patient's retina to provide a clinical decision as to whether the patient needs to be referred to an eyecare professional for diabetic retinopathy or rescreened in twelve months (negative for mild diabetic retinopathy). Also, in CY 2021, we began paying for CPT code 0615T (Eye-movement analysis without spatial calibration, with interpretation and report), which involves the use of the EyeBOX system as an aid in the diagnosis of concussion. We assigned EyeBOX to APC 5734 with the status indicator "Q1," to indicate that the code is conditionally packaged when performed with another service on the same day (85 FR 85952 to 85953).

Over the past several years, the AMA has established several codes that describe SaaS procedures. HeartFlow, IDx-DR, and the EyeBox System are each described by single CPT codes. But for a procedure known by the tradename LiverMultiScan, the CPT editorial panel created two CPT codes for CY 2022, a primary code and an add-on code:

- 0648T: Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic MRI examination of the same anatomy (e.g., organ, gland, tissue, target structure) during the same session.
- 0649T: Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the same anatomy (e.g., organ, gland, tissue, target structure) (List separately in addition to code for primary procedure).

LiverMultiScan uses clinical software to aid the diagnosis and management of chronic liver disease through analysis using proprietary algorithms of MR images acquired from patients' providers. As described above, the coding for LiverMultiScan is bifurcated into CPT code 0648T, billable when LiverMultiScan is used to analyze already existing images, and CPT add-on code 0649T, describing the LiverMultiScan software analysis, which is adjunctive to the

acquisition of the MR images. In accordance with our OPPS policy, we review all new CPT codes and, for those that are payable under the OPPS, we assign them to appropriate APCs and make status indicator assignments for them. In the CY 2022 OPPS/ASC final rule with comment period, we assigned CPT code 0648T to New Technology APC 1511 (86 FR 63542).

Given the dependent nature and adjunctive characteristics of procedures described by add-on codes and in light of our longstanding OPPS packaging principles, payment for add-on codes is generally packaged into the primary procedure. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74942 through 74945) and in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66817 through 66818), we stated that procedures described by add-on codes represent an extension or continuation of a primary procedure, which means they are ancillary, supportive, dependent, or adjunctive to a primary service. Add-on codes describe services that are always performed in addition to a primary procedure and are never reported as a stand-alone code. Because the second LiverMultiScan code – CPT code 0649T – is an add-on code, in accordance with our current OPPS policy, we packaged payment for it with the primary service with which it is furnished, rather than paying for it separately as we do for the primary LiverMultiScan code – CPT code 0648T (86 FR 63541 through 63543).

2. Recent CPT Codes for SaaS Procedures

The AMA has continued to establish new CPT codes that describe SaaS procedures using two codes: a primary code that describes the standalone clinical software service and an add-on code that describes a clinical software service that is adjunctive to and billed concurrent with a diagnostic imaging service. The standalone code is billed when no additional imaging is required because raw images from a prior scan are available for the software to analyze, while the add-on code is billed with an imaging service when a prior imaging scan is unavailable, or the prior images are insufficient. If a patient needs a SaaS procedure and has no existing diagnostic images, the patient would undergo the diagnostic imaging (i.e., CT or MRI), and the SaaS procedure. In this scenario, the provider would report the diagnostic imaging service code and

the SaaS add-on code on the same day of service. In contrast, if a patient has pre-existing diagnostic images, the provider would only need to perform the SaaS procedure and would only report the standalone SaaS code.

Please see Table 49 for recent CPT codes for SaaS procedures, including LiverMultiScan. For CY 2022, the CPT Editorial Panel also established CPT codes 0721T, 0722T, 0723T, and 0724T.

Table 49: SAAS PROCEDURE CPT CODES, LONG DESCRIPTORS, APC ASSIGNMENTS AND STATUS INDICATORS

CPT code	Trade Name	Long Descriptor	APC	Status Indicator
0648T	LiverMultiScan	Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic MRI examination of the same anatomy (e.g., organ, gland, tissue, target structure) during the same session	1511	S
0649T	LiverMultiScan	Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the same anatomy (e.g., organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)	NA	N
0721T	Optellum LCP	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained without concurrent CT examination of any structure contained in previously acquired diagnostic imaging	1508	S
0722T	Optellum LCP	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained with concurrent CT examination of any structure contained in the concurrently	NA	N

CPT code	Trade Name	Long Descriptor	APC	Status Indicator
		acquired diagnostic imaging dataset (List separately in addition to code for primary procedure)		
0723T	Quantitative Magnetic Resonance Cholangiopancreatography (QMRCP)	Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained without diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (e.g., organ, gland, tissue, target structure) during the same session	1511	S
0724T	Quantitative Magnetic Resonance Cholangiopancreatography (QMRCP)	Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained with diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (e.g., organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)	NA	N

The standalone codes associated with LiverMultiScan (CPT code 0648T), Optellum LCP (CPT code 0721T), and QMRCP (CPT code 0723T) are paid separately under the OPPS and assigned to specific APCs as described in Table 49. However, according to our existing packaging policy, we would package payment for the add-on codes, specifically, CPT codes 0649T, 0722T, and 0724T, into the associated diagnostic imaging service.

3. CY 2023 Proposal for SaaS Add-on Codes

From 2021 to 2022, we reviewed and approved New Technology applications for the LiverMultiScan, Optellum, and QMRCP SaaS procedures. LiverMultiScan was assigned to a New Technology APC effective January 1, 2022, and Optellum and QMRCP were assigned to New Technology APCs effective July 1, 2022. While the standalone codes for these services are assigned to New Technology APCs and are separately payable, applicants have informed us that

the services described by the add-on codes, specifically, CPT codes 0649T, 0722T, and 0724T, should also be paid separately because the technologies are new and associated with significant costs.

Although the CPT Editorial Panel has designated these codes as add-on codes, the services described by CPT codes 0649T, 0722T, and 0724T are not consistent with our definition of add-on services. In many instances, the costs associated with the add-on codes exceed the costs of the imaging service with which they would be billed, and we believe these add-on codes describe separate and distinct services that should be paid separately, rather than as services that are ancillary, supportive, dependent, or adjunctive to a primary service into which their payment is packaged. Therefore, for CY 2023, we propose not to recognize the select CPT add-on codes that describe SaaS procedures under the OPPS and instead establish HCPCS codes, specifically, C-codes, to describe the add-on codes as standalone services that would be billed with the associated imaging service. We believe the payment for the proposed C-codes describing the SaaS procedures with add-on CPT codes, when billed concurrent with the acquisition of the images, should be equal to the payment for the SaaS procedures when the services are furnished without imaging and described by the standalone CPT code because the SaaS procedure is the same regardless of whether it is furnished with or without the imaging service. Therefore, we propose the C-codes be assigned to identical APCs and have the same status indicator assignments as their standalone codes.

For the LiverMultiScan service, we propose not to recognize CPT code 0649T under the OPPS and instead propose to establish C97X1 to describe the analysis of the quantitative magnetic resonance images that must be billed alongside the relevant CPT code describing the acquisition of the images. Below is the proposed long descriptor for the service:

- C97X1: Quantitative magnetic resonance analysis of tissue composition (e.g., fat, iron, water content), includes multiparametric data acquisition, preparation, transmission,

interpretation and report, performed in the same session and/or same date with diagnostic MRI examination of the same anatomy (e.g., organ, gland, tissue, target structure).

For the Optellum LCP service, we propose not to recognize CPT code 0722T and instead propose to establish C97X2 to describe the use of Optellum LCP that must be billed alongside a concurrent CT scan. Below is the proposed long descriptor for the service:

- C97X2: Quantitative computed tomography (CT) tissue characterization, includes data acquisition, preparation, transmission, interpretation and report, performed in the same session and/or same date with concurrent CT examination of any structure contained in the acquired diagnostic imaging dataset.

For the QMRCP service, we propose not to recognize CPT code 0724T and instead propose to establish C97X3 to describe the use of QMRCP that must be billed alongside a concurrent CT scan. Below is the proposed long descriptor for the service:

- C97X3: Quantitative magnetic resonance cholangiopancreatography (QMRCP) includes data acquisition, preparation, transmission, interpretation and report, performed in the same session and/or same date with diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (e.g., organ, gland, tissue, target structure).

The proposed payment rates for C97X1, C97X2, and C97X3, as well as the standalone CPT codes that describe the same SaaS procedures, can be found in Addendum B to this proposed rule, which is available via the CMS website.

4. Comment Solicitation on Payment Policy for SaaS Procedures

Consistent with our OPPS payment policies, we review new CPT codes and determine whether the items or services described by the codes are appropriate for payment under the OPPS. For codes that are appropriate for payment, we propose the appropriate payment indicator, known as the status indicator (SI) under the OPPS, and APC assignment, according to our OPPS policies. We note the new SaaS procedures have been assigned Category III CPT codes by the AMA. Because we generally do not have hospital claims data for new codes, the

payment indicator and APC assignments are determined based on several factors, which include but are not limited to:

- Review of resource costs and clinical similarity of the service to existing procedures;
- Input from our medical advisors; and
- Other information available to us (75 FR 71909).

Although we have begun paying separately for SaaS procedures under the OPPS relatively recently, with the HeartFlow procedure being the first separately payable SaaS procedure in CY 2018, we recognize that certain clinical decision support software, including machine learning or “AI,” has been available for many years. In the past ten years, clinical decision support software has been commonly used alongside electronic medical records by medical practitioners. Nonetheless, the number of FDA approved or cleared “machine learning” or “AI” clinical software programs has rapidly increased in the past few years. We note that the FDA has approved many SaaS procedures for similar functions: there are at least six software products that purport to detect findings in Computed Tomography studies of the chest.¹³⁹ Additionally, we note some clinical software developers are now using alternative licensing that charges per use rather than using the traditional annual subscription or bulk use subscription. Empirical research has shown that pay-per-use may lead to overuse of “AI” technology.¹⁴⁰ As a result of these variables and potentially others, there is significant price variation within the SaaS procedure space.

We recognize that, as described in the introduction to this section, SaaS procedures are a heterogenous group of services, which presents challenges when it comes to adopting payment policy for SaaS procedures as a whole. Due to the novel and evolving nature of these technologies, it has been challenging to compare some SaaS procedures to existing medical services for purposes of determining clinical and resource similarity.

¹³⁹ <https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices>

¹⁴⁰ <https://www.nature.com/articles/s41746-022-00609-6.pdf>

We are therefore soliciting public comment on a payment approach that would broadly apply to SaaS procedures, including:

- How to identify services that should be separately recognized as an analysis distinct from both the underlying imaging test or the professional service paid under the PFS;
- How to identify costs associated with these kinds of services;
- How these services might be available and paid for in other settings (physician offices, for example); and
- How we should consider payment strategies for these services across settings of care.

We are also seeking comment on the specific payment approach we might use for these services under the OPSS as SaaS-type technology becomes more widespread across healthcare which are not limited to imaging services. For example, we could consider packaging payment for the diagnostic image and the SaaS procedure under new HCPCS codes, (i.e., G-codes), to efficiently and cost-effectively pay for SaaS procedures. These G-codes could broadly describe the diagnostic image service and any SaaS procedure performed. Under this approach, the OPSS would not recognize either the standalone or the add-on codes describing SaaS procedures. Instead, all associated imaging and the SaaS would be described by a single HCPCS code, which could be assigned to a relevant clinical APC. An example of this would be hypothetical code GXXX1 (Computed tomography, thorax, diagnostic; with or without contrast material and with concurrent or subsequent computed analysis of the original image for further interpretation and report using a standardized computing instrument.), which describes both diagnostic imaging and any associated SaaS for the thorax region of the body and could be assigned to APC 5573 (Level 3 Imaging with Contrast).

Alternatively, we could expand composite APCs, which provide a single payment for groups of services that are performed together, including the diagnostic imaging and SaaS procedure, during a single clinical encounter to result in the provision of a complete service.

A third approach could utilize HCPCS codes (i.e., G- or C- codes) to describe both the diagnostic imaging and the SaaS procedure, and then assign the code that describes the combined services to New Technology APCs that would pay for both services.

We welcome input from interested parties on these payment approaches and any additional payment approaches that would enhance our ability to provide equitable payment for SaaS procedures while protecting the Medicare trust fund.

Finally, we are aware that bias in software algorithms has the potential to disparately affect the health of certain populations.¹⁴¹ Therefore, in addition to our comment solicitation on payment approaches, we are seeking comments on how we could encourage software developers and other vendors to prevent and mitigate bias in their algorithms and predictive modeling. We would also appreciate feedback on how we can accurately evaluate and ensure that the necessary steps have been taken to prevent and mitigate bias in software algorithms to the extent possible.

H. Proposed Payment Adjustments under the IPPS and OPSS for Domestic NIOSH-Approved Surgical N95 Respirators

In the FY 2023 IPPS/LTCH PPS proposed rule, we requested public comments on potential IPPS and OPSS payment adjustments for wholly domestically made National Institute for Occupational Safety & Health (NIOSH)-approved surgical N95 respirators (87 FR 28622 through 28625). Given the importance of NIOSH-approved surgical N95 respirators in protecting hospital personnel and beneficiaries from the SARS-CoV-2 virus and future respiratory pandemic illnesses, we indicated we were considering whether it might be appropriate to provide payment adjustments to hospitals to recognize the additional resource costs they incur to acquire NIOSH-approved surgical N95 respirators that are wholly domestically made. We stated that NIOSH-approved surgical N95 respirators, which faced severe shortage at the onset of the COVID-19 pandemic, are essential for the protection of patients and hospital personnel that interface with patients. We indicated that procurement of

¹⁴¹ <https://www.science.org/doi/10.1126/science.aax2342>

NIOSH-approved surgical N95 respirators that are wholly domestically made, while critical to pandemic preparedness and protecting health care workers and patients, can result in additional resource costs for hospitals.

We said we were interested in feedback and comments on the appropriateness of payment adjustments that would account for these additional resource costs. We stated that we believe such payment adjustments could help achieve a strategic policy goal, namely, sustaining a level of supply resilience for NIOSH-approved surgical N95 respirators that is critical to protect the health and safety of personnel and patients in a public health emergency. We stated we were considering such payment adjustments for 2023 and potentially subsequent years.

As described in more detail in the sections that follow, and for the reasons discussed, we propose to make a payment adjustment under the OPPI and IPPS for the additional resource costs of domestic NIOSH-approved surgical N95 respirators for cost reporting periods beginning on or after January 1, 2023.

2. General Background and Overview of Proposal

As discussed in the FY 2023 IPPS/LTCH PPS proposed rule, President Biden issued Executive Order (E.O.) 13987, titled “Organizing and Mobilizing the United States Government To Provide a Unified and Effective Response To Combat COVID–19 and To Provide United States Leadership on Global Health and Security” on January 20, 2021 (86 FR 7019). This order launched a whole-of-government approach to combat the coronavirus disease 2019 (COVID-19) and prepare for future biological and pandemic threats. This response has continued over the past year. In March 2022, President Biden released the National COVID-19 Preparedness Plan that builds on the progress of the prior 13 months and lays out a roadmap to fight COVID-19 in the future.¹⁴² Both the ongoing threat of COVID-19 and the potential for future pandemics necessitate significant investments in pandemic preparedness.

¹⁴² White House, National COVID-19 Preparedness Plan, March 2022; <https://www.whitehouse.gov/wpcontent/uploads/2022/03/NAT-COVID-19-PREPAREDNESS-PLAN.pdf>

Availability of personal protective equipment (PPE) in the health care sector is a critical component of this preparedness, and one that displayed significant weakness in the beginning of the COVID-19 pandemic. In spring of 2020, supply chains for PPE faced severe disruption due to lockdowns that limited production, and unprecedented demand spikes across multiple industries. Supply of surgical N95 respirators—a specific type of filtering facepiece respirator used in clinical settings—was one type of PPE that was strained in hospitals. So-called “just-in-time” supply chains that minimize stockpiling, in addition to reliance on overseas production, left U.S. hospitals unable to obtain enough surgical N95 respirators to protect health care workers. Prices for surgical N95s soared, from an estimated \$0.25–\$0.40 range¹⁴³ to \$5.75¹⁴⁴ or even \$12.00 in some cases.¹⁴⁵ Unable to obtain surgical N95s regulated by NIOSH, hospitals had to turn to KN95s—a Chinese standard of respirator— and other non-NIOSH-approved disposable respirators that were authorized under Emergency Use Authorization (EUA). Concerns were raised during the COVID-19 pandemic regarding counterfeit respirators. NIOSH evaluates and approves surgical N95s to meet efficacy standards for air filtration and protection from fluid hazards present during medical procedures. KN95 respirators, on the other hand, are not regulated by NIOSH. KN95s have faced particular counterfeit and quality risks—with NIOSH finding that about 60 percent of KN95 respirators that it evaluated during the COVID-19 pandemic in 2020 and 2021 did not meet the particulate filter efficiency requirements that they

¹⁴³ Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Supply Chain Control Tower analysis

¹⁴⁴ Society for Healthcare Organization Procurement Professionals, COVID-19 PPD Cost Analysis, April 2020;

http://cdn.cnn.com/cnn/2020/images/04/16/shopp.covid.ppd.costs.analysis_.pdf

¹⁴⁵ Washington Post, “U.S. sent millions of face masks to China early this year, ignoring pandemic warning signs,” April 2020;

https://www.washingtonpost.com/health/us-sent-millions-of-face-masks-to-china-early-this-yearignoring-pandemic-warning-signs/2020/04/18/aaccf54a-7ff5-11ea-8013-1b6da0e4a2b7_story.html

intended to meet.¹⁴⁶ Failure to meet these requirements compromises safety of health care personnel and patients.

Over the course of the pandemic, U.S. industry responded to the shortages and dramatically increased production of N95s. Today, the majority of surgical N95s purchased by hospitals are assembled in the U.S., and prices have returned to rates closer to \$0.70 per respirator.¹⁴⁷ However, risks remain to maintain preparedness for COVID-19 and future pandemics. It is important to maintain this level of domestic production for surgical N95s, which provide the highest level of protection from particles when worn consistently and properly, protecting both health care personnel and patients from the transfer of microorganisms, body fluids, and particulate material—including the virus that causes COVID-19. Additionally, it is important as a long-term goal to ensure that a sufficient share of those surgical N95s are wholly made in the U.S.—that is, including raw materials and components. The COVID-19 pandemic has illustrated how overseas production shutdowns, foreign export restrictions, or ocean shipping delays can jeopardize availability of raw materials and components needed to make critical public health supplies. In a future pandemic or COVID-19-driven surge, hospitals need to be able to count on PPE manufacturers to deliver the equipment they need on a timely basis in order to protect health care workers and their patients. Sustaining a level of wholly domestic production of surgical N95 respirators is integral to maintaining that assurance.

This policy goal—ensuring that quality PPE is available to health care personnel when needed by maintaining production levels of wholly domestically made PPE—is emphasized in the National Strategy for a Resilient Public Health Supply Chain, published in July 2021 as a deliverable of President Biden’s Executive Order 14001 on “A Sustainable Public Health Supply Chain.” To help achieve this goal, the U.S. Government is committing to purchase wholly

¹⁴⁶ U.S. Centers for Disease Control and Prevention “Types of Masks and Respirators”; <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/types-of-masks.html>

¹⁴⁷ Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Supply Chain Control Tower analysis

domestically made PPE in line with new requirements in section 70953 of the Infrastructure Investment and Jobs Act (Pub. L. 117-58). These new contract requirements stipulate that PPE purchased by covered departments must be wholly domestically made—that is, the products as well as their materials and components must be grown, reprocessed, reused, or produced in the U.S.

The Federal Government’s procurement of wholly domestically made PPE will help achieve the stated policy goal. However, the U.S. Government alone cannot sustain the necessary level of production. As outlined in the previously mentioned National Strategy for a Resilient Public Health Supply Chain, the U.S. Government is only one small part of the market for PPE. Hospitals are the primary purchasers and users of medical PPE including surgical N95 respirators. Sustaining a strong domestic industrial base for PPE—in order to be prepared for future pandemics or COVID-19-driven surges and protect Americans’ health during such times—therefore, requires hospitals’ support.

Surgical N95 respirators are a particularly critical type of PPE needed to protect personnel and beneficiaries from the SARS-CoV-2 virus and future respiratory pandemic illnesses. However, wholly domestically made NIOSH-approved surgical N95 respirators are generally more expensive than foreign-made ones. Therefore, we stated in the FY 2023 IPPS/LTCH PPS proposed rule that we believe a payment adjustment that reflects, and offsets, the additional marginal costs that hospitals face in procuring wholly domestically made NIOSH-approved surgical N95 respirators might be appropriate. These marginal costs are due to higher prices for wholly domestically made NIOSH-approved surgical N95s, which, in turn, primarily stem from higher costs of manufacturing labor in the U.S. compared to costs in countries such as China, where many N95 and other respirators are made. We stated that such a payment adjustment might provide sustained support over the long term to hospitals that purchase wholly domestically made NIOSH-approved surgical N95 respirators, and could help safeguard

personnel and beneficiary safety over the long term by sustaining production and availability of these respirators.

As previously noted, in the FY 2023 IPPS/LTCH PPS proposed rule, we requested public comments on potential IPPS and OPSS payment adjustments for wholly domestically made NIOSH-approved surgical N95 respirators. We received many comments that were helpful in developing the proposed payment adjustment discussed later in this section. For instance, many commenters were supportive of a payment adjustment, acknowledging the importance of surgical N95 respirators in keeping health care workers and patients safe and attesting to the difficulties of procuring surgical N95 respirators during the height of the COVID-19 pandemic. The majority of commenters supported an approach of CMS making biweekly interim lump-sum payments that would be reconciled at cost report settlement, although some commenters preferred a claims-based approach. Many commenters urged CMS to minimize the administrative burden on hospitals in the development of any N95 payment policy. We also acknowledge the comments of MedPAC and others stating that Medicare payment policy is not the most appropriate mechanism to support domestic manufacturing of medical supplies. As discussed, because hospitals are the primary purchasers and users of medical PPE, including surgical N95 respirators, we believe a payment adjustment that reflects the additional marginal costs that hospitals face in procuring wholly domestically made NIOSH-approved surgical N95 respirators may help to sustain their domestic production and availability, and thereby help to safeguard personnel and beneficiary safety over the long term. We thank everyone who submitted comments for their feedback.

We propose to make a payment adjustment under the OPSS and IPPS for the additional resource costs that hospitals face in procuring domestic NIOSH-approved surgical N95 respirators, as defined in Section X.H.3 of this proposed rule, for cost reporting periods beginning on or after January 1, 2023. For the IPPS, we propose to make this payment adjustment under section 1886(d)(5)(I) of the Act, which authorizes the Secretary to provide by

regulation for such other exceptions and adjustments to the payment amounts under section 1886(d) of the Act as the Secretary deems appropriate. For the OPSS, we propose to make this payment adjustment under section 1833(t)(2)(E) of the Act, which authorizes the Secretary to establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments.

3. Proposed Definition of Domestic NIOSH-approved Surgical N95 Respirators

For purposes of this policy, we propose to categorize all NIOSH-approved surgical N95 respirators purchased by hospitals into two categories: 1) Domestic NIOSH-approved surgical N95 respirators; and 2) Non-domestic NIOSH-approved surgical N95 respirators.

As discussed, it is critically important to ensure that a sufficient share of surgical N95s are wholly made in the U.S.—that is, including raw materials and components. We believe that the most appropriate framework for determining if a NIOSH-approved surgical N95 respirator is wholly made in the U.S. and therefore, considered domestic for purposes of the proposed adjustments, is the Berry Amendment. The Berry Amendment is a statutory requirement familiar to manufacturers that restricts the Department of Defense (DoD) from using funds appropriated or otherwise available to DoD for procurement of food, clothing, fabrics, fibers, yarns, other made-up textiles, and hand or measuring tools that are not grown, reprocessed, reused, or produced in the United States.¹⁴⁸ Berry Amendment restrictions are implemented by the DoD Federal Acquisition Regulation Supplement (DFARS) 252.225-7002, and State DOD cannot acquire specified “items, either as end products or components, unless the items have been grown, reprocessed, reused, or produced in the United States.”¹⁴⁹ Unless DOD grants a waiver because domestic firms do not make the product or because other exceptions in the law are met, the entire production process of an affected product, from the production of raw

¹⁴⁸ <https://www.trade.gov/berry-amendment>

¹⁴⁹ <https://www.trade.gov/berry-amendment-implementation>

materials to the manufacture of all components to final assembly, must be performed in the United States.¹⁵⁰

The Berry Amendment has been critical to the viability of the textile and clothing production base in the United States and has been critical to maintaining the safety and security of our armed forces, by requiring covered items to be produced in the United States.¹⁵¹ We believe that using the Berry Amendment as the basis for defining domestic NIOSH-approved surgical N95 respirators will provide similar support to U.S. surgical N95 respirator manufacturers and help ensure that quality surgical N95 respirators are available to health care personnel when needed.

Therefore, based on the Berry Amendment, we propose to define a NIOSH-approved surgical N95 respirator as domestic if the respirator and all of its components are grown, reprocessed, reused, or produced in the United States. We propose that for purposes of this policy all other NIOSH-approved surgical N95 respirators would be non-domestic.

We recognize that a hospital cannot fully independently determine if a NIOSH-approved surgical N95 respirator it purchases is domestic under our proposed definition. Therefore, we propose that a hospital may rely on a written statement from the manufacturer stating that the NIOSH-approved surgical N95 respirator the hospital purchased is domestic under our proposed definition. The written statement must have been certified by one of the following: (i) the manufacturer's Chief Executive Officer (CEO); (ii) the manufacturer's Chief Operating Officer (COO); or (iii) an individual who has delegated authority to sign for, and who reports directly to, the manufacturer's CEO or COO. The written statement, or a copy of such statement, could be obtained by the hospital directly from the manufacturer, obtained through the supplier or Group Purchasing Organization (GPO) for the hospital who obtained it from the manufacturer, or obtained by the hospital because it was included with or printed on the packaging by the

¹⁵⁰ <https://sgp.fas.org/crs/misc/R44850.pdf>

¹⁵¹ <https://www.trade.gov/berry-amendment>

manufacturer. This written statement may be required to substantiate the data included on the supplemental cost reporting form as discussed in section X.H.5 of this proposed rule. The recordkeeping requirements at current § 413.20, require providers of services to maintain sufficient financial records and statistical data for proper determination of costs payable under Medicare.

4. Proposed Payment Adjustment Amount under the IPPS and OPSS for Domestic NIOSH-approved Surgical N95 Respirators

We expect that domestic NIOSH-approved surgical N95 respirators will continue to be generally more costly than non-domestic respirators. However, it is challenging to precisely predict and quantify the future cost differences given the dynamic nature of the current marketplace and data limitations. Therefore, we propose to initially base the payment adjustments on the IPPS and OPSS shares of the estimated difference in the reasonable costs¹⁵² of a hospital to purchase domestic NIOSH-approved surgical N95 respirators compared to non-domestic respirators. These payments would be provided biweekly as interim lump-sum payments to the hospital and would be reconciled at cost report settlement. Under this proposal the biweekly interim lump-sum payments would be available for cost reporting periods beginning on or after January 1, 2023. Any provider could make a request for these biweekly interim lump sum payments for an applicable cost reporting period, as provided under 42 CFR 413.64 (Payments to providers: Specific rules) and 42 CFR 412.116(c) (Special interim payments for certain costs). These payment amounts would be determined by the MAC, consistent with existing policies and procedures. In general, interim payments are determined by estimating the reimbursable amount for the year using Medicare principles of cost reimbursement and dividing it into twenty-six equal biweekly payments. The estimated amount is based on the most current cost data available, which will be reviewed and, if necessary,

¹⁵² In accordance with the principles of reasonable cost as set forth in section 1861(v)(1)(A) of the Act and in 42 CFR 413.1 and 413.9

adjusted at least twice during the reporting period. (See CMS Pub 15-1 2405.2 for additional information.) The MACs would determine the interim lump-sum payments based on the data the hospital may provide that reflects the information that will be included on the N95 supplemental cost reporting form as discussed in section X.H.5 of this proposed rule. In future years, if finalized, the MACs would determine the interim biweekly lump-sum payments utilizing information from the prior year's surgical N95 supplemental cost reporting form, which may be adjusted based on the most current data available. This would be consistent with the current policies for medical education costs, and bad debts for uncollectible deductibles and coinsurance paid on interim biweekly basis as noted in CMS Pub 15-1 2405.2. As described in more detail in section X.H.5 of this proposed rule, a hospital would separately report on its cost report the aggregate cost and total quantity of domestic NIOSH-approved surgical N95 respirators and non-domestic respirators for cost reporting periods beginning on or after January 1, 2023. This information, along with existing information already collected on the cost report as shown in section X.H.5 of this proposed rule, would be used to calculate a Medicare payment for the estimated cost differential, specific to each hospital, incurred due to the purchase of domestic NIOSH-approved surgical N95 respirators compared to non-domestic respirators.

As previously discussed, for the IPPS, we propose to make this payment adjustment for the additional resource costs of domestic NIOSH-approved surgical N95 respirators under section 1886(d)(5)(I) of the Act. To further support the strategic policy goal of sustaining a level of supply resilience for NIOSH-approved surgical N95 respirators that is critical to protect the health and safety of personnel and patients in a public health emergency, we are not proposing to make the IPPS payment adjustment budget neutral under the IPPS.

As also previously discussed, for the OPSS, we propose to make the payment adjustment for these additional resource costs under section 1833(t)(2)(E) of the Act. Section 1833(t)(2)(E) of the Act provides that the Secretary shall establish, in a budget neutral manner, other adjustments (in addition to outlier and transitional pass-through payments) necessary to ensure

equitable payments, such as adjustments for certain classes of hospitals. Consistent with this authority, the proposed OPSS payment adjustment would be budget neutral.

As we gain more experience with this payment policy, if finalized, its impact on the N95 marketplace, and the data collected, we may revisit the approach of payments based on the reasonable costs of each hospital. See the discussion in section X.H.8 of this proposed rule regarding potential future rulemaking to refine our proposed approach.

5. Proposed Calculation of the OPSS and IPSS Payment Adjustments on the Cost Report

In order to calculate the N95 payment adjustment for each eligible cost reporting period, we propose to create a new supplemental cost reporting form that will collect from hospitals the additional information described in this section. This information would be used along with other information already collected on the hospital cost report to calculate IPSS and OPSS payment adjustment amounts. The information collection requirements for the proposed new supplemental cost reporting worksheet are discussed in section XXII.F of this proposed rule.

In this section we describe the information we propose to collect on the new supplemental cost reporting form and the proposed steps for determining the IPSS and OPSS payment adjustment amounts.

Step 1 – Collect additional information on the new supplemental cost reporting form.

To determine the IPSS and OPSS payment adjustments, we propose to collect the following information on a new supplemental cost reporting form:

1) Total quantity of domestic NIOSH-approved surgical N95 respirators purchased by hospital.¹⁵³

2) Total aggregate cost of domestic NIOSH-approved surgical N95 respirators purchased by hospital.

¹⁵³ We note for this discussion, reference to the “hospital” refers to the “hospital and hospital healthcare complex” that completes the cost report form CMS-2552-10.

3) Total quantity of non-domestic NIOSH-approved surgical N95 respirators purchased by hospital.

4) Total aggregate cost of non-domestic NIOSH-approved surgical N95 respirators purchased by hospital.

Step 2 – Calculate a hospital-specific unit cost differential between domestic and non-domestic NIOSH-approved surgical N95 respirators.

With the respirator information reported on the new supplemental cost reporting form we propose to calculate the following statistics on the new cost report form:

1) The average cost of domestic NIOSH-approved surgical N95 respirators purchased. This would be calculated by dividing the reported total aggregate cost of the domestic NIOSH-approved surgical N95 respirators purchased by the reported total quantity of domestic NIOSH-approved surgical N95 respirators purchased. If the hospital purchased zero NIOSH-approved surgical N95 domestic respirators, this value would be set to 0.

2) The average cost of non-domestic NIOSH-approved surgical N95 respirators purchased. This would be calculated by dividing the reported total aggregate cost of the non-domestic NIOSH-approved surgical N95 respirators purchased by the reported total quantity of non-domestic NIOSH-approved respirators purchased. If the hospital purchased zero non-domestic NIOSH-approved surgical N95 respirators, this value would be set to 0.

3) The hospital-specific unit cost differential between domestic and non-domestic NIOSH-approved surgical N95 respirators. This would be calculated by subtracting the average cost of non-domestic NIOSH-approved surgical N95 respirators purchased from the average cost of domestic NIOSH-approved surgical N95 respirators purchased. If the average cost of non-domestic NIOSH-approved surgical N95 respirators purchased is greater than the average cost of domestic NIOSH-approved surgical N95 respirators purchased, this value would be set to 0.

As discussed in section X.H.8, we may consider in future rulemaking establishing a national minimum average cost for non-domestic NIOSH-approved surgical N95 respirators purchased

that could be used in determining the hospital-specific unit cost differential for hospitals that only purchased domestic NIOSH-approved surgical N95 respirators or that have unusually low average costs for their non-domestic NIOSH-approved surgical N95 respirators.

Step 3 – Calculate a total cost differential for the purchase of domestic NIOSH-approved surgical N95 respirators.

The next step in the proposed payment adjustment calculation is determining the total cost differential for the purchase of domestic NIOSH-approved surgical N95 respirators. This amount represents the total additional costs the hospital incurred by purchasing domestic NIOSH-approved surgical N95 respirators over purchasing non-domestic NIOSH-approved surgical N95 respirators. We propose to calculate this amount by multiplying the hospital-specific unit cost differential calculated in Step 2 by the total quantity of domestic NIOSH-approved surgical N95 respirators purchased reported in Step 1.

Step 4 – Determine IPPS and OPSS share of total hospital costs.

The total cost differential calculated in Step 3 is reflective of all domestic NIOSH-approved surgical N95 respirators used throughout the hospital while treating all patients. This total cost differential needs to be disaggregated to estimate the additional costs incurred by purchasing domestic NIOSH-approved surgical N95 respirators used in treating patients receiving services paid under IPPS and OPSS, specifically. To apportion the total cost differential to the IPPS and OPSS services, we propose to use cost data already reported on the hospital cost report. We specifically propose to use the following from the Form CMS-2552-10:

a) Total costs for all inpatient routine services, ancillary services, outpatient services, and other reimbursable services as reported in Worksheet C Part I line 202 column 5.

b) Total Medicare Part A hospital inpatient costs as reported in Worksheet D-1 Part II, line 49, column 5.

c) Total Medicare Part B hospital outpatient costs as reported in Worksheet D Part V, line 202, column 5 + column 6 + column 7.

We propose to calculate the IPPS percent share of the total cost differential (calculated in Step 3) as total Medicare Part A hospital inpatient costs (Step 4b) divided by total costs for all inpatient routine services, ancillary services, outpatient services, and other reimbursable services (Step 4a). We propose to calculate the OPSS percent share of the total cost differential as total Medicare Part B hospital outpatient costs (Step 4c) divided by total costs for all inpatient routine services, ancillary services, outpatient services, and other reimbursable services (Step 4a).

Step 5 – Determine IPPS and OPSS Payment Adjustment for Domestic NIOSH-Approved Surgical N95 Respirators.

To calculate the IPPS payment adjustment for domestic NIOSH-approved surgical N95 respirators, we propose to multiply the IPPS cost share (determined in Step 4) by the total cost differential for the purchase of domestic respirators (Step 3). To calculate the OPSS payment adjustment for domestic NIOSH-approved surgical N95 respirators, we propose to multiply the OPSS cost share (determined in Step 4) by the total cost differential for the purchase of domestic respirators (Step 3). As described previously, these calculated payment adjustments would be reconciled against interim lump-sum payments received by the hospital for this policy.

To demonstrate these calculations, in table 50 we have provided an example for a mock hospital that purchased both domestic and non-domestic NIOSH-approved surgical N95 respirators during its cost reporting period beginning on or after January 1, 2023. The example shows the additional data the hospital would report on its supplemental cost reporting form, the cost data pulled from other hospital cost report worksheets, and the calculations performed to determine the hospital’s IPPS and OPSS payment adjustment for domestic NIOSH-approved surgical N95 respirators.

TABLE 50: Mock N95 Supplemental Cost Reporting Form

Line Description	Data Source	Value
Line 1: Total quantity of domestic NIOSH-approved surgical N95 respirators purchased by hospital.	Entered by hospital on new form.	150,000

Line Description	Data Source	Value
Line 2: Total aggregate cost of domestic NIOSH-approved surgical N95 respirators purchased by hospital.	Entered by hospital on new form.	\$112,500
Line 3: Total quantity of non-domestic NIOSH-approved surgical N95 respirators purchased by hospital.	Entered by hospital on new form.	150,000
Line 4: Total aggregate cost of non-domestic NIOSH-approved surgical N95 respirators purchased by hospital .	Entered by hospital on new form.	\$82,500
Line 5: Total costs for all inpatient routine services, ancillary services, outpatient services, and other reimbursable services	Worksheet C Part I, line 202 column 5.	\$100,000,000
Line 6: Total Medicare Part A hospital inpatient costs	Worksheet D-1 Part II, line 49, column 5.	\$20,000,000
Line 7: Total Medicare Part B hospital outpatient costs	Worksheet D Part V, line 202, column 5 + column 6 + column 7.	\$10,000,000
Line 8: Average unit cost of domestic NIOSH-approved surgical N95 respirators purchased.	Calculation: Line 2 / Line 1. If line 1 is equal to 0, then set value to 0.	\$0.75
Line 9: Average unit cost of non-domestic NIOSH-approved surgical N95 respirators purchased.	Calculation: Line 4 / Line 3. If Line 3 is equal to 0, then set value to 0.	\$0.55
Line 10: Difference in average unit cost of domestic and non-domestic NIOSH-approved surgical N95 respirators purchased.	Calculation: Line 8 - Line 9. If value is less than 0, then set value to 0.	\$0.20
Line 11: Total cost differential for purchasing domestic NIOSH-approved surgical N95 respirators.	Calculation: Line 1 * Line 10.	\$30,000
Line 12: Medicare Part A hospital inpatient cost share.	Calculation: Line 6 / Line 5.	0.20
Line 13: Medicare Part B hospital outpatient cost share.	Calculation: Line 7 / Line 5.	0.10
Line 14: IPPS Payment Adjustment for Domestic NIOSH-Approved Surgical N95 Respirators.	Calculation: Line 11 * Line 12.	\$6,000
Line 15: OPSS Payment Adjustment for Domestic NIOSH-Approved Surgical N95 Respirators.	Calculation: Line 11 * Line 13.	\$3,000

6. Proposed Establishment of the OPSS Payment Adjustment for Domestic NIOSH-Approved Surgical N95 Respirators in a Budget Neutral Manner

As noted earlier, section 1833(t)(2)(E) of the Act provides that the Secretary shall establish adjustments necessary to ensure equitable payments in a budget neutral manner. In

order to maintain OPSS budget neutrality, we propose to develop a spending estimate associated with this proposed policy. Specifically, this spending estimate would reflect the OPSS payment adjustment that would be made in CY 2023 for the additional resource costs of domestic NIOSH-approved surgical N95 respirators used in the treatment of OPSS patients. The data currently available to calculate this spending estimate is limited. However, we believe the proposed methodology described next to calculate this spending estimate for CY 2023 is reasonable based on the information available.

We propose to calculate the estimated total spending associated with this policy by multiplying together estimates of the following:

- 1) Estimate of the total number of NIOSH-approved surgical N95 respirators used in the treatment of OPSS patients in CY 2023.

- 2) Estimate of the difference in the average unit cost of domestic and non-domestic NIOSH-approved surgical N95 respirators.

- 3) Estimate of the percentage of NIOSH-approved surgical N95 respirators used in the treatment of OPSS patients in CY 2023 that are domestic.

For purposes of this estimate, we believe it is reasonable to assume that one NIOSH-approved surgical N95 respirator is used per OPSS encounter. Based on the outpatient claims volume available for ratesetting in this CY 2023 OPSS proposed rule, we have approximately 103.4 million OPSS claims. Therefore, for CY 2023, we are estimating that the total number of NIOSH-approved surgical N95 respirators (both domestic and non-domestic) used in the treatment of OPSS patients in CY 2023 is 103.4 million. Based on available data, our best estimate of the difference in the average unit cost of domestic and non-domestic NIOSH-approved surgical N95 respirators is \$0.20.

It is particularly challenging to estimate the percentage of domestically manufactured NIOSH-approved surgical N95 respirators that will be used in the treatment of OPSS patients in CY 2023. The OMB's Made in America Office recently conducted a data call on capacity in

which several entities attested to being able to supply 3.6 billion NIOSH-approved and Berry-compliant surgical N95 respirators annually in the future if there were sufficient demand. We recognize that it may take time for this capacity to be fully reflected in hospital purchases. Therefore, although this would be sufficient capacity to supply the entire hospital industry if it were to be available and focused on this segment of the marketplace in 2023, we believe it is reasonable to assume that this will not happen instantaneously and hospitals in aggregate may in fact be able to purchase less than half of their NIOSH-approved surgical N95 respirators as domestic in 2023. Therefore, for purposes of this OPSS budget neutrality estimate, we propose to set the percentage of NIOSH-approved surgical N95 respirators used in the treatment of OPSS patients in CY 2023 that are domestic to 40 percent, or slightly less than half.

We estimate that total CY 2023 OPSS payments associated with this policy will be \$8.3 million (or 103.4 million claims * \$0.20 * 40 percent). This represents approximately 0.01 percent of the OPSS, which we propose to budget neutralize through an adjustment to the OPSS conversion factor. We note that the volume of claims data available for ratesetting typically increases between the proposed and final rules, so this spending estimate may change. However, we believe this proposed methodology will best approximate CY 2023 OPSS spending associated with the proposed policy.

We recognize that this proposed approach to estimating budget neutrality under the OPSS is based on the limited data available. If finalized, we may consider refining this approach for future years, especially once data collected on cost reports for this policy is available.

7. Proposed Regulation Amendments

For the IPPS, we propose to codify this payment adjustment in the regulations by adding new paragraph (f) to § 412.113 to specify that, for cost reporting periods beginning on or after January 1, 2023, a payment adjustment is made to a hospital for the additional resource costs of domestic NIOSH-approved surgical N95 respirators. The payment adjustment is based on the estimated difference in the reasonable cost incurred by the hospital for domestic

NIOSH-approved surgical N95 respirators purchased during the cost reporting period as compared to other NIOSH-approved surgical N95 respirators purchased during the cost reporting period. We also propose to make conforming changes to § 412.1(a) and § 412.2(f) to reflect the proposed payment adjustment for the additional resource costs of domestic NIOSH-approved surgical N95 respirators.

For the OPSS, we propose to codify this payment adjustment in the regulations by adding a new paragraph (j) to § 419.43 to specify at new paragraph (j)(1) that, for cost reporting periods beginning on or after January 1, 2023, CMS makes a payment adjustment for the additional resource costs of domestic NIOSH-approved surgical N95 respirators. New paragraph (j)(2) would provide that the payment adjustment is based on the estimated difference in the reasonable cost incurred by the hospital for domestic NIOSH-approved surgical N95 respirators purchased during the cost reporting period as compared to other NIOSH-approved surgical N95 respirators purchased during the cost reporting period. Finally, new paragraph (j)(3) would state that CMS establishes the payment adjustment under paragraph (j)(2) in a budget neutral manner.

8. Alternatives Considered

As we gain more experience with this payment policy, if finalized, its impact on the N95 marketplace, and the data collected, we may revisit our proposed approach of payments based on the reasonable costs of each hospital as discussed in section X.H.4 and section X.H.5 of this proposed rule. As one example, we might base the payment adjustment on the national average cost differential between a domestic NIOSH-approved surgical N95 respirator and a non-domestic one as collected on the hospital cost reports, rather than use hospital specific differentials. A single national average cost differential could continue to be implemented as biweekly interim lump-sum payments reconciled at cost report settlement, or it could be implemented as a claims-based add-on payment under the IPPS and OPSS. As another example of a potential future refinement, even if we were to maintain hospital specific differentials, it may be appropriate to establish a national minimum average cost for non-domestic NIOSH-

approved surgical N95 respirators for use in calculating the payment differential for a hospital that only uses domestic NIOSH-approved surgical N95 respirators or that has unusually low average costs for its non-domestic NIOSH-approved surgical respirators. We could potentially establish such a national minimum average cost using an appropriate percentile of the average unit cost of non-domestic NIOSH-approved surgical N95 respirators across hospitals, as calculated on the cost report.

We might also revisit in future rulemaking our proposed budget neutrality approach for the OPSS payments discussed in section X.H.6 of this proposed rule, as we gain more experience with this payment policy, if finalized, and the data collected.

We received several comments on the FY 2023 IPPS/LTCH PPS proposed rule requesting these payment adjustments be expanded to include other forms of PPE such as gowns and gloves. Therefore, as we gain more experience with this payment policy, if finalized, we might also consider in future rulemaking expanding this policy to include other forms of PPE that are critical for responding to a public health emergency, including but not limited to elastomeric respirators, surgical/procedural masks, gloves, and medical gowns.

I. Proposal to Exempt Rural Sole Community Hospitals from the Method to Control Unnecessary Increases in the Volume of Clinic Visit Services Furnished in Excepted Off-Campus Provider-Based Departments (PBDs)

In the CY 2019 OPSS/ASC final rule with comment period (83 FR 59004 through 59015), we adopted a method to control unnecessary increases in the volume of the clinic visit service furnished in excepted off-campus provider-based departments (PBDs) by removing the payment differential that drives the site-of-service decision and, as a result, unnecessarily increases service volume in this care setting as compared to the physician's office setting. We refer readers to the CY 2019 OPSS/ASC final rule with comment period for a detailed discussion of the background, legislative provisions, and rationale for the volume control method we adopted beginning in CY 2019. Below we discuss the specific policy we finalized in the

CY 2019 OPPS/ASC final rule with comment period and its full application under the OPPS beginning in CY 2020.

1. Implementation of a Method to Control Unnecessary Increases in the Volume of Certain Clinic Visit Services

For the CY 2019 OPPS, under our authority at section 1833(t)(2)(F) of the Act, we applied an amount equal to the site-specific Medicare Physician Fee Schedule (PFS) payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the PFS-equivalent rate) for the clinic visit service, as described by HCPCS code G0463, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act (departments that bill the modifier “PO” on claim lines). The PFS-equivalent rate, however, was not immediately applied in full. Instead, we phased in the reduction in payment for the clinic visit service described by HCPCS code G0463 in the excepted off-campus PBD setting over two years. For CY 2019, the payment reduction was transitioned by applying 50 percent of the total reduction in payment that would have applied if these departments (departments that bill the modifier “PO” on claim lines) were paid the PFS-equivalent rate for the clinic visit service. The PFS-equivalent rate was 40 percent of the OPPS payment for CY 2019 (that is, 60 percent less than the OPPS rate). Consequently, these departments were paid approximately 70 percent of the OPPS rate (100 percent of the OPPS rate minus the 30-percent payment reduction that was applied in CY 2019) for the clinic visit service in CY 2019.

For CY 2020, the second and final year of the 2-year phase-in, we stated that we would apply the total reduction in payment that would be applied if these departments (departments that bill the modifier “PO” on claim lines) were paid the site-specific PFS-equivalent rate for the clinic visit service described by HCPCS code G0463. The PFS-equivalent rate for CY 2020 was 40 percent of the proposed OPPS payment (that is, 60 percent less than the proposed OPPS rate) for CY 2020. Under this policy, departments were paid approximately 40 percent of the OPPS rate (100 percent of the OPPS rate minus the 60-percent payment reduction that is applied in

CY 2020) for the clinic visit service in CY 2020. The fully phased-in policy has been in effect since CY 2020.

In addition, as we stated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59013), for CY 2019 and subsequent years, this policy has been implemented in a non-budget neutral manner. To effectively establish a method for controlling the unnecessary growth in the volume of clinic visits furnished by excepted off-campus PBDs that does not simply increase other expenditures that are unnecessary within the OPPS, we explained that we believed the method must be adopted in a non-budget neutral manner in accordance with the OPPS statute. The impact of this policy is further described in section X of this proposed rule.

We note that this policy was previously litigated. On July 17, 2020, the United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit) ruled in favor of CMS, holding that our regulation was a reasonable interpretation of the statutory authority to adopt a method to control for unnecessary increases in the volume of the relevant service. The appellees petitioned the United States Supreme Court for a writ of certiorari. On June 29, 2021, the Supreme Court denied the petition.

In the CY 2019 OPPS/ASC proposed rule (83 FR 37143), we sought public comment on whether there should be exceptions from this policy for rural providers, such as those providers that are at risk of hospital closure or those providers that are rural sole community hospitals (SCHs). Commenters to the CY 2019 OPPS/ASC proposed rule expressed concern that this policy proposal would disproportionately affect safety net hospitals and rural providers (83 FR 59013). Numerous commenters representing a rural SCH and beneficiaries in the State of Washington expressed concern about the impact the proposal would have on their rural SCH. Several commenters also requested that both urban and rural SCHs, rural referral centers (RRCs), and Medicare-dependent hospitals be exempted from this policy.

At the time we responded that we shared the commenters' concerns about access to care, especially in rural areas where access issues may be more pronounced than in other areas of the

country. We stated that we believed that implementing our policy with a 2-year phase-in would help to mitigate the immediate impact on rural hospitals (83 FR 59013). We noted that we might revisit this policy to consider potential exemptions in the CY 2020 OPPS rulemaking.

In CY 2020 OPPS/ASC final rule with comment period (84 FR 61367), we again discussed commenters' continued concerns about this policy's impact on rural providers and safety net health systems. While acknowledging the validity of these concerns, we emphasized our belief that a phased-in implementation would help mitigate the impact rural hospitals might otherwise face. We reiterated that we would continue to monitor trends for any access to care issues and would potentially revisit this policy in future rulemaking.

2. Proposed Exemption for Rural Sole Community Hospitals from the Method to Control Unnecessary Increases in the Volume of Clinic Visits Furnished Beginning in CY 2023

Since the volume control method was fully phased in by the CY 2020 OPPS/ASC final rule with comment period (84 FR 61142), we have continued to assess how this policy has been implemented, as it affects both the Medicare program itself and the beneficiaries it serves. This policy was designed to address unnecessary increases in the volume of clinic visit services furnished in excepted off-campus PBDs. While we believe that the method we adopted to control this growth is appropriate, we are continuing to examine whether all excepted off-campus PBDs should be subject to the site-specific PFS-equivalent payment rate for the clinic visit service, as described by HCPCS code G0463. In the CY 2019 OPPS/ASC proposed rule (83 FR 37142), we explained our position that shifts in the sites of service are unnecessary if the beneficiary can safely receive the same service in a lower cost setting but instead receives care in a higher cost setting due to payment incentives. We described this as beneficiaries moving from (lower cost) physician offices to (higher cost) HOPDs because of the higher payment rate available in the HOPD. In these cases, we maintain that to the extent similar services can be safely provided in more than one setting, we do not believe it is prudent for the Medicare program to pay more for these services in one setting than another as doing so results in service volume increases that we

believe are unnecessary. We continue to believe the difference in payment for these services is a significant factor in the shift in services from the physician's office setting to the hospital outpatient department for many hospital types, which unnecessarily increases hospital outpatient department volume and Medicare program and beneficiary expenditures. Nonetheless, we recognize that the volume of clinic visits furnished in off-campus PBDs of certain hospital types may primarily be driven by factors other than higher payment, such as service shifts from the inpatient hospital to outpatient hospital setting and access issues. As explained further below, we propose to exempt excepted off-campus PBDs of rural SCHs from our volume control method policy because we believe the volume of the clinic visit service in PBDs of these hospitals is driven by factors other than the payment differential for this service. We propose to pay the full OPPS payment rate, rather than the PFS-equivalent rate under our volume control method, when the clinic visit is furnished in these departments.

a. Special Payment Treatment for Rural SCHs

Across the various Medicare payment systems, CMS has established a number of special payment provisions for rural providers to ensure access to high quality care for beneficiaries in rural areas. CMS administers five rural hospital payment designations in which rural or isolated hospitals that meet specified eligibility criteria receive higher reimbursement for hospital services than they otherwise would receive under Medicare's standard payment methodologies. A rural hospital may qualify as a Critical Access Hospital¹⁵⁴, Sole Community Hospital (SCH)¹⁵⁵, or Medicare Dependent Hospital¹⁵⁶—each of which has different eligibility criteria and payment methodologies. With the exception of Critical Access Hospitals, rural hospitals may also qualify as Low Volume Hospitals¹⁵⁷ and Rural Referral Centers (RRCs)¹⁵⁸, which qualify eligible hospitals for additional payments or exemptions. Not all rural or isolated hospitals

¹⁵⁴ 42 CFR 485.601–647

¹⁵⁵ 42 CFR 412.92

¹⁵⁶ 42 CFR 412.108

¹⁵⁷ 42 CFR 412.101

¹⁵⁸ 42 CFR 412.96

receive special payment treatment under the OPSS. For instance, CAHs are not paid under the OPSS and are reimbursed at 101 percent of reasonable costs for outpatient services. PBDs of CAHs are not subject to Section 603 of the Bipartisan Budget Act of 2015.

Rural SCHs are a hospital type that has received special payment treatment under the OPSS to account for their higher costs and the disproportionately harmful impact that payment reductions could have on them. In the CY 2006 OPSS final rule with comment period (70 FR 68556 through 68561), we finalized a payment increase for rural SCHs of 7.1 percent for all services and procedures paid under the OPSS, excluding separately payable drugs and biologicals, brachytherapy sources, items paid at charges reduced to costs, and devices paid under the pass-through payment policy. This policy was adopted under section 1833(t)(13)(B) of the Act, which required the Secretary by January 1, 2006 to provide for an appropriate adjustment under paragraph (t)(2)(E) to reflect the higher costs of hospitals in rural areas if the Secretary determined, pursuant to a study required by section 1833(t)(13)(A), that the costs to rural hospitals by APC exceeded those costs for hospitals in urban areas. Our analysis revealed that rural SCHs had significantly higher costs per unit than urban hospitals. We have continued to adjust payments for rural SCHs by 7.1 percent each year since 2006. As discussed in Section II.E of this proposed rule, for CY 2023 we propose to continue the current policy of utilizing a 7.1 percent payment adjustment for rural SCHs.

Rural SCHs have also been excluded from our policy to adjust payment for drugs and biologicals acquired under the 340B program. When we proposed to adjust payments for 340B drugs in the CY 2018 OPSS/ASC proposed rule (82 FR 33635), we sought public comment on whether, due to access to care issues, exceptions should be granted to certain groups of hospitals, such as those with special adjustments under the OPSS (for example, rural SCHs or PPS-exempt cancer hospitals). Commenters noted that rural 340B covered entity hospitals depend on the drug discounts they receive through the 340B Program to provide access to expensive, necessary care such as labor and delivery and oncology infusions (82 FR 59365).

Commenters expressed that even with 340B discounts, rural hospitals like rural SCHs are financially threatened. They noted that rural hospitals are typically located in lower income economic areas and would not be able to absorb the proposed reduction in payment for 340B-purchased drugs. Moreover, commenters suggested that the proposal would disproportionately affect rural hospitals compared to urban hospitals and requested that CMS exempt hospitals with an RRC or SCH designation from the 340B drug payment policy. The commenters asserted that RRCs and SCHs are rural safety-net hospitals that provide localized care for Medicare beneficiaries and also serve as “economic engines” for many rural communities. Taking into consideration these comments, for CY 2018 we finalized a policy to exclude rural SCHs from our 340B drug payment policy and have continued to do so in CYs 2019 through 2022.

b. Utilization of the Clinic Visit Service in Off-Campus Provider-Based Departments of Rural SCHs

In the CY 2019 OPPS/ASC final rule with comment period in which we adopted the volume control method policy for certain clinic visits, we said that to the extent there are lower-cost sites of service available, beneficiaries and the physicians treating them should be able to choose the appropriate care setting and not be encouraged to receive or provide care in settings for which payment rates are higher solely for financial reasons (83 FR 37139). However, many rural providers, and rural SCHs in particular, are often the only source of care in their communities¹⁵⁹, which means beneficiaries and providers are not merely choosing between a higher paying off-campus PBD of a hospital and a lower paying physicians’ office setting. The closure of inpatient departments of hospitals and the shortage of primary care providers in rural areas further drives utilization to off-campus PBDs in areas where rural SCHs are located.

¹⁵⁹ https://www.shepscenter.unc.edu/wp-content/uploads/dlm_uploads/2017/11/SCHs_Differences_in_Community_Characteristics.pdf

Rural areas often experience lower availability of health care professionals and hospitals than urban areas¹⁶⁰. Access to outpatient services, particularly in rural areas, is vital to keeping beneficiaries healthy and out of the hospital because beneficiaries in rural settings face unique challenges that impact their health. Compared to their urban counterparts, rural residents generally are older and poorer.¹⁶¹ Rural areas are also disproportionately affected by declining population rates and decreasing employment rates.¹⁶² We have targeted rural SCHs with their add-on payment and exemption from the 340B payment reductions in an effort to ensure that these providers with demonstrated additional resource costs remain open to serve the beneficiaries who rely on them for their care.

We believe that exempting rural Sole Community Hospitals (rural SCHs) from payment of the site-specific Medicare Physician Fee Schedule (PFS)-equivalent payment for the clinic visit service, as described by HCPCS code G0463, when furnished at an off-campus PBD excepted from section 1833(t)(21) of the Act (departments that bill the modifier “PO” on claim lines) would help to maintain access to care in rural areas by ensuring rural providers are paid for clinic visit services provided at off-campus PBDs at rates comparable to those paid at on-campus departments. Exempting rural SCHs would also target payment of the full OPPS rate for the clinic visit service to off-campus PBDs of these hospitals, the majority of which are located in Medically Underserved Areas (MUAs) as defined by the Health Resources and Services Administration. Our proposal also aligns with the special payment treatment rural SCHs receive under the OPPS.

Accordingly, for CY 2023, we propose that excepted off-campus PBDs (departments that bill the modifier “PO” on claim lines) of rural SCHs, as described under 42 CFR 412.92 and designated as rural for Medicare payment purposes, would be exempt from our volume control method of paying the PFS-equivalent rate for the clinic visit service, as described by HCPCS

¹⁶⁰ <https://www.gao.gov/assets/gao-21-93.pdf>

¹⁶¹ <https://www.gao.gov/assets/gao-21-93.pdf>

¹⁶² <https://www.gao.gov/assets/gao-21-93.pdf>

code G0463. Additionally, we are soliciting comments on whether it would be appropriate to exempt other rural hospitals, such as those with under 100 beds, from our volume control method of paying the PFS-equivalent rate for the clinic visit service.

In CY 2023, for a Medicare beneficiary who receives a clinic visit service in a non-excepted off-campus PBD of a rural SCH, the standard unadjusted Medicare OPPS proposed payment would be approximately \$131, with an approximate average copayment of \$26. The proposed PFS-equivalent rate for a clinic visit would be approximately \$52, with an approximate average copayment of \$10. Under this proposal, an excepted off-campus PBD of a rural SCH would continue to bill HCPCS code G0463 with the “PO” modifier in CY 2023, but the payment rate for services described by HCPCS code G0463 when billed with modifier “PO” would now be the full OPPS payment rate. This would cost beneficiaries an average of an additional \$16 per visit.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59013), we implemented the volume control method in a non-budget neutral manner consistent with the OPPS statute. In order to effectively establish a method for controlling the unnecessary growth in the volume of clinic visits furnished by excepted off-campus PBDs that does not simply increase other expenditures that are unnecessary within the OPPS, we stated that the volume control method in general would be implemented in a non-budget neutral manner. Here, we propose to simply remove the effects of this volume control method for one type of provider (rural SCHs), which is only a subset of the providers currently affected by our policy, and thus propose this exception would not increase OPPS spending overall as compared to OPPS spending with no volume control method whatsoever. We estimate that this exemption would increase OPPS spending by approximately \$75 million in CY 2023 compared to spending if we did not implement this exemption to the volume control method. The impact associated with this policy is further described in section XXVI of this proposed rule.

XI. Proposed CY 2023 OPPS Payment Status and Comment Indicators

A. Proposed CY 2023 OPSS Payment Status Indicator Definitions

Payment status indicators (SIs) that we assign to HCPCS codes and APCs serve an important role in determining payment for services under the OPSS. They indicate whether a service represented by a HCPCS code is payable under the OPSS or another payment system, and whether particular OPSS policies apply to the code.

For CY 2023, we propose to revise the definition of status indicator “A” to include unclassified drugs and biologicals that are reportable under HCPCS code C9399. When HCPCS code C9399 appears on a claim, the Outpatient Code Editor (OCE) suspends the claim for manual pricing by the Medicare Administrative Contractor (MAC). The MAC prices the claim at 95 percent of the drug or biological’s average wholesale price (AWP) using the Red Book or an equivalent recognized compendium, and processes the claim for payment. The payment at 95 percent of AWP is made under the OPSS.

In addition, we propose to revise the definition of status indicator “F” by removing hepatitis B vaccines. Hepatitis B vaccines should not be subject to deductible and coinsurance similar to other preventive vaccines, but services that are currently listed under the definition of status indicator “F” are subject to deductible and coinsurance. We also propose to revise the definition of status indicator “L” in order to add hepatitis B vaccines to the list of other preventive vaccines that are not subject to deductible and coinsurance.

The complete list of proposed CY 2023 payment status indicators and their definitions is displayed in Addendum D1 to this proposed rule, which is available on the CMS website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices>.

We are requesting public comments on the proposed definitions of the OPSS payment status indicators for 2023.

The proposed CY 2023 payment status indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B, respectively, to this proposed rule, which

are available on the CMS website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>.

B. Proposed CY 2023 Comment Indicator Definitions

In this proposed rule, we propose to use four comment indicators for the CY 2023 OPSS. These comment indicators, “CH”, “NC”, “NI”, and “NP”, are in effect for CY 2022 and we propose to continue their use in CY 2023. The proposed CY 2023 OPSS comment indicators are as follows:

- “CH”—Active HCPCS code in current and next calendar year, status indicator and/or APC assignment has changed; or active HCPCS code that will be discontinued at the end of the current calendar year.
- “NC”—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year for which we requested comments in the proposed rule, final APC assignment; comments will not be accepted on the final APC assignment for the new code.
- “NI”—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year, interim APC assignment; comments will be accepted on the interim APC assignment for the new code.
- “NP”—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year, proposed APC assignment; comments will be accepted on the proposed APC assignment for the new code.

The definitions of the proposed OPSS comment indicators for CY 2023 are listed in Addendum D2 to this proposed rule, which is available on the CMS website at:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>.

We believe that the existing CY 2022 definitions of the OPSS comment indicators continue to be appropriate for CY 2023. Therefore, we propose to use those definitions without modification for CY 2023.

We are requesting public comments on our proposed definitions of the OPSS comment indicators for 2023.

XII. MedPAC Recommendations

The Medicare Payment Advisory Commission (MedPAC) was established under section 1805 of the Act in large part to advise the U.S. Congress on issues affecting the Medicare program. As required under the statute, MedPAC submits reports to the Congress no later than March and June of each year that present its Medicare payment policy recommendations. The March report typically provides discussion of Medicare payment policy across different payment systems and the June report typically discusses selected Medicare issues. We are including this section to make stakeholders aware of certain MedPAC recommendations for the OPSS and ASC payment systems as discussed in its March 2022 report.

A. Proposed OPSS Payment Rates Update

The March 2022 MedPAC “Report to the Congress: Medicare Payment Policy,” recommended that Congress update Medicare OPSS payment rates by the amount specified in current law. We refer readers to the March 2022 report for a complete discussion of this recommendation.¹⁶³ We appreciate MedPAC’s recommendation and, as discussed further in Section II.A.4 of this proposed rule, we propose to increase the OPSS payment rates by the amount specified in current law. Comments received from MedPAC for other OPSS policies are discussed in the applicable sections of this proposed rule.

¹⁶³ Medicare Payment Advisory Committee. March 2022 Report to the Congress. Chapter 3: Hospital inpatient and outpatient services, pp.65-66. Available at: <http://www.medpac.gov>.

B. Proposed ASC Conversion Factor Update

In the March 2022 MedPAC “Report to the Congress: Medicare Payment Policy,” MedPAC found that, based on its analysis of indicators of payment adequacy, the number of ASCs had increased, beneficiaries’ use of ASCs had increased prior to the effects of COVID-19 PHE in CY 2020, and ASC access to capital has been adequate.¹⁶⁴ As a result, MedPAC stated that payments to ASCs are adequate and recommended that, in the absence of cost report data, no payment update should be applied for CY 2023 (that is, the update factor would be zero percent).

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59079), we adopted a policy, which we codified at 42 CFR 416.171(a)(2), to apply the productivity-adjusted hospital market basket update to ASC payment system rates for an interim period of 5 years. We refer readers to the CY 2019 OPPS/ASC final rule with comment period for complete details regarding our policy to use the productivity-adjusted hospital market basket update for the ASC payment system for CY 2019 through CY 2023. Therefore, consistent with our policy for the ASC payment system, as discussed in section XIII.G of this proposed rule, we propose to apply a 2.7 percent productivity-adjusted hospital market basket update factor to the CY 2022 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the proposed CY 2023 ASC payment amounts. The proposed CY 2023 ASC conversion factor for ASCs meeting quality reporting requirements and the proposed hospital market basket update factor are discussed in section XIII of this proposed rule.

C. Proposed ASC Cost Data

In the March 2022 MedPAC “Report to the Congress: Medicare Payment Policy,” MedPAC recommended that Congress require ASCs to report cost data to enable the Commission to examine the growth of ASCs’ costs over time and analyze Medicare payments relative to the costs of efficient providers, and that CMS could use ASC cost data to examine

¹⁶⁴ Medicare Payment Advisory Committee. March 2020 Report to the Congress. Chapter 5: Ambulatory surgical center services, p.161-162. Available at: https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/mar20_entirereport_sec.pdf.

whether an existing Medicare price index is an appropriate proxy for ASC costs or whether an ASC-specific market basket should be developed. Further, MedPAC suggested that CMS could limit the scope of the cost reporting system to minimize administrative burden on ASCs and the program but should make cost reporting a condition of ASC participation in the Medicare program.¹⁶⁵

While we recognize that the submission of cost data could place additional administrative burden on most ASCs, and we are not proposing any cost reporting requirements for ASCs in this CY 2023 OPPS/ASC proposed rule, we continue to seek public comment on methods that would mitigate the burden of reporting costs on ASCs while also collecting enough data to reliably use such data in the determination of ASC costs. Such cost data would be beneficial in establishing an ASC-specific market basket index for updating payment rates under the ASC payment system.

XIII. Proposed Updates to the Ambulatory Surgical Center (ASC) Payment System

A. Background

1. Legislative History, Statutory Authority, and Prior Rulemaking for the ASC Payment System

For a detailed discussion of the legislative history and statutory authority related to payments to ASCs under Medicare, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74377 through 74378) and the June 12, 1998 proposed rule (63 FR 32291 through 32292). For a discussion of prior rulemaking on the ASC payment system, we refer readers to the CYs 2012 to 2022 OPPS/ASC final rules with comment period (76 FR 74378 through 74379; 77 FR 68434 through 68467; 78 FR 75064 through 75090; 79 FR 66915 through 66940; 80 FR 70474 through 70502; 81 FR 79732 through 79753; 82 FR 59401 through 59424; 83 FR 59028 through 59080; 84 FR 61370 through 61410, 85 FR 86121 through 86179, and 86 FR 63761 through 63815 respectively).

¹⁶⁵ Medicare Payment Advisory Committee. March 2022 Report to the Congress. Chapter 5: Ambulatory surgical center services, p.162. Available at: https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_SEC.pdf.

2. Policies Governing Changes to the Lists of Codes and Payment Rates for ASC Covered Surgical Procedures and Covered Ancillary Services

Under §§ 416.2 and 416.166 of the Medicare regulations, subject to certain exclusions, covered surgical procedures in an ASC are surgical procedures that are separately paid under the OPPS, are not designated as requiring inpatient care under § 419.22(n) as of December 31, 2020, are not only able to be reported using a CPT unlisted surgical procedure code, and are not otherwise excluded under § 411.15.

Since the implementation of the ASC prospective payment system, we have historically defined a “surgical” procedure under the payment system as any procedure described within the range of Category I CPT codes that the CPT Editorial Panel of the American Medical Association (AMA) defines as “surgery” (CPT codes 10000 through 69999) (72 FR 42478). We also have included as “surgical” procedures that are described by Level II HCPCS codes or by Category III CPT codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range.

As we noted in the August 7, 2007 ASC final rule that implemented the revised ASC payment system, using this definition of surgery would exclude from ASC payment certain invasive, “surgery-like” procedures, such as cardiac catheterization or certain radiation treatment services that are assigned codes outside the CPT surgical range (72 FR 42477). We stated in that final rule that we believed continuing to rely on the CPT definition of surgery is administratively straightforward, is logically related to the categorization of services by physician experts who both establish the codes and perform the procedures, and is consistent with a policy to allow ASC payment for all outpatient surgical procedures.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59029 through 59030), after consideration of public comments received in response to the CY 2019 OPPS/ASC proposed rule and earlier OPPS/ASC rulemaking cycles, we revised our definition of a surgical procedure under the ASC payment system. In that final rule, we defined a surgical procedure

under the ASC payment system as any procedure described within the range of Category I CPT codes that the CPT Editorial Panel of the AMA defines as “surgery” (CPT codes 10000 through 69999) (72 FR 42476), as well as procedures that are described by Level II HCPCS codes or by Category I CPT codes or by Category III CPT codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that we determined met the general standards established in previous years for addition to the ASC CPL. These criteria included that a procedure is not expected to pose a significant risk to beneficiary safety when performed in an ASC, that standard medical practice dictates that the beneficiary would not typically be expected to require an overnight stay following the procedure, and that the procedure is separately paid under the OPSS.

In CY 2021, we revised the definition of covered surgical procedures to only surgical procedures specified by the Secretary that are separately paid under the OPSS, are not designated as requiring inpatient care under § 419.22(n) as of December 31, 2020, are not only able to be reported using a CPT unlisted surgical procedure code, and are not otherwise excluded under § 411.15 (85 FR 86153). However, in the CY 2022 OPSS/ASC final rule with comment period, we finalized our proposal to reinstate the general standards and exclusion criteria in place prior to CY 2021 (86 FR 63779) and revised the language in the regulation text at § 416.166 accordingly.

Covered ancillary services are specified in § 416.164(b) and, as stated previously, are eligible for separate ASC payment. As provided at § 416.164(b), we make separate ASC payments for the following ancillary items and services when they are provided integral to ASC covered surgical procedures: (1) brachytherapy sources; (2) certain implantable items that have pass-through payment status under the OPSS; (3) certain items and services that we designate as contractor-priced, including, but not limited to, procurement of corneal tissue; (4) certain drugs and biologicals for which separate payment is allowed under the OPSS; (5) certain radiology services for which separate payment is allowed under the OPSS; and (6) non-opioid pain

management drugs that function as a supply when used in a surgical procedure. Payment for ancillary items and services that are not paid separately under the ASC payment system is packaged into the ASC payment for the covered surgical procedure.

We update the lists and payment rates for covered surgical procedures and covered ancillary services in ASCs in conjunction with the annual proposed and final rulemaking process to update the OPSS and the ASC payment system (§ 416.173; 72 FR 42535). We base ASC payment and policies for most covered surgical procedures, drugs, biologicals, and certain other covered ancillary services on the OPSS payment policies, and we use quarterly change requests (CRs) to update services paid for under the OPSS. We also provide quarterly update CRs for ASC covered surgical procedures and covered ancillary services throughout the year (January, April, July, and October). We release new and revised Level II HCPCS codes and recognize the release of new and revised CPT codes by the AMA and make these codes effective (that is, the codes are recognized on Medicare claims) via these ASC quarterly update CRs. We recognize the release of new and revised Category III CPT codes in the July and January CRs. These updates implement newly created and revised Level II HCPCS and Category III CPT codes for ASC payments and update the payment rates for separately paid drugs and biologicals based on the most recently submitted ASP data. New and revised Category I CPT codes, except vaccine codes, are released only once a year, and are implemented only through the January quarterly CR update. New and revised Category I CPT vaccine codes are released twice a year and are implemented through the January and July quarterly CR updates. We refer readers to Table 41 in the CY 2012 OPSS/ASC proposed rule for an example of how this process is used to update HCPCS and CPT codes, which we finalized in the CY 2012 OPSS/ASC final rule with comment period (76 FR 42291; 76 FR 74380 through 74384).

In our annual updates to the ASC list of, and payment rates for, covered surgical procedures and covered ancillary services, we undertake a review of excluded surgical procedures, new codes, and codes with revised descriptors, to identify any that we believe meet

the criteria for designation as ASC covered surgical procedures or covered ancillary services.

Updating the lists of ASC covered surgical procedures and covered ancillary services, as well as their payment rates, in association with the annual OPPS rulemaking cycle is particularly important because the OPPS relative payment weights and, in some cases, payment rates, are used as the basis for the payment of many covered surgical procedures and covered ancillary services under the revised ASC payment system. This joint update process ensures that the ASC updates occur in a regular, predictable, and timely manner.

B. Proposed ASC Treatment of New and Revised Codes

1. Background on Current Process for Recognizing New and Revised HCPCS Codes

Payment for ASC procedures, services, and items are generally based on medical billing codes, specifically, HCPCS codes, that are reported on ASC claims. The HCPCS is divided into two principal subsystems, referred to as Level I and Level II of the HCPCS. Level I is comprised of CPT (Current Procedural Terminology) codes, a numeric and alphanumeric coding system maintained by the AMA, and includes Category I, II, III, MAAA, and PLA CPT codes. Level II of the HCPCS, which is maintained by CMS, is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes. Together, Level I and II HCPCS codes are used to report procedures, services, items, and supplies under the ASC payment system. Specifically, we recognize the following codes on ASC claims:

- Category I CPT codes, which describe surgical procedures, diagnostic and therapeutic services, and vaccine codes;
- Category III CPT codes, which describe new and emerging technologies, services, and procedures; and
- Level II HCPCS codes (also known as alpha-numeric codes), which are used primarily to identify drugs, devices, supplies, temporary procedures, and services not described by CPT codes.

We finalized a policy in the August 2, 2007 ASC final rule (72 FR 42533 through 42535) to evaluate each year all new and revised Category I and Category III CPT codes and Level II HCPCS codes that describe surgical procedures, and to make preliminary determinations during the annual OPPS/ASC rulemaking process regarding whether or not they meet the criteria for payment in the ASC setting as covered surgical procedures and, if so, whether or not they are office-based procedures. In addition, we identify new and revised codes as ASC covered ancillary services based upon the final payment policies of the revised ASC payment system. In prior rulemakings, we referred to this process as recognizing new codes. However, this process has always involved the recognition of new and revised codes. We consider revised codes to be new when they have substantial revision to their code descriptors that necessitate a change in the current ASC payment indicator. To clarify, we refer to these codes as new and revised in this proposed rule.

We have separated our discussion below based on when the codes are released and whether we propose to solicit public comments in this proposed rule or whether we will be soliciting public comments in the CY 2023 OPPS/ASC final rule with comment period.

2. April 2022 HCPCS Codes for Which We Are Soliciting Public Comments in This Proposed Rule

For the April 2022 update, there were no new CPT codes; however, there were several new Level II HCPCS codes. In the April 2022 ASC quarterly update (Transmittal 11303, dated March 24, 2022, CR 12679), we added several new Level II HCPCS codes to the list of covered ancillary services. Table 51 (New Level II HCPCS Codes for Ancillary Services Effective April 1, 2022) lists the new Level II HCPCS codes that were implemented April 1, 2022. The proposed comment indicators (CI), payment indicators (PI), and payment rates for these April codes can be found in Addendum BB to this proposed rule. The list of proposed ASC PIs and corresponding definitions can be found in Addendum DD1 to this proposed rule. The new codes that are effective April 1, 2022, are assigned to comment indicator "NP" in Addendum BB to this

proposed rule to indicate that the codes are assigned to an interim payment indicator assignment and that comments will be accepted on the interim assignments. The list of comment indicators and definitions used under the ASC payment system can be found in Addendum DD2 to this proposed rule. We note that the following ASC addenda are available via the Internet on the CMS website:

- ASC Addendum AA: Proposed ASC Covered Surgical Procedures for CY 2023
(Including Surgical Procedures for Which Payment is Packaged)
- ASC Addendum BB: Proposed ASC Covered Ancillary Services Integral to Covered Surgical Procedures for CY 2023 (Including Ancillary Services for Which Payment is Packaged)
- ASC Addendum DD1: Proposed ASC Payment Indicators (PI) for CY 2023, and
- ASC Addendum DD2: Proposed ASC Comment Indicators (CI) for CY 2023

We are inviting public comments on these proposed payment indicators for the new HCPCS codes that were recognized as ASC covered ancillary services in April 2022 through the quarterly update CRs, as listed in Table 51 (New Level II HCPCS Codes for Ancillary Services Effective April 1, 2022). We propose to finalize the payment indicators in the CY 2023 OPPS/ASC final rule with comment period.

TABLE 51: NEW LEVEL II HCPCS CODES FOR COVERED ANCILLARY SERVICES EFFECTIVE APRIL 1, 2022

CY 2022 HCPCS Code	CY 2022 Long Descriptor
A2011	Supra sdrm, per square centimeter
A2012	Suprathel, per square centimeter
A2013	Innovamatrix fs, per square centimeter
A4100	Skin substitute, fda cleared as a device, not otherwise specified
C9090	Injection, plasminogen, human-tvmh, 1 mg
C9091	Injection, sirolimus protein-bound particles, 1 mg
C9092	Injection, triamcinolone acetonide, suprachoroidal, 1 mg
C9093	Injection, ranibizumab, via intravitreal implant, 0.1 mg

C9781	Arthroscopy, shoulder, surgical; with implantation of subacromial spacer (e.g., balloon), includes debridement (e.g., limited or extensive), subacromial decompression, acromioplasty, and biceps tenodesis when performed
J0219	Injection, avalglucosidase alfa-ngpt, 4 mg
J0491	Injection, anifrolumab-fnia, 1 mg
J9071	Injection, cyclophosphamide, (auromedics), 5 mg
J9273	Injection, tisotumab vedotin-tftv, 1 mg
J9359	Injection, loncastuximab tesirine-lpyl, 0.1 mg
Q4224	Human health factor 10 amniotic patch (hhf10-p), per square centimeter
Q4225	Amniobind, per square centimeter
Q4256	Mlg-complete, per square centimeter
Q4257	Release, per square centimeter
Q4258	Enverse, per square centimeter

3. July 2022 HCPCS Codes for Which We Are Soliciting Public Comments in This Proposed Rule

In the July 2022 ASC quarterly update (Transmittal 11472, Change Request 12773, dated June 23, 2022), we added several separately payable CPT and Level II HCPCS codes to the list of covered surgical procedures and ancillary services. Table 52 (New Level II HCPCS Codes for Ancillary Services Effective July 1, 2022) lists the new HCPCS codes that are effective July 1, 2022. The proposed comment indicators, payment indicators, and payment rates for the codes can be found in Addendum AA and Addendum BB to this proposed rule. The list of proposed ASC PIs and corresponding definitions can be found in Addendum DD1 to this proposed rule. In addition, these new codes that are effective July 1, 2022 are assigned to comment indicator "NP" in Addendum BB to this proposed rule to indicate that the codes are assigned to an interim payment indicator and that comments will be accepted on the interim assignments. The list of comment indicators and definitions used under the ASC payment system can be found in Addendum DD2 to this proposed rule. We note that ASC Addenda AA, BB, DD1, and DD2 are available via the Internet on the CMS website.

TABLE 52: NEW LEVEL II HCPCS CODES FOR COVERED SURGICAL PROCEDURES AND COVERED ANCILLARY SERVICES EFFECTIVE JULY 1, 2022

CY 2022 HCPCS Code	CY 2022 Long Descriptor
A9596	Gallium ga-68 gozetotide, diagnostic, (illuccix), 1 millicurie
A9601	Flortaucipir f 18 injection, diagnostic, 1 millicurie
C9094	Inj, sutimlimab-jome, 10 mg
C9095	Inj, tebentafusp-tebn, 1 mcg
C9096	Injection, filgrastim-ayow, biosimilar, (releuko), 1 microgram
C9097	Inj, faricimab-svoa, 0.1 mg
C9098	ciltacabtagene autoleucel, up to 100 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
J0739	Injection, cabotegravir, 1 mg
J1306	Injection, inclisiran, 1 mg
J1551	Injection, immune globulin (cutaquig), 100 mg
J2356	Injection, tezepelumab-ekko, 1 mg
J2779	Injection, ranibizumab, via intravitreal implant (susvimo), 0.1 mg
J2998	Injection, plasminogen, human-tvmh, 1 mg
J3299	Injection, triamcinolone acetonide (xipere), 1 mg
J9331	Injection, sirolimus protein-bound particles, 1 mg
J9332	Injection, efgartigimod alfa-fcab, 2mg
Q4259	Celera dual layer or celera dual membrane, per square centimeter
Q4260	Signature apatch, per square centimeter
Q4261	Tag, per square centimeter

Furthermore, through the July 2022 quarterly update CR, we added three new Category III CPT codes to the list of ASC covered ancillary services, effective July 1, 2022. These codes are listed in Table 53 (New Category III CPT Codes for Covered Ancillary Services Effective July 1, 2022). The CY 2023 proposed payment indicators, proposed comment indicators, and proposed payment rates for these new Category III CPT codes can be found in Addendum BB to this proposed rule. As noted above, the list of payment indicators and comment indicators used under the ASC can be found in Addendum DD1 and DD2, respectively, of this proposed rule. We note that ASC Addenda AA, BB, DD1, and DD2 are available via the Internet on the CMS website.

TABLE 53: NEW CATEGORY III CPT CODES FOR COVERED ANCILLARY SERVICES EFFECTIVE JULY 1, 2022

CY 2022 HCPCS Code	CY 2022 Long Descriptor
0714T	Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance
0715T	Percutaneous transluminal coronary lithotripsy (List separately in addition to code for primary procedure)
0716T	Cardiac acoustic waveform recording with automated analysis and generation of coronary artery disease risk score

We are inviting public comments on the proposed payment indicators for the new CPT and Level II HCPCS codes newly recognized as ASC covered surgical procedures for covered ancillary services effective April 1, 2022, and July 1, 2022, through the quarterly update CRs, as listed in Tables 51, 52, and 53. We propose to finalize the payment indicators in the CY 2023 OPPS/ASC final rule with comment period.

4. October 2022 HCPCS Codes for Which We Will Be Soliciting Public Comments in the CY 2023 OPPS/ASC Final Rule with Comment Period

For CY 2023, consistent with our established policy, we propose that the Level II HCPCS codes that will be effective October 1, 2022, would be flagged with comment indicator “NI” in Addendum BB in the CY 2023 OPPS/ASC final rule with comment period to indicate that we have assigned the codes interim ASC payment indicators for CY 2023. We will invite public comments in the CY 2023 OPPS/ASC final rule with comment period on the interim payment indicators, which would then be finalized in the CY 2024 OPPS/ASC final rule with comment period.

5. January 2023 HCPCS Codes

a. Level II HCPCS Codes for Which We Will Be Soliciting Public Comments in the CY 2023 OPPS/ASC Final Rule with Comment Period

As has been our practice in the past, we incorporate those new Level II HCPCS codes that are effective January 1 in the final rule with comment period, thereby updating the ASC

payment system for the calendar year. We note that, unlike the CPT codes that are effective January 1 and are included in the OPPS/ASC proposed rules, and except for the C and G-codes listed in Addendum O to this proposed rule, most Level II HCPCS codes are not released until sometime around November to be effective January 1. Because these codes are not available until November, we are unable to include them in the OPPS/ASC proposed rules. Therefore, these Level II HCPCS codes will be released to the public through the CY 2023 OPPS/ASC final rule with comment period, January 2023 ASC Update CR, and the CMS HCPCS website.

In addition, for CY 2023, we will propose to continue our established policy of assigning comment indicator “NI” in Addendum AA and Addendum BB to the OPPS/ASC final rule with comment period to the new Level II HCPCS codes that will be effective January 1, 2023, to indicate that we are assigning them an interim payment indicator, which is subject to public comment. We will be inviting public comments in the CY 2023 OPPS/ASC final rule with comment period on the payment indicator assignments, which would then be finalized in the CY 2024 OPPS/ASC final rule with comment period.

b. CPT Codes for Which We Are Soliciting Public Comments in This Proposed Rule

For the CY 2023 ASC update, we received the CPT codes that will be effective January 1, 2023, from the AMA in time to be included in this proposed rule. The new, revised, and deleted CPT codes can be found in Addendum BB to this proposed rule (which is available via the Internet on the CMS website). We note that the new and revised CPT codes are assigned to comment indicator “NP” in ASC Addendum AA and Addendum BB of this proposed rule to indicate that the code is new for the next calendar year or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to the current calendar year with a proposed payment indicator assignment. We will accept comments and finalize the payment indicators in the CY 2023 OPPS/ASC final rule with comment period. Further, we remind readers that the CPT code descriptors that appear in Addendum AA and Addendum BB are short descriptors and do not describe the complete procedure, service, or item

described by the CPT code. Therefore, we include the 5-digit placeholder codes and their long descriptors for the new CY 2023 CPT codes in Addendum O to this proposed rule so that the public can comment on our proposed payment indicator assignments. The 5-digit placeholder codes can be found in Addendum O to this proposed rule, specifically under the column labeled “CY 2023 OPPTS/ASC Proposed Rule 5-Digit Placeholder Code.” We intend to include the final CPT code numbers the CY 2023 OPPTS/ASC final rule with comment period.

In summary, we are soliciting public comments on the proposed CY 2023 payment indicators for the new Category I and III CPT codes that will be effective January 1, 2023. Because these codes are listed in Addendum AA and Addendum BB with short descriptors only, we are listing them again in Addendum O with the long descriptors. We also propose to finalize the payment indicator for these codes (with their final CPT code numbers) in the CY 2023 OPPTS/ASC final rule with comment period. The codes, along with their proposed payment indicators, and proposed comment indicators, are listed in ASC Addendum AA and BB. The definitions for the proposed payment indicators and comment indicators can be found in ASC Addendum DD1 and DD2, respectively. All the ASC proposed rule payment files, including ASC Addenda AA, BB, DD1, and DD2, are available via the Internet on the CMS website.

Finally, in Table 54 , we summarize our process for updating codes through our ASC quarterly update CRs, seeking public comments, and finalizing the treatment of these new codes under the ASC.

TABLE 54: COMMENT AND FINALIZATION TIMEFRAMES FOR NEW AND REVISED HCPCS CODES

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 2022	HCPCS (CPT and Level II codes)	April 1, 2022	CY 2023 OPPTS/ASC proposed rule	CY 2023 OPPTS/ASC final rule with comment period
July 2022	HCPCS (CPT and Level II codes)	July 1, 2022	CY 2023 OPPTS/ASC proposed rule	CY 2023 OPPTS/ASC final rule with comment period

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
October 2022	HCPCS (CPT and Level II codes)	October 1, 2022	CY 2023 OPPTS/ASC final rule with comment period	CY 2024 OPPTS/ASC final rule with comment period
January 2023	CPT Codes	January 1, 2023	CY 2023 OPPTS/ASC proposed rule	CY 2023 OPPTS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2023	CY 2023 OPPTS/ASC final rule with comment period	CY 2024 OPPTS/ASC final rule with comment period

C. Proposed Update to the List of ASC Covered Surgical Procedures and Covered Ancillary Services

1. Covered Surgical Procedures

a. Covered Surgical Procedures Designated as Office-Based

(1) Background

In the August 2, 2007 ASC final rule, we finalized our policy to designate as “office-based” those procedures that are added to the ASC Covered Procedures List (CPL) in CY 2008 or later years that we determine are furnished predominantly (more than 50 percent of the time) in physicians’ offices based on consideration of the most recent available volume and utilization data for each individual procedure code and/or, if appropriate, the clinical characteristics, utilization, and volume of related codes. In that rule, we also finalized our policy to exempt all procedures on the CY 2007 ASC list from application of the office-based classification (72 FR 42512). The procedures that were added to the ASC CPL beginning in CY 2008 that we determined were office-based were identified in Addendum AA to that rule with payment indicator “P2” (Office-based surgical procedure added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on OPPTS relative payment weight); “P3” (Office-based surgical procedures added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on MPFS nonfacility PE RVUs); or “R2” (Office-based

surgical procedure added to ASC list in CY 2008 or later without MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight), depending on whether we estimated the procedure would be paid according to the ASC standard ratesetting methodology based on its OPPS relative payment weight or at the MPFS nonfacility PE RVU-based amount.

Consistent with our final policy to annually review and update the ASC CPL to include all covered surgical procedures eligible for payment in ASCs, each year we identify covered surgical procedures as either temporarily office-based (these are new procedure codes with little or no utilization data that we have determined are clinically similar to other procedures that are permanently office-based), permanently office-based, or nonoffice-based, after taking into account updated volume and utilization data.

(2) Proposed Changes for CY 2023 to Covered Surgical Procedures Designated as Office-Based

In developing this CY 2023 OPPS/ASC proposed rule, we followed our policy to annually review and update the covered surgical procedures for which ASC payment is made and to identify new procedures that may be appropriate for ASC payment (described in detail in section XIII.C.1.d. of this final rule with comment period), including their potential designation as office-based. Historically, we would also review the most recent claims volume and utilization data (CY 2021 claims) and the clinical characteristics for all covered surgical procedures that are currently assigned a payment indicator in CY 2022 of “G2” (Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) as well as for those procedures assigned one of the temporary office-based payment indicators, specifically “P2”, “P3”, or “R2” in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63769 through 63773).

In our CY 2022 OPPS/ASC final rule with comment period (86 FR 63770), we discussed that we, historically, review the most recent claims volume and utilization data and clinical characteristics for all covered surgical procedures that were assigned a payment indicator of “G2” for CY 2021. For the CY 2022 OPPS/ASC final rule with comment period, the most

recent claims volume and utilization data was CY 2020 claims. However, given our concerns with the use of CY 2020 claims data as a result of the COVID-19 PHE as further discussed in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63751 through 63754), we adopted a policy to not review CY 2020 claims data and did not assign permanent office-based designations to covered surgical procedures that were assigned a payment indicator of “G2” in CY 2021 (86 FR 63770 through 63771).

As discussed further in section X.B of this proposed rule, in our review of the CY 2021 outpatient claims available for ratesetting for this CY 2023 OPPS proposed rule, we observed that many outpatient service volumes have partially returned to their pre-PHE levels and it is reasonable to assume that there will continue to be some effects of the COVID-19 PHE on the outpatient claims that we use for OPPS ratesetting. As a result, we propose to use the CY 2021 claims for CY 2023 OPPS ratesetting. Similarly, for this proposed rule, we propose to resume our historical practice and review the most recent claims and utilization data, in this case data from CY 2021 claims, for determining office-based assignments under the ASC payment system.

Our review of the CY 2021 volume and utilization data of covered surgical procedures currently assigned a payment indicator of “G2” (Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) resulted in the identification of 6 surgical procedures that we believe meet the criteria for designation as permanently office-based. The data indicate that these procedures are performed more than 50 percent of the time in physicians’ offices, and we believe that the services are of a level of complexity

consistent with other procedures performed routinely in physicians’ offices. The CPT codes that we propose to permanently designate as office-based for CY 2023 are listed in Table 55.

TABLE 55: ASC COVERED SURGICAL PROCEDURES PROPOSED TO BE NEWLY DESIGNATED AS PERMANENTLY OFFICE-BASED FOR CY 2023

CY 2023 CPT/HCPCS Code	CY 2022 Long Descriptor	CY 2022 ASC Payment Indicator	Proposed CY 2023 ASC Payment Indicator*
0101T	Extracorporeal shock wave involving musculoskeletal system, not otherwise specified, high energy	G2	P3*
0446T	Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training	G2	P2*
15275	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area	G2	R2*
21198	Osteotomy, mandible, segmental;	G2	R2*
31574	Laryngoscopy, flexible; with injection(s) for augmentation (eg, percutaneous, transoral), unilateral	G2	R2*
40830	Closure of laceration, vestibule of mouth; 2.5 cm or less	G2	R2*

* Payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the CY 2023 PFS proposed rates. For a discussion of the proposed PFS rates, we refer readers to the CY 2023 PFS proposed rule.

We also reviewed CY 2021 volume and utilization data for 8 surgical procedures designated as temporarily office-based in the CY 2022 OPPTS/ASC final rule with comment period and temporarily assigned one of the office-based payment indicators, specifically “P2,” “P3” or “R2” as shown in Table 56. For all 8 surgical procedures, there were fewer than 50 claims or no claims in our data. Therefore, we propose to continue to designate these procedures, shown in Table 56, as temporarily office-based for CY 2023. The procedures for which the proposed office-based designation for CY 2023 is temporary are indicated by an asterisk in Addendum AA to this proposed rule (which is available via the internet on the CMS website).

TABLE 56: PROPOSED CY 2023 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED IN THE CY 2022 OPPTS/ASC FINAL RULE

CY 2022 CPT/HCPCS Code	CY 2022 Long Descriptor	Final CY 2022 ASC Payment Indicator	Proposed CY 2023 ASC Payment Indicator*
64454	Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed	P3	P3*
65785	Implantation of intrastromal corneal ring segments	P2	P2*
67229	Treatment of extensive or progressive retinopathy, 1 or more sessions, preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (e.g., retinopathy of prematurity), photocoagulation or cryotherapy	R2	R2*
0402T	Collagen cross-linking of cornea, including removal of the corneal epithelium and intraoperative pachymetry, when performed (report medication separately)	R2	R2*
0512T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound	R2	R2*
0588T	Revision or removal of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve	R2	R2*
93985	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete bilateral study	P2	P2*
93986	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete unilateral study	P2	P2*

* Payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the CY 2023 PFS proposed rates. For a discussion of the proposed PFS rates, we refer readers to the CY 2023 PFS proposed rule.

As discussed in the August 2, 2007 ASC final rule (72 FR 42533 through 42535), we finalized our policy to designate certain new surgical procedures as temporarily office-based until adequate claims data are available to assess their predominant sites of service, whereupon if we confirm their office-based nature, the procedures would be permanently assigned to the list of office-based procedures. In the absence of claims data, we stated we would use other available information, including our clinical advisors' judgment, predecessor CPT and Level II HCPCS

codes, information submitted by representatives of specialty societies and professional associations, and information submitted by commenters during the public comment period. For CY 2023, there are no new CY 2023 CPT codes for ASC covered surgical procedures that have been temporarily assigned office-based.

b. Device-Intensive ASC Covered Surgical Procedures

(1) Background

We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59040 through 59041), for a summary of our existing policies regarding ASC covered surgical procedures that are designated as device-intensive.

(2) Proposed Changes to List of ASC Covered Surgical Procedures Designated as Device-Intensive for CY 2023

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59040 through 59043), for CY 2019, we modified our criteria for device-intensive procedures to better capture costs for procedures with significant device costs. We adopted a policy to allow procedures that involve surgically inserted or implanted, high-cost, single-use devices to qualify as device-intensive procedures. In addition, we modified our criteria to lower the device offset percentage threshold from 40 percent to 30 percent. The device offset percentage is the percentage of device costs within a procedure's total costs. Specifically, for CY 2019 and subsequent years, we adopted a policy that device-intensive procedures would be subject to the following criteria:

- All procedures must involve implantable devices assigned a CPT or HCPCS code;
- The required devices (including single-use devices) must be surgically inserted or implanted; and
- The device offset amount must be significant, which is defined as exceeding 30 percent of the procedure's mean cost. Corresponding to this change in the cost criterion, we adopted a policy that the default device offset for new codes that describe procedures that

involve the implantation of medical devices will be 31 percent beginning in CY 2019. For new codes describing procedures that are payable when furnished in an ASC and involve the implantation of a medical device, we adopted a policy that the default device offset would be applied in the same manner as the policy we adopted in section IV.B.2 of the CY 2019 OPPTS/ASC final rule with comment period (83 FR 58944 through 58948). We amended § 416.171(b)(2) of the regulations to reflect these new device criteria.

In addition, as also adopted in section IV.B.2 of CY 2019 OPPTS/ASC final rule with comment period, to further align the device-intensive policy with the criteria used for device pass-through status, we specified, for CY 2019 and subsequent years, that for purposes of satisfying the device-intensive criteria, a device-intensive procedure must involve a device that:

- Has received FDA marketing authorization, has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by FDA in accordance with 42 CFR 405.203 through 405.207 and 405.211 through 405.215, or meets another appropriate FDA exemption from premarket review;

- Is an integral part of the service furnished;
- Is used for one patient only;
- Comes in contact with human tissue;
- Is surgically implanted or inserted (either permanently or temporarily); and
- Is not any of the following:

++ Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15-1); or

++ A material or supply furnished incident to a service (for example, a suture, customized surgical kit, scalpel, or clip, other than a radiological site marker).

In the CY 2022 OPPTS/ASC final rule with comment period (86 FR 63773 through 63775), we modified our approach to assigning device-intensive status to surgical procedures

under the ASC payment system. First, we adopted a policy of assigning device-intensive status to procedures that involve surgically inserted or implanted, high-cost, single-use devices to qualify as device-intensive procedures if their device offset percentage exceeds 30 percent under the ASC standard ratesetting methodology, even if the procedure is not designated as device-intensive under the OPPS. Second, we adopted a policy that if a procedure is assigned device-intensive status under the OPPS, but has a device offset percentage below the device-intensive threshold under the standard ASC ratesetting methodology, the procedure will be assigned device-intensive status under the ASC payment system with a default device offset percentage of 31 percent. The policies were adopted to provide consistency between the OPPS and ASC payment system and provide a more appropriate payment rate for surgical procedures with significant device costs under the ASC payment system.

As discussed in more detail in section XIII.D.1.c of this proposed rule, we propose to create a special payment policy under the ASC payment system whereby we would add 52 new C codes to the ASC CPL to provide a special payment for code combinations eligible for complexity adjustments under the OPPS. These code combinations reflect separately payable primary procedures on the ASC CPL as well as add-on procedures that are packaged with an ASC payment indicator of “N1” (Packaged service/item; no separate payment made.). Under our proposal, the C code would retain the device-intensive status of the primary procedure as well as the device portion (or device offset amount) of the primary procedure and not the device offset percentage. The device offset percentage for a C code would be established by dividing the device portion of the primary procedure by the OPPS complexity-adjusted APC payment rate based on the ASC standard ratesetting methodology. Although this may yield results where the device offset percentage is not greater than 30 percent of the OPPS complexity-adjusted APC payment rate, we believe this is an appropriate methodology to apply where primary procedures assigned device-intensive status are a component of a C code.

Based on our existing criteria as well as our proposal to add to the ASC CPL new C codes that reflect code combinations eligible for complexity adjustments under the OPSS, for CY 2023, we propose to update the ASC CPL to indicate procedures that are eligible for payment according to our device-intensive procedure payment methodology. For CY 2023, where CY 2021 claims data are available, the device-intensive payment methodology relies on the proposed device-offset percentages of each device-intensive procedure using the CY 2021 OPSS claims and cost report data available for this proposed rule.

The ASC covered surgical procedures that we propose to designate as device-intensive, and therefore subject to the device-intensive procedure payment methodology for CY 2023, are assigned payment indicator “J8” and are included in ASC Addendum AA to this proposed rule (which is available via the internet on the CMS website). The CPT code, the CPT code short descriptor, the proposed CY 2023 ASC payment rate are also included in Addendum AA to this proposed rule (which is available via the internet on the CMS website). We are soliciting public comments on our proposal to assign device-intensive status to 11 of the new C codes that we propose to add to the ASC CPL as well as our methodology for determining the device portion for such procedures.

c. Proposed Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices

Our ASC payment policy for costly devices implanted or inserted in ASCs at no cost/full credit or partial credit is set forth in § 416.179 of our regulations, and is consistent with the OPSS policy that was in effect until CY 2014. We refer readers to the CY 2008 OPSS/ASC final rule with comment period (72 FR 66845 through 66848) for a full discussion of the ASC payment adjustment policy for no cost/full credit and partial credit devices. ASC payment is reduced by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device.

Effective CY 2014, under the OPSS, we finalized our proposal to reduce OPSS payment for applicable APCs by the full or partial credit a provider receives for a device, capped at the device offset amount. Although we finalized our proposal to modify the policy of reducing payments when a hospital furnishes a specified device without cost or with full or partial credit under the OPSS, in the CY 2014 OPSS/ASC final rule with comment period (78 FR 75076 through 75080), we finalized our proposal to maintain our ASC policy for reducing payments to ASCs for specified device-intensive procedures when the ASC furnishes a device without cost or with full or partial credit. Unlike the OPSS, there is currently no mechanism within the ASC claims processing system for ASCs to submit to CMS the amount of the actual credit received when furnishing a specified device at full or partial credit. Therefore, under the ASC payment system, we finalized our proposal for CY 2014 to continue to reduce ASC payments by 100 percent or 50 percent of the device offset amount when an ASC furnishes a device without cost or with full or partial credit, respectively.

Under current ASC policy, all ASC device-intensive covered surgical procedures are subject to the no cost/full credit and partial credit device adjustment policy. Specifically, when a device-intensive procedure is performed to implant or insert a device that is furnished at no cost or with full credit from the manufacturer, the ASC would append the HCPCS “FB” modifier on the line in the claim with the procedure to implant or insert the device. The contractor would reduce payment to the ASC by the device offset amount that we estimate represents the cost of the device when the necessary device is furnished without cost or with full credit to the ASC. We continue to believe that the reduction of ASC payment in these circumstances is necessary to pay appropriately for the covered surgical procedure furnished by the ASC.

In the CY 2019 OPSS/ASC final rule with comment period (83 FR 59043 through 59044) we adopted a policy to reduce the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit if the credit to the ASC is 50 percent or more (but less

than 100 percent) of the cost of the new device. The ASC will append the HCPCS “FC” modifier to the HCPCS code for the device-intensive surgical procedure when the facility receives a partial credit of 50 percent or more (but less than 100 percent) of the cost of a device. To report that the ASC received a partial credit of 50 percent or more (but less than 100 percent) of the cost of a new device, ASCs have the option of either: (1) submitting the claim for the device-intensive procedure to their Medicare contractor after the procedure’s performance, but prior to manufacturer acknowledgment of credit for the device, and subsequently contacting the contractor regarding a claim adjustment, once the credit determination is made; or (2) holding the claim for the device implantation or insertion procedure until a determination is made by the manufacturer on the partial credit and submitting the claim with the “FC” modifier appended to the implantation procedure HCPCS code if the partial credit is 50 percent or more (but less than 100 percent) of the cost of the device. Beneficiary coinsurance would be based on the reduced payment amount. As finalized in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66926), to ensure our policy covers any situation involving a device-intensive procedure where an ASC may receive a device at no cost or receive full credit or partial credit for the device, we apply our “FB”/“FC” modifier policy to all device-intensive procedures.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59043 through 59044) we stated we would reduce the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the device. In the CY 2020 OPPS/ASC final rule with comment period, we finalized continuing our existing policies for CY 2020. We note that we inadvertently omitted language that this policy would apply not just in CY 2019 but also in subsequent calendar years. We intended to apply this policy in CY 2019 and subsequent calendar years. Therefore, we proposed to apply our policy for partial credits specified in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59043 through 59044) in CY 2022 and

subsequent calendar years. Specifically, for CY 2022 and subsequent calendar years, we would reduce the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the device. To report that the ASC received a partial credit of 50 percent or more (but less than 100 percent) of the cost of a device, ASCs have the option of either: (1) submitting the claim for the device intensive procedure to their Medicare contractor after the procedure's performance, but prior to manufacturer acknowledgment of credit for the device, and subsequently contacting the contractor regarding a claim adjustment, once the credit determination is made; or (2) holding the claim for the device implantation or insertion procedure until a determination is made by the manufacturer on the partial credit and submitting the claim with the "FC" modifier appended to the implantation procedure HCPCS code if the partial credit is 50 percent or more (but less than 100 percent) of the cost of the device. Beneficiary coinsurance would be based on the reduced payment amount.

We are not proposing any changes to our policies related to no/cost full credit or partial credit devices for CY 2023.

d. Proposed Additions to the List of ASC Covered Surgical Procedures

Section 1833(i)(1) of the Act requires us, in part, to specify, in consultation with appropriate medical organizations, surgical procedures that are appropriately performed on an inpatient basis in a hospital but that can also be safely performed in an ASC, a CAH, or an HOPD, and to review and update the list of ASC covered surgical procedures at least every 2 years. We evaluate the ASC covered procedures list (ASC CPL) each year to determine whether procedures should be added to or removed from the list, and changes to the list are often made in response to specific concerns raised by stakeholders.

Under our regulations at §§ 416.2 and 416.166, covered surgical procedures furnished on or after January 1, 2022, are surgical procedures that meet the general standards specified in

§ 416.166(b) and are not excluded under the general exclusion criteria specified in § 416.166(c). Specifically, under § 416.166(b), the general standards provide that covered surgical procedures are surgical procedures specified by the Secretary and published in the **Federal Register** and/or via the Internet on the CMS website that are separately paid under the OPPTS, that would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure.

Section 416.166(c) sets out the general exclusion criteria used under the ASC payment system to evaluate the safety of procedures for performance in an ASC. The general exclusion criteria provide that covered surgical procedures do not include those surgical procedures that: (1) generally result in extensive blood loss; (2) require major or prolonged invasion of body cavities; (3) directly involve major blood vessels; (4) are generally emergent or life-threatening in nature; (5) commonly require systemic thrombolytic therapy; (6) are designated as requiring inpatient care under § 419.22(n); (7) can only be reported using a CPT unlisted surgical procedure code; or (8) are otherwise excluded under § 411.15.

For a detailed discussion of the history of our policies for adding surgical procedures to the ASC CPL, we refer readers to the CY 2021 and CY 2022 OPPTS/ASC final rules with comment period (85 FR 86143 through 86145; 86 FR 63777 through 63805).

1. Proposed Changes to the List of ASC Covered Surgical Procedures for CY 2023

Our current policy, which includes consideration of the general standards and exclusion criteria we have historically used to determine whether a surgical procedure should be added to the ASC CPL, is intended to ensure that surgical procedures added to the ASC CPL can be performed safely in the ASC setting on the typical Medicare beneficiary. For CY 2023, we conducted a review of procedures that currently are paid under the OPPTS and not included on the ASC CPL. We also assessed procedures against our regulatory safety criteria at § 416.166.

Based upon this review, we propose to update the ASC CPL by adding one lymphatic procedure to the list for CY 2023, as shown in Table 57 below.

After reviewing the clinical characteristics of this procedure, as well as consulting with stakeholders and multiple clinical advisors, we determined that this procedure is separately paid under the OPPI, would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, and would not be expected to require active medical monitoring and care of the beneficiary at midnight following the procedure. This procedure does not result in extensive blood loss, require major or prolonged invasion of body cavities, or directly involve major blood vessels. We believe this procedure may be appropriately performed in an ASC on a typical Medicare beneficiary. Therefore, we propose to include this procedure on the ASC CPL for CY 2023.

TABLE 57: CY 2023 PROPOSED SURGICAL PROCEDURES FOR THE ASC CPL

CY 2023 CPT/HCPCS Code	CY 2023 Long Descriptor
38531	Biopsy or excision of lymph node(s); open, inguino-femoral node(s)

We continue to focus on maximizing patient access to care by adding procedures to the ASC CPL when appropriate. While expanding the ASC CPL offers benefits, such as preserving the capacity of hospitals to treat more acute patients and promoting site neutrality, we also believe that any additions to the CPL should be added in a carefully calibrated fashion to ensure that the procedure is safe to be performed in the ASC setting for a typical Medicare beneficiary. We expect to continue to gradually expand the ASC CPL, as medical practice and technology continue to evolve and advance in future years. We encourage stakeholders to submit procedure recommendations to be added to the ASC CPL, particularly if there is evidence that these procedures meet our criteria and can be safely performed on the typical Medicare beneficiary in the ASC setting.

Proposed Name Change and Start Date of Nominations Process

In the CY 2022 OPPTS/ASC final rule with comment period, we finalized our proposal to add a nominations process for adding surgical procedures to the ASC CPL at § 416.166(d), (86 FR 63782) which we titled “Nominations.” As we have discussed in previous rulemaking, this process is simply an opportunity outside of the existing public comment period process for interested parties to submit recommendations before the proposed rule period so CMS can consider the suggestions as we develop the proposed rule. We believe this process enhances transparency and allows interested parties an additional opportunity to provide input for the ASC CPL.

However, the nominations process is not the only way for interested parties to make recommendations to CMS for adding surgical procedures to the ASC CPL. We emphasize that interested parties have been able, and may continue, to suggest surgical procedures they believe should be added to the ASC CPL during the public comment period following the proposed rule. That process remains unchanged. When interested parties submit procedure recommendations for the ASC CPL through the public comment process, CMS will consider them for the final rule with comment period. We understand, however, that the terminology we used in the CY 2022 OPPTS/ASC final rule with comment period and codified at § 416.166(d) – “Nominations” – may have led to some confusion that this process is the primary or only pathway for interested parties to suggest procedures to be added to the ASC CPL. Therefore, we propose to change the name of the process finalized last year in the CY 2022 OPPTS/ASC final rule with comment period from “Nominations” to the “Pre-Proposed Rule CPL Recommendation Process.” Where the current name of the process may suggest a formality or limitation that we did not intend – one that implies the nominations process is the preferred, primary, or only means by which interested parties may submit recommendations – we believe this proposed new name would not.

In addition, we are currently working on developing the technological infrastructure and Paperwork Reduction Act (PRA) package for the recommendations process. Because we were

unable to complete the infrastructure development and PRA processes (which have taken longer than we originally anticipated when we finalized the policy) in time for commenters to recommend procedures to be added to the ASC CPL prior to the CY 2023 proposed rule, we propose to revise the start date of the recommendation process in the regulatory text. We propose to change January 1, 2023, to January 1, 2024, so that the text at § 416.166(d) would specify that on or after January 1, 2024, an external party may recommend a surgical procedure by March 1 of a calendar year for the list of ASC covered surgical procedures for the following calendar year. We continue to welcome all procedure submissions through the public comment process, as we have in previous years.

2. Covered Ancillary Services

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59062 through 59063), consistent with the established ASC payment system policy (72 FR 42497), we finalized the policy to update the ASC list of covered ancillary services to reflect the payment status for the services under the OPPS and to continue this reconciliation of packaged status for subsequent calendar years. As discussed in prior rulemaking, maintaining consistency with the OPPS may result in changes to ASC payment indicators for some covered ancillary services. For example, if a covered ancillary service was separately paid under the ASC payment system in CY 2022, but will be packaged under the CY 2023 OPPS, we would also package the ancillary service under the ASC payment system for CY 2023 to maintain consistency with the OPPS. Comment indicator “CH”, which is discussed in section XIII.G of this proposed rule, is used in Addendum BB (which is available via the Internet on the CMS website) to indicate covered ancillary services for which we propose a change in the ASC payment indicator to reflect a proposed change in the OPPS treatment of the service for CY 2023.

In the CY 2022 OPPS/ASC final rule with comment period, we finalized our proposal to revise 42 CFR 416.164(b)(6) to include, as ancillary items that are integral to a covered surgical procedure and for which separate payment is allowed, non-opioid pain management drugs and

biologicals that function as a supply when used in a surgical procedure as determined by CMS (86 FR 63490).

New CPT and HCPCS codes for covered ancillary services for CY 2023 can be found in section XIII.B of this proposed rule. All ASC covered ancillary services and their proposed payment indicators for CY 2023 are also included in Addendum BB to this proposed rule (which is available via the internet on the CMS website).

D. Proposed Update and Payment for ASC Covered Surgical Procedures and Covered Ancillary Services

1. Proposed ASC Payment for Covered Surgical Procedures

a. Background

Our ASC payment policies for covered surgical procedures under the revised ASC payment system are described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66828 through 66831). Under our established policy, we use the ASC standard ratesetting methodology of multiplying the ASC relative payment weight for the procedure by the ASC conversion factor for that same year to calculate the national unadjusted payment rates for procedures with payment indicators “G2” and “A2”. Payment indicator “A2” was developed to identify procedures that were included on the list of ASC covered surgical procedures in CY 2007 and, therefore, were subject to transitional payment prior to CY 2011. Although the 4-year transitional period has ended and payment indicator “A2” is no longer required to identify surgical procedures subject to transitional payment, we have retained payment indicator “A2” because it is used to identify procedures that are exempted from the application of the office-based designation.

Payment rates for office-based procedures (payment indicators “P2”, “P3”, and “R2”) are the lower of the PFS nonfacility PE RVU-based amount or the amount calculated using the ASC standard rate setting methodology for the procedure. As detailed in section XIII.C.1.a of this proposed rule, we update the payment amounts for office-based procedures (payment indicators

“P2”, “P3”, and “R2”) using the most recent available MPFS and OPSS data. We compare the estimated current year rate for each of the office-based procedures, calculated according to the ASC standard rate setting methodology, to the PFS nonfacility PE RVU-based amount to determine which was lower and, therefore, would be the current year payment rate for the procedure under our final policy for the revised ASC payment system (§ 416.171(d)).

The rate calculation established for device-intensive procedures (payment indicator “J8”) is structured so only the service portion of the rate is subject to the ASC conversion factor. We update the payment rates for device-intensive procedures to incorporate the most recent device offset percentages calculated under the ASC standard ratesetting methodology, as discussed in section XIII.C.1.b of this proposed rule.

In the CY 2014 OPSS/ASC final rule with comment period (78 FR 75081), we finalized our proposal to calculate the CY 2014 payment rates for ASC covered surgical procedures according to our established methodologies, with the exception of device removal procedures. For CY 2014, we finalized a policy to conditionally package payment for device removal procedures under the OPSS. Under the OPSS, a conditionally packaged procedure (status indicators “Q1” and “Q2”) describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a covered surgical procedure, HCPCS codes that are conditionally packaged under the OPSS are always packaged (payment indicator “N1”) under the ASC payment system. Under the OPSS, device removal procedures are conditionally packaged and, therefore, would be packaged under the ASC payment system. There is no Medicare payment made when a device removal procedure is performed in an ASC without another surgical procedure included on the claim; therefore, no Medicare payment would be made if a device was removed but not replaced. To ensure that the ASC payment system provides separate payment for surgical procedures that only involve device removal – conditionally packaged in the OPSS (status indicator “Q2”) – we have continued to

provide separate payment since CY 2014 and assign the current ASC payment indicators associated with these procedures.

b. Update to ASC Covered Surgical Procedure Payment Rates for CY 2023

We propose to update ASC payment rates for CY 2023 and subsequent years using the established rate calculation methodologies under § 416.171 and using our definition of device-intensive procedures, as discussed in section XII.C.1.b of this proposed rule. As the proposed OPPS relative payment weights are generally based on geometric mean costs, we propose that the ASC payment system will generally use the geometric mean cost to determine proposed relative payment weights under the ASC standard methodology. We propose to continue to use the amount calculated under the ASC standard ratesetting methodology for procedures assigned payment indicators “A2” and “G2”.

We propose to calculate payment rates for office-based procedures (payment indicators “P2”, “P3”, and “R2”) and device-intensive procedures (payment indicator “J8”) according to our established policies and to identify device-intensive procedures, using the methodology discussed in section XII.C.1.b of this proposed rule. Therefore, we propose to update the payment amount for the service portion (the non-device portion) of the device-intensive procedures using the standard ASC ratesetting methodology and the payment amount for the device portion based on the proposed CY 2023 device offset percentages that have been calculated using the standard OPPS APC ratesetting methodology. We propose that payment for office-based procedures would be at the lesser of the proposed CY 2023 MPFS nonfacility PE RVU-based amount or the proposed CY 2023 ASC payment amount calculated according to the ASC standard ratesetting methodology.

As we did for CYs 2014 through 2022, for CY 2023, we propose to continue our policy for device removal procedures, such that device removal procedures that are conditionally packaged in the OPPS (status indicators “Q1” and “Q2”) will be assigned the current ASC

payment indicators associated with those procedures and will continue to be paid separately under the ASC payment system.

c. Proposed ASC Payment for Combinations of Primary and Add-On Procedures Eligible for Complexity Adjustments under the OPSS

In this section we propose a policy to provide increased payment under the ASC payment system for combinations of certain “J1” service codes and add-on procedure codes that are eligible for a complexity adjustment under the OPSS.

OPSS C-APC Complexity Adjustment Policy

Under the OPSS, complexity adjustments are utilized to provide increased payment for certain comprehensive services. As discussed in section II.b.1 of this proposed rule, we apply a complexity adjustment by promoting qualifying paired “J1” service code combinations or paired code combinations of “J1” services and add-on codes from the originating Comprehensive APC (C-APC) (the C-APC to which the designated primary service is first assigned) to the next higher paying C-APC in the same clinical family of C-APCs. A “J1” status indicator refers to a hospital outpatient service paid through a C-APC. We package payment for all add-on codes, which are codes that describe a procedure or service always performed in addition to a primary service or procedure, into the payment for the C-APC. However, certain combinations of primary service codes and add-on codes may qualify for a complexity adjustment.

We apply complexity adjustments when the paired code combination represents a complex, costly form or version of the primary service when the frequency and cost thresholds are met. The frequency threshold is met when there are 25 or more claims reporting the code combination, and the cost threshold is met when there is a violation of the 2 times rule, as specified in section 1833(t)(2) of the Act and described in section III.A.2.b of this proposed rule, in the originating C-APC. These paired code combinations that meet the frequency and cost threshold criteria represent those that exhibit materially greater resource requirements than the primary service. After designating a single primary service for a claim, we evaluate that service

in combination with each of the other procedure codes reported on the claim that are either assigned to status indicator “J1” or add-on codes to determine if there are paired code combinations that meet the complexity adjustment criteria. Once we have determined that a particular combination of “J1” services, or combinations of a “J1” service and add-on code, represents a complex version of the primary service because it is sufficiently costly, frequent, and a subset of the primary comprehensive service overall according to the criteria described above, we promote the claim to the next higher cost C-APC within the clinical family unless the primary service is already assigned to the highest cost APC within the C-APC clinical family or assigned to the only C-APC in a clinical family. We do not create new C-APCs with a comprehensive geometric mean cost that is higher than the highest geometric mean cost (or only) C-APC in a clinical family just to accommodate potential complexity adjustments. Therefore, the highest payment for any claim including a code combination for services assigned to a C-APC would be the highest paying C-APC in the clinical family (79 FR 66802).

As previously stated, we package payment for add-on codes into the C-APC payment rate. If any add-on code reported in conjunction with the “J1” primary service code does not qualify for a complexity adjustment, payment for the add-on service continues to be packaged into the payment for the primary service and the primary service code reported with the add-on code is not reassigned to the next higher cost C-APC. We list the complexity adjustments for “J1” and add-on code combinations for CY 2022, along with all of the other final complexity adjustments, in Addendum J to the CY 2022 OPSS/ASC final rule (which is available via the internet on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices>).

Proposed ASC Special Payment Policy for OPSS Complexity-Adjusted C-APCs

Comprehensive APCs cannot be adopted in the ASC payment system due to limitations of the ASC claims processing systems. Thus, we do not use the OPSS comprehensive services ratesetting methodology in the ASC payment system. Under the standard ratesetting

methodology used for the ASC payment system, comprehensive “J1” claims that exist under the OPPS are treated the same as other claims that contain separately payable procedure codes. As comprehensive APCs do not exist under the ASC payment system, there is not a process similar to the OPPS complexity adjustment policy in the ASC payment system to provide higher payment for more complex code combinations. In the ASC payment system, when multiple procedures are performed together in a single operative session, most covered surgical procedures are subject to a 50-percent reduction for the lower-paying procedure (72 FR 66830). This multiple procedure reduction gives providers additional payment when they perform multiple procedures during the same session, while still encouraging providers to provide necessary services as efficiently as possible. Add-on procedure codes are not separately payable under the ASC payment system and are always packaged into the ASC payment rate for the procedure. Unlike the multiple procedure discounting process used for other surgical procedures in the ASC payment system, providers do not receive any additional payment when they perform a primary service with an add-on code in the ASC payment system.

In previous rulemaking, we have received suggestions from commenters requesting that we explore ways to increase payment to ASCs when services corresponding to add-on codes are performed with procedures, as certain code combinations may represent increased procedure complexity or resource intensity when performed together. For example, in the CY 2022 OPPS/ASC final rule with comment period, one commenter suggested that we modify the device-intensive criteria to allow packaged procedures that trigger a complexity adjustment under the OPPS to be eligible for device-intensive status under the ASC payment system (86 FR 63775). Based on our internal data review and assessment at that time, our response to that comment noted that we did not believe any changes were warranted to our packaging policies under the ASC payment system but that we would consider it in future rulemaking.

For this CY 2023 rulemaking, we evaluated the differences in payment in the OPPS and ASC settings for code pairs that included a primary procedure and add-on codes that were

eligible for complexity adjustments under the OPSS and also performed in the ASC setting. Under the ASC payment system, we identified 26 packaged procedures (payment indicator = “N1”) that combine with 42 primary procedures, which would be C-APCs (status indicator = “J1”) under the OPSS, to produce 52 different complexity adjustment code combinations. We generally estimate that ASC services were paid approximately 55 percent of the OPSS rate for similar services in CY 2021. When we compared the OPSS complexity-adjusted payment rate of these primary procedure and add-on code combinations to the ASC payment rate for the same code combinations, we found that the average rate of ASC payment as a percent of OPSS payment for these code combinations was 25 to 35 percent, which is significantly lower than 55 percent.

We recognize that this payment differential between the C-APC-assigned code combinations eligible for complexity adjustments under the OPSS and the same code combinations under the ASC payment system could potentially create financial disincentives for providers to offer these services in the ASC setting, which could potentially result in Medicare beneficiaries encountering difficulties accessing these combinations of services in ASC settings. As noted above, our current policy does not include additional payment for services corresponding to add-on codes, unlike our payment policy for multiple surgical procedures performed together, for which we provide additional payment under the multiple procedure reduction. However, these primary procedure and add-on code combinations that would be eligible for a complexity adjustment under the OPSS still represent more complex and costly versions of the service, and we believe that providers not receiving additional payment under the ASC payment system to compensate for that increased complexity could lead to providers not being able to provide these services in the ASC setting which could result in barriers to beneficiary access.

In order to address this issue, we propose a new ASC payment policy that would apply to certain code combinations in the ASC payment system where CMS would pay for those code

combinations at a higher payment rate to reflect that the code combination is a more complex and costlier version of the procedure performed, similar to the way in which the OPPS APC complexity adjustment is applied to certain paired code combinations that exhibit materially greater resource requirements than the primary service. We propose to add new § 416.172(h) to codify this policy.

We propose that combinations of a primary procedure code and add-on codes that are eligible for a complexity adjustment under the OPPS (as listed in OPPS Addendum J) would be eligible for this proposed payment policy in the ASC setting. Specifically, we propose that the ASC payment system code combinations eligible for additional payment under this proposed policy would consist of a separately payable surgical procedure code and one or more packaged add-on codes from the ASC Covered Procedures List (CPL) and ancillary services list. Add-on codes are assigned payment indicator “N1” (Packaged service/item; no separate payment made), as listed in the ASC addenda.

Regarding eligibility for this special payment policy, we propose that we would assign each eligible code combination a new C code that describes the primary and the add-on procedure(s) performed. C codes are unique temporary codes and are only valid for claims for HOPD and ASC services and procedures. Under our proposal, we would add these C codes to the ASC CPL and the ancillary services list, and when ASCs bill this C code, they would receive a higher payment rate that reflects that the code combination is a more complex and costlier version of the procedure performed. We anticipate that the C codes eligible for this proposed payment policy would change slightly each year, as the complexity adjustment assignments change under the OPPS and we expect we would add new C codes each year accordingly. We propose 52 such new C codes to add to the ASC CPL. These proposed C codes for CY 2023 can be found in the ASC addenda. We propose to add new § 416.172(h)(1), titled Eligibility, to codify this policy.

We propose the following payment methodology for this proposed policy, which we would reflect in new § 416.172(h)(2), titled Calculation of Payment. We propose that the C codes would be subject to all ASC payment policies, including the standard ASC payment system ratesetting methodology, meaning, they would be treated the same way as other procedure codes in the ASC setting. For example, the multiple procedure discounting rules would apply to the primary procedure in cases where the services corresponding to the C code are performed with another separately payable covered surgical procedure in the ASC setting. We propose to use the OPPS complexity-adjusted C-APC rate to determine the ASC payment rate for qualifying code combinations, similar to how we use OPPS APC relative weights in the standard ASC payment system ratesetting methodology. Under the ASC payment system, we use the OPPS APC relative payment weights to update the ASC relative payment weights for covered surgical procedures since ASCs do not submit cost reports. We then scale those ASC relative weights for the ASC payment system to ensure budget neutrality. To calculate the ASC payment rates for most ASC covered surgical procedures, we multiply the ASC conversion factor by the ASC relative payment weight. A more detailed discussion of this methodology is provided in the in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66828 through 66831).

For this proposal, we propose to use the OPPS complexity-adjusted C-APC rate for each corresponding code combination to calculate the OPPS relative weight for each corresponding ASC payment system C code, which we believe would appropriately reflect the complexity and resource intensity of these ASC procedures being performed together. For C codes that are not assigned device-intensive status (discussed below), we would multiply the OPPS relative weight by the ASC budget neutrality adjustment (or ASC weight scalar) to determine the ASC relative weight. We would then multiply the ASC relative weight by the ASC conversion factor to determine the ASC payment rate for each C code. In short, we would apply the standard ASC

ratesetting process to the C codes. We propose to add new § 416.172(h)(2)(i) to codify this policy.

As discussed in section XIII.C.1.b of this proposed rule, certain C codes under our proposed policy may include a primary procedure that also qualifies for device-intensive status under the ASC payment system. For primary procedures assigned device-intensive status and that are a component of a C code created under this proposal, we believe it would be appropriate for the C code to retain the device-intensive status of the primary procedure as well as the device portion (or device offset amount) of the primary procedure and not the device offset percentage. For example, if the primary procedure had a device offset percentage of 31 percent (a proposed device offset percentage of greater than 30 percent would be needed to qualify for device-intensive status) and a device portion (or device offset amount) of \$3,000, C codes that included this primary procedure would be assigned device-intensive status and a device portion of \$3,000 to be held constant with the OPPS. We would apply our standard ASC payment system ratesetting methodology to the non-device portion of the OPPS complexity-adjusted APC rate of the C codes; that is, we would apply the ASC budget neutrality adjustment and ASC conversion factor. We believe assigning device-intensive status and transferring the device portion from the primary procedure's ASC payment rate to the C code's ASC payment rate calculation is consistent with our treatment of device costs and determining device-intensive status under the ASC payment system and is an appropriate methodology for determining the ASC payment rate. The non-device portion would be the difference between the device portion of the primary procedure and the OPPS complexity-adjusted APC payment rate for the C code based on the ASC standard ratesetting methodology. Although this may yield results where the device offset percentage is not greater than 30 percent of the OPPS complexity-adjusted APC payment rate, we believe this is an appropriate methodology to apply where primary procedures assigned device-intensive status are a component of a C code. As is the case for all device-intensive procedures, we would apply the ASC standard ratesetting methodology to the OPPS relative

weights of the non-device portion for any C code eligible for payment under this proposal. That is, we would multiply the OPPS relative weight by the ASC budget neutrality adjustment and the ASC conversion factor and sum that amount with the device portion to calculate the ASC payment rate. We propose to add new § 416.172(h)(2)(ii) to codify this policy.

In order to include these C codes in the budget neutrality calculations for the ASC payment system, we propose to estimate the potential utilization for these C codes. We do not have claims data for packaged codes in the ASC setting because ASCs do not report packaged codes under the ASC payment system. Therefore, we propose to estimate CY 2023 ASC utilization based upon how often these combinations are performed in the HOPD setting. Specifically, we would use the ratio of the primary procedure volume to add-on procedure volume from CY 2021 OPPS claims and apply that ratio against ASC primary procedure utilization to estimate the increased spending as a result of our proposal for budget neutrality purposes. We believe this method would provide a reasonable estimate of the utilization of these code combinations in the ASC setting, as it is based on the specific code combination utilization in the OPPS. We anticipate that we would continue this estimation process until we have sufficient claims data for the C codes that can be used to more accurately calculate code combination utilization in ASCs, likely for the CY 2025 rulemaking.

We welcome comments on this proposal, including comments or suggestions regarding additional approaches that we should consider for this policy.

d. Proposed Low Volume APCs and Limit on ASC Payment Rates for Procedures Assigned to Low Volume APCs

As stated in section XIII.D.1.b of this proposed rule, the ASC payment system generally uses OPPS geometric mean costs under the standard methodology to determine proposed relative payment weights under the standard ASC ratesetting methodology.

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63743 through 63747), we adopted a universal Low Volume APC policy for CY 2022 and subsequent calendar

years. Under our policy, we expanded the low volume adjustment policy that is applied to procedures assigned to New Technology APCs to also apply to clinical and brachytherapy APCs. Specifically, a clinical APC or brachytherapy APC with fewer than 100 claims per year would be designated as a Low Volume APC. For items or services assigned to a Low Volume APC, we use up to 4 years of claims data to establish a payment rate for the APC as we currently do for low volume services assigned to New Technology APCs. The payment rate for a Low Volume APC or a low volume New Technology procedure would be based on the highest of the median cost, arithmetic mean cost, or geometric mean cost calculated using multiple years of claims data.

Based on claims data available for this proposed rule, we propose to designate 4 brachytherapy APCs and 4 clinical APCs as Low Volume APCs under the ASC payment system. The 4 clinical APCs and 4 brachytherapy APCs shown in Table 58 meet our criteria of having fewer than 100 single claims in the claims year (CY 2021 for this proposed rule) and therefore, we propose that they would be subject to our universal Low Volume APC policy and the APC cost metric would be based on the greater of the median cost, arithmetic mean cost, or geometric mean cost using up to 4 years of claims data. These 8 APCs were designated as Low Volume APCs in CY 2022; however, as we noted under the comprehensive ratesetting methodology section, APC 2647 (Brachytherapy, non-stranded, Gold-198), which was previously designated as a Low Volume APC for CY 2022, did not meet our claims threshold for this proposed rule.

**TABLE 58 : COST STATISTICS FOR PROPOSED LOW VOLUME APCS
STANDARD (ASC) RATESETTING METHODOLOGY FOR CY 2023**

APC	APC Description	CY 2021 Claims Available for Ratesetting	Geometric Mean Cost without Low Volume APC Designation	Proposed Median Cost	Proposed Arithmetic Mean Cost	Proposed Geometric Mean Cost	Proposed CY 2023 APC Cost
2632	Iodine I-125 sodium iodide	9	\$141.23	\$31.74	\$44.35	\$37.26	\$44.35

APC	APC Description	CY 2021 Claims Available for Ratesetting	Geometric Mean Cost without Low Volume APC Designation	Proposed Median Cost	Proposed Arithmetic Mean Cost	Proposed Geometric Mean Cost	Proposed CY 2023 APC Cost
2635	Brachytx, non-str, HA, P-103	26	\$125.24	\$34.04	\$51.09	\$42.77	\$51.09
2636	Brachy linear, non-str, P-103	0	---*	\$49.65	\$53.38	\$38.80	\$53.38
2647	Brachytx, NS, Non-HDRIr-192	14	\$144.37	\$184.49	\$377.65	\$141.18	\$377.65
5244	Level 4 Blood Product Exchanges and Related Services	0	---*	\$45,068.10	\$44,803.39	\$42,607.70	\$45,068.10
5493	Level 3 Intraocular Procedures	11	\$11,224.89	\$11,959.68	\$11,639.45	\$10,858.70	\$11,959.68
5494	Level 4 Intraocular Procedures	28	\$1,736.78	\$3,003.25	\$3,371.21	\$2,901.57	\$3,371.21
5495	Level 5 Intraocular Procedures	7	\$13,013.71	\$17,567.13	\$17,798.92	\$15,941.10	\$17,798.92

* For this proposed rule, there are no CY 2021 claims that contain the HCPCS code assigned to APC 2636 (HCPCS code C2636) or APC 5244 (CPT code 38240) that are available for CY 2023 OPPTS/ASC ratesetting.

2. Payment for Covered Ancillary Services

a. Background

Our payment policies under the ASC payment system for covered ancillary services generally vary according to the particular type of service and its payment policy under the OPPTS. Our overall policy provides separate ASC payment for certain ancillary items and services integrally related to the provision of ASC covered surgical procedures that are paid separately under the OPPTS and provides packaged ASC payment for other ancillary items and services that are packaged or conditionally packaged (status indicators “N”, “Q1”, and “Q2”) under the OPPTS.

In the CY 2013 OPPTS/ASC rulemaking (77 FR 45169 and 77 FR 68457 through 68458), we further clarified our policy regarding the payment indicator assignment for procedures that are conditionally packaged in the OPPTS (status indicators “Q1” and “Q2”). Under the OPPTS, a conditionally packaged procedure describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the

claim without a significant procedure. Because ASC services always include a surgical procedure, HCPCS codes that are conditionally packaged under the OPSS are generally packaged (payment indicator “N1”) under the ASC payment system (except for device removal procedures, as discussed in the CY 2022 OPSS/ASC proposed rule (86 FR 42083)). Thus, our policy generally aligns ASC payment bundles with those under the OPSS (72 FR 42495). In all cases, in order for ancillary items and services also to be paid, the ancillary items and services must be provided integral to the performance of ASC covered surgical procedures for which the ASC bills Medicare.

Our ASC payment policies generally provide separate payment for drugs and biologicals that are separately paid under the OPSS at the OPSS rates and package payment for drugs and biologicals for which payment is packaged under the OPSS. However, as discussed in the CY 2022 OPSS/ASC final rule with comment period, for CY 2022, we finalized a policy to unpackage and pay separately at ASP plus 6 percent for the cost of non-opioid pain management drugs and biologicals that function as a supply when used in a surgical procedure as determined by CMS under § 416.174 (86 FR 63483).

We generally pay for separately payable radiology services at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (72 FR 42497). However, as finalized in the CY 2011 OPSS/ASC final rule with comment period (75 FR 72050), payment indicators for all nuclear medicine procedures (defined as CPT codes in the range of 78000 through 78999) that are designated as radiology services that are paid separately when provided integral to a surgical procedure on the ASC list are set to “Z2” so that payment is made based on the ASC standard ratesetting methodology rather than the MPFS nonfacility PE RVU amount (“Z3”), regardless of which is lower (§ 416.171(d)(1)).

Similarly, we also finalized our policy to set the payment indicator to “Z2” for radiology services that use contrast agents so that payment for these procedures will be based on the OPSS

relative payment weight using the ASC standard ratesetting methodology and, therefore, will include the cost for the contrast agent (§ 416.171(d)(2)).

ASC payment policy for brachytherapy sources mirrors the payment policy under the OPPS. ASCs are paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS or, if OPPS rates are unavailable, at contractor-priced rates (72 FR 42499). Since December 31, 2009, ASCs have been paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS.

Our ASC policies also provide separate payment for: (1) certain items and services that CMS designates as contractor-priced, including, but not limited to, the procurement of corneal tissue; and (2) certain implantable items that have pass-through payment status under the OPPS. These categories do not have prospectively established ASC payment rates according to ASC payment system policies (72 FR 42502 and 42508 through 42509; § 416.164(b)). Under the ASC payment system, we have designated corneal tissue acquisition and hepatitis B vaccines as contractor-priced. Corneal tissue acquisition is contractor-priced based on the invoiced costs for acquiring the corneal tissue for transplantation. Hepatitis B vaccines are contractor-priced based on invoiced costs for the vaccine.

Devices that are eligible for pass-through payment under the OPPS are separately paid under the ASC payment system and are contractor-priced. Under the revised ASC payment system (72 FR 42502), payment for the surgical procedure associated with the pass-through device is made according to our standard methodology for the ASC payment system, based on only the service (non-device) portion of the procedure's OPPS relative payment weight if the APC weight for the procedure includes other packaged device costs. We also refer to this methodology as applying a “device offset” to the ASC payment for the associated surgical procedure. This ensures that duplicate payment is not provided for any portion of an implanted device with OPPS pass-through payment status.

In the CY 2015 OPPTS/ASC final rule with comment period (79 FR 66933 through 66934), we finalized that, beginning in CY 2015, certain diagnostic tests within the medicine range of CPT codes for which separate payment is allowed under the OPPTS are covered ancillary services when they are integral to an ASC covered surgical procedure. We finalized that diagnostic tests within the medicine range of CPT codes include all Category I CPT codes in the medicine range established by CPT, from 90000 to 99999, and Category III CPT codes and Level II HCPCS codes that describe diagnostic tests that crosswalk or are clinically similar to procedures in the medicine range established by CPT. In the CY 2015 OPPTS/ASC final rule with comment period, we also finalized our policy to pay for these tests at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (79 FR 66933 through 66934). We finalized that the diagnostic tests for which the payment is based on the ASC standard ratesetting methodology be assigned to payment indicator “Z2” and revised the definition of payment indicator “Z2” to include a reference to diagnostic services and those for which the payment is based on the PFS nonfacility PE RVU-based amount be assigned payment indicator “Z3,” and revised the definition of payment indicator “Z3” to include a reference to diagnostic services.

b. Proposed Payment for Covered Ancillary Services for CY 2023

We propose to update the ASC payment rates and to make changes to ASC payment indicators, as necessary, to maintain consistency between the OPPTS and ASC payment system regarding the packaged or separately payable status of services and the proposed CY 2023 OPPTS and ASC payment rates and subsequent years’ payment rates. We also propose to continue to set the CY 2023 ASC payment rates and subsequent years’ payment rates for brachytherapy sources and separately payable drugs and biologicals equal to the OPPTS payment rates for CY 2023 and subsequent years’ payment rates.

Covered ancillary services and their proposed payment indicators for CY 2023 are listed in Addendum BB of this proposed rule (which is available via the internet on the CMS website).

For those covered ancillary services where the payment rate is the lower of the rate under the ASC standard rate setting methodology and the PFS proposed rates (similar to our office-based payment policy), the proposed payment indicators and rates set forth in this proposed rule are based on a comparison using the proposed PFS rates effective January 1, 2023. For a discussion of the PFS rates, we refer readers to the CY 2023 PFS proposed rule, which is available on the CMS website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html>.

3. Proposal in Physician Fee Schedule Proposed Rule to Require HOPDs and ASCs to Report Discarded Amounts of Certain Single-dose or Single-use Package Drugs

Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117-9, November 15, 2021) (“the Infrastructure Act”) amended section 1847A of the Act to re-designate subsection (h) as subsection (i) and insert a new subsection (h), which requires manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. Section III.A. of the CY 2023 Physician Fee Schedule (PFS) proposed rule includes proposals to implement section 90004 of the Infrastructure Act, including a proposal that HOPDs and ASCs would be required to report the JW modifier or any successor modifier to identify discarded amounts of refundable single-dose container or single-use package drugs that are separately payable under the OPPS or ASC payment system. Specifically, we propose in the CY 2023 PFS proposed rule that the JW modifier would be used to determine the total number of billing units of the HCPCS code (that is, the identifiable quantity associated with a HCPCS code, as established by CMS) of a refundable single-dose container or single-use package drug, if any, that were discarded for dates of service during a relevant quarter for the purpose of calculating the refund amount described in section 1847A(h)(3) of the Act. The CY 2023 PFS proposed rule also proposes to require HOPDs and ASCs to use a separate modifier, JZ, in cases where no billing units of such drugs were discarded and for which the JW modifier would be required if there were discarded amounts.

Because the CY 2023 PFS proposed rule proposes to codify certain billing requirements for HOPDs and ASCs, we want to ensure interested parties are aware of them and know to refer to that rule for a full description of the proposed policy. Interested parties should submit comments on this and any other proposals to implement Section 90004 of the Infrastructure Act in response to the CY 2023 PFS proposed rule. Public comments on these proposals will be addressed in the CY 2023 PFS final rule. We note that this same notice appears in section V.A.C. of this proposed rule.

E. ASC Payment System Policy for Non-Opioid Pain Management Drugs and Biologicals that Function as Surgical Supplies

1. Background on OPPS/ASC Non-Opioid Pain Management Packaging Policies

On October 24, 2018, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT) Act (Pub. L. 115-271) was enacted. Section 1833(t)(22)(A)(i) of the Act, as added by section 6082(a) of the SUPPORT Act, states that the Secretary must review payments under the OPPS for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives. As part of this review, under section 1833(t)(22)(A)(iii) of the Act, the Secretary must consider the extent to which revisions to such payments (such as the creation of additional groups of covered outpatient department (OPD) services to separately classify those procedures that utilize opioids and non-opioid alternatives for pain management) would reduce the payment incentives for using opioids instead of non-opioid alternatives for pain management. In conducting this review and considering any revisions, the Secretary must focus on covered OPD services (or groups of services) assigned to C-APCs, APCs that include surgical services, or services determined by the Secretary that generally involve treatment for pain management. If the Secretary identifies revisions to payments pursuant to section 1833(t)(22)(A)(iii) of the Act, section 1833(t)(22)(C) of the Act

requires the Secretary to, as determined appropriate, begin making revisions for services furnished on or after January 1, 2020. Revisions under this paragraph are required to be treated as adjustments for purposes of paragraph (9)(B) of the Act, which requires any adjustments to be made in a budget neutral manner. Section 1833(i)(8) of the Act, as added by section 6082(b) of the SUPPORT Act, requires the Secretary to conduct a similar type of review as required for the OPPS and to make revisions to the ASC payment system in an appropriate manner, as determined by the Secretary.

For a detailed discussion of rulemaking on non-opioid alternatives prior to CY 2020, we refer readers to the CYs 2018 and 2019 OPPS/ASC final rules with comment period (82 FR 59345; 83 FR 58855 through 58860).

For the CY 2020 OPPS/ASC proposed rule (84 FR 39423 through 39427), as required by section 1833(t)(22)(A)(i) of the Act, we reviewed payments under the OPPS for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives. For the CY 2020 OPPS/ASC proposed rule (84 FR 39423 through 39427), we proposed to continue our policy to pay separately at ASP plus 6 percent for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures when they are furnished in the ASC setting and to continue to package payment for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures in the hospital outpatient department setting.

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61173 through 61180), after reviewing data from stakeholders and Medicare claims data, we did not find compelling evidence to suggest that revisions to our OPPS payment policies for non-opioid pain management alternatives were necessary for CY 2020. We finalized our proposal to continue to unpackage and pay separately at ASP plus 6 percent for non-opioid pain management drugs that

function as surgical supplies when furnished in the ASC setting for CY 2020. Under this policy, for CY 2020, the only drug that qualified for separate payment in the ASC setting as a non-opioid pain management drug that functions as a surgical supply was Exparel.

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 85896 to 85899), we continued the policy to pay separately at ASP plus 6 percent for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures when they were furnished in the ASC setting and to continue to package payment for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures in the hospital outpatient department setting for CY 2021. For CY 2021, only Exparel and Omidria met the criteria as non-opioid pain management drugs that function as surgical supplies in the ASC setting, and received separate payment under the ASC payment system.

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63483), we finalized a policy to unpackage and pay separately at ASP plus 6 percent for non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting, are FDA-approved, have an FDA-approved indication for pain management or as an analgesic, and have a per-day cost above the OPPS/ASC drug packaging threshold, and we finalized our proposed regulation text changes at 42 CFR 416.164(a)(4) and (b)(6), § 416.171(b)(1), and § 416.174 as proposed. We determined that four products were eligible for separate payment in the ASC setting under our final policy for CY 2022. We noted that future products, or products not discussed in that rulemaking that may be eligible for separate payment under this policy would be evaluated in future rulemaking (86 FR 63496). Table 59 lists the four drugs that met our finalized criteria established in CY 2022 and received separate payment under the ASC payment system when furnished in the ASC setting for CY 2022 as described in the CY 2022 final rule with comment period (86 FR 63496).

TABLE 59: SUMMARY OF PRODUCTS MEETING CMS'S CRITERIA FOR SEPARATE PAYMENT IN THE ASC SETTING UNDER THE NON-OPIOID PAIN

**MANAGEMENT DRUGS THAT FUNCTION AS A SURGICAL SUPPLY PACKAGING
POLICY FOR CY 2022**

HCPCS Code	Long Descriptor	Final CY 2022 OPPS Status Indicator (SI)*	Final CY 2022 ASC Payment Indicator (PI)*
C9290	Injection, bupivacaine liposome, 1 mg	N	K2
J1097	Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml	N	K2
C9088	Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg	N	K2
C9089	Bupivacaine, collagen-matrix implant, 1 mg	N	K2

*Please see ASC Addenda BB for proposed applicable payment rates, OPPS Addenda D1 for proposed SI definitions, and ASC Addenda DD1 for proposed PI definitions. All are available via the internet on the CMS website.

2. Eligibility Criteria Technical Clarification and Proposed Regulation Text Changes

Regarding Pass-Through Status and Separately Payable Status

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63489), we finalized a policy that non-opioid pain management drugs and biologicals that function as supplies in surgical procedures that are already paid separately, including through transitional drug pass-through status under the OPPS, are not eligible for payment under § 416.174. As we previously noted in the CY 2022 OPPS/ASC final rule with comment period, once transitional pass-through payment status expires, a drug or biological may qualify for separate payment under the ASC payment system if it meets the eligibility criteria at § 416.174 (86 FR 63489). OPPS pass-through status expires on a quarterly basis. Therefore, for products for which pass-through status has expired that qualify for separate payment under the ASC payment system as non-opioid pain management drugs and biologicals that function as surgical supplies, separate payment may begin the first day of the next calendar year quarter following pass-through expiration. For example, a drug with expiring pass-through status on June 30, 2024, may begin to receive separate payment in the ASC setting on July 1, 2024, under this proposed policy, if it meets the other relevant criteria and such separate payment is finalized in the applicable year’s OPPS/ASC rulemaking.

Although we established this policy in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63489), we did not reflect it in regulation text. We propose now to clarify our policy by codifying the two additional criteria for separate payment for non-opioid pain management drugs and biologicals that function as surgical supplies in the regulatory text at § 416.174 as a technical change. First, we propose to provide at new § 416.174(a)(3) that non-opioid pain management drugs or biologicals that function as a supply in a surgical procedure are eligible for separate payment if the drug or biological does not have transitional pass-through payment status under § 419.64. In the case where a drug or biological otherwise meets the requirements under § 416.174 and has transitional pass-through payment status that will expire during the calendar year, the drug or biological would qualify for separate payment under § 416.174 during such calendar year on the first day of the next calendar year quarter after its pass-through status expires. Second, we propose that new § 416.174(a)(4) would reflect that the drug or biological must not already be separately payable in the OPPS or ASC payment system under a policy other than the one specified in § 416.174.

3. Proposed CY 2023 Qualification Evaluation for Separate Payment of Non-Opioid Pain Management Drugs and Biologicals that Function as a Surgical Supply

As noted above, in the CY 2022 OPPS/ASC final rule with comment period, we finalized a policy to unpackage and pay separately at ASP plus 6 percent for non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting, are FDA-approved, have an FDA-approved indication for pain management or as an analgesic, and have a per-day cost above the OPPS drug packaging threshold beginning on or after January 1, 2022. For CY 2023, the OPPS drug packaging threshold is proposed to be \$135. For more information on the drug packaging threshold, see section V.B.1.a of this proposed rule.

The following sections include the non-opioid alternatives of which we are aware and our evaluations of whether these non-opioid alternatives meet the criteria established at § 416.174. We welcome stakeholder comment on these evaluations.

a. Proposed Annual Eligibility Re-Evaluations of Non-Opioid Alternatives that Were Separately Paid in the ASC Setting During CY 2022

In the CY 2022 final rule with comment period, we finalized that four drugs would receive separate payment in the ASC setting for CY 2022 under the policy for non-opioid pain management drugs and biologicals that function as surgical supplies (86 FR 63496). These drugs are described by HCPCS code C9290 (*Injection, bupivacaine liposome, 1 mg*), HCPCS code J1097 (*Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml*), HCPCS code C9088 (*Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg*), and HCPCS code C9089 (*Bupivacaine, collagen-matrix implant, 1 mg*).

We re-evaluated these products outlined in the previous paragraph against the criteria specified in § 416.174, including the technical clarifications we propose to that section, to determine whether they continue to qualify for separate payment in CY 2023. Based on our evaluation, we propose that the drugs described by HCPCS codes C9290, J1097, and C9089 continue to meet the required criteria and should receive separate payment in the ASC setting. We propose that the drug described by HCPCS code C9088 would not receive separate payment in the ASC setting under this policy as this drug will be separately payable during CY 2023 under OPSS transitional pass-through status. Please see section V.A, “OPSS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals” of this proposed rule for additional details on the pass-through status of HCPCS code C9088.

We welcome comment on our evaluations below.

(a) Proposed Eligibility Evaluation for the Separate Payment of Exparel

Based on our internal review, we believe that Exparel, described by HCPCS code C9290 (*Injection, bupivacaine liposome, 1 mg*), meets the criteria described at § 416.174, including the technical clarifications we propose to that section, and we propose to continue making separate payment for it under the ASC payment system for CY 2023. Exparel was approved by FDA with a New Drug Application (NDA #022496) under section 505(c) of the Federal Food, Drug,

and Cosmetic Act on October 28, 2011.¹⁶⁶ Exparel’s FDA-approved indication is “in patients 6 years of age and older for single-dose infiltration to produce postsurgical local analgesia” and “in adults as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia”.¹⁶⁷ No component of Exparel is opioid-based. Accordingly, we propose that Exparel meets the criterion described at § 416.174(a)(1). Under the methodology described at V.B.1.a. of this proposed rule, the per-day cost of Exparel exceeds the proposed \$135 per-day cost threshold. Therefore, we propose that Exparel meets the criterion described at § 416.174(a)(2).

Additionally, Exparel will not have transitional pass-through payment status under § 419.64 in CY 2023, nor will it be otherwise separately payable in the OPPI or ASC payment system in CY 2023 under a policy other than the one specified in § 416.174. Therefore, we propose that Exparel meets the criteria we propose to add to the regulation text at §§ 416.174(a)(3) and (4).

Based on the above discussion, we believe that Exparel meets the criteria described at § 416.174 and we propose to continue making separate payment for it as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2023.

(b) Proposed Eligibility Evaluation for the Separate Payment of Omidria

Based on our internal review, we believe that Omidria, described by HCPCS code J1097 (*Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml*), meets the criteria described at § 416.174(a), and we propose to continue making separate payment for it under the ASC payment system for CY 2023. Omidria was approved by FDA with a New Drug Application (NDA #205388) under section 505(c) of the Federal Food, Drug, and Cosmetic Act on May 30, 2014.¹⁶⁸ Omidria’s FDA-approved indication is as “an alpha 1-adrenergic receptor agonist and nonselective cyclooxygenase inhibitor indicated for: Maintaining

¹⁶⁶ Exparel. FDA Letter. 28 October 2011.

https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2011/022496s000ltr.pdf

¹⁶⁷ Exparel. FDA Package Insert. 22 March 2021.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/022496s0351bl.pdf

¹⁶⁸ Omidria. FDA Letter. 30 May 2014.

https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2014/205388Orig1s000ltr.pdf

pupil size by preventing intraoperative miosis; Reducing postoperative pain”.¹⁶⁹ No component of Omidria is opioid-based. Accordingly, we propose that Omidria meets the criterion described at § 416.174(a)(1). Under the methodology described at V.B.1.a of this proposed rule, the per-day cost of Omidria exceeds the proposed \$135 per-day cost threshold. Therefore, we propose that Omidria meets the criterion described at § 416.174(a)(2). Additionally, we believe that Omidria will not have transitional pass-through payment status under § 419.64 in CY 2023, nor will it be otherwise separately payable in the OPPS or ASC payment system in CY 2023 under a policy other than the one specified in § 416.174. Therefore, we propose that if Omidria meets the criteria we propose to add to the regulation text at §§ 416.174(a)(3) and (4).

Based on the above discussion, we propose that Omidria meets the criteria described at § 416.174 and should receive separate payment as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2023.

(c) Proposed Eligibility Evaluation for the Separate Payment of Xaracoll

Based on our internal review, we believe Xaracoll, described by C9089 (*Bupivacaine, collagen-matrix implant, 1 mg*), meets the criteria described at § 416.174(a), and we propose to continue making separate payment for it under the ASC payment system for CY 2023. Xaracoll was approved by FDA with a New Drug Application (NDA # 209511) under section 505(c) of the Federal Food, Drug, and Cosmetic Act on August 28, 2020.¹⁷⁰ Xaracoll is “indicated in adults for placement into the surgical site to produce postsurgical analgesia for up to 24 hours following open inguinal hernia repair”.¹⁷¹ No component of Xaracoll is opioid-based. Accordingly, we propose that Xaracoll meets the criterion described at § 416.174(a)(1). Under the methodology described at V.B.1.a. of this proposed rule, the per-day cost of Xaracoll exceeds the proposed \$135 per-day cost threshold. Therefore, we propose that Xaracoll meets the

¹⁶⁹ Omidria. FDA Package Insert. December 2017.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/205388s006lbl.pdf

¹⁷⁰ Xaracoll. FDA Letter. August 2020.

https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2020/209511Orig1s000ltr.pdf

¹⁷¹ Xaracoll. FDA Labeling. August 2020.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/209511s000lbl.pdf

criterion described at § 416.174(a)(2). Additionally, at this time we do not believe that Xaracoll will have transitional pass-through payment status under § 419.64 in CY 2023, nor do we believe it will otherwise be separately payable in the OPPS or ASC payment system under a policy other than the one specified in § 416.174. Therefore, we propose that if Xaracoll meets the criteria we propose to add to the regulation text at §§ 416.174(a)(3) and (4).

Based on the above discussion, we propose that Xaracoll meets the criteria described at § 416.174 and should receive separate payment as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2023.

(d) Proposed Eligibility Evaluation for the Separate Payment of Zynrelef

Zynrelef, the drug described by HCPCS code C9088 (*Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg*), received drug pass-through payment status as of April 1, 2022. As discussed above, our policy, as finalized in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63489), states that non-opioid pain management drugs and biologicals that function as supplies in surgical procedures that are already paid separately, or have transitional drug pass-through status under the OPPS, would not be candidates for this policy as they are already paid separately under the OPPS and ASC payment systems. Also discussed above, we propose to include this requirement as a technical change in new regulation text at § 416.174(a)(3). Zynrelef receives separate payment consistent with its drug pass-through approval and we have proposed in section V.A of this proposed rule that its pass-through status will not expire until after CY 2023. Accordingly, we propose that Zynrelef would not be eligible for separate payment under the ASC payment system policy for non-opioid pain management drugs and biologicals that function as surgical supplies in CY 2023. Please see section V.A, “OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals” of this proposed rule for additional details on transitional drug pass-through payments.

b. Proposed Evaluations of Newly Eligible Non-Opioid Alternatives

In this section, we evaluate drugs or biologicals, of which we are aware, that we believe may be newly eligible for separate payment in the ASC setting as a non-opioid pain management drug that functions as a surgical supply against the criteria described at § 416.174(a). We evaluated whether Dextenza, described by HCPCS code J1096 (*Dexamethasone, lacrimal ophthalmic insert, 0.1 mg*), a drug with pass-through status expiring December 31, 2022, meets the criteria specified in § 416.174, including the technical clarifications we propose to that section. We propose that Dextenza receive separate payment in the ASC setting as a non-opioid pain management drug that functions as a surgical supply for CY 2023. We welcome stakeholder comment on this evaluation.

(a) Proposed Eligibility Evaluation for the Separate Payment of Dextenza

Based on our internal review, we believe Dextenza, described by HCPCS code J1096 (*Dexamethasone, lacrimal ophthalmic insert, 0.1 mg*), meets the criteria described at § 416.174 and we propose to provide separate payment for it under the ASC payment system for CY 2023. Dextenza was approved by FDA with a New Drug Application (NDA # 208742) under section 505(c) of the Federal Food, Drug, and Cosmetic Act on November 30, 2018.¹⁷² Dextenza's FDA-approved indication is as "a corticosteroid indicated for the treatment of ocular pain following ophthalmic surgery" and "the treatment of ocular itching associated with allergic conjunctivitis".¹⁷³ No component of Dextenza is opioid-based. Accordingly, we believe Dextenza meets the criterion described at § 416.174(a)(1). Under the methodology described at V.B.1.a. of this proposed rule, the per-day cost of Dextenza exceeds the proposed \$135 per-day OPPS drug packaging cost threshold, so Dextenza also meets the criterion described at § 416.174(a)(2). Additionally, Dextenza's pass-through status expires on December 31, 2022, and we do not believe that it will otherwise be separately payable in the OPPS or ASC payment

¹⁷²* Dextenza. FDA Letter. November 2018.

https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/208742Orig1s000Approv.pdf

¹⁷³ Dextenza. FDA Labeling. October 2021.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208742s0071bl.pdf

system under a policy other than the one specified in § 416.174. Therefore, we propose that if Dextenza meets the criteria we propose to add to the regulation text at §§ 416.174(a)(3) and (4).

Based on the above discussion, we propose that Dextenza meets the criteria described at § 416.174 and should receive separate payment as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2023.

Table 60 below lists the four drugs that we propose to meet the criteria described at § 416.174 to receive separate payment as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2023.

TABLE 60: SUMMARY OF PROPOSED PRODUCTS MEETING CMS'S CRITERIA FOR SEPARATE PAYMENT IN THE ASC SETTING UNDER THE NON-OPIOID PAIN MANAGEMENT DRUGS THAT FUNCTION AS A SURGICAL SUPPLY PACKAGING POLICY FOR CY 2023

HCPCS Code	Long Descriptor	Proposed CY 2023 OPPS Status Indicator (SI)*	Proposed CY 2023 ASC Payment Indicator (PI)*
C9290	Injection, bupivacaine liposome, 1 mg	N	K2
J1097	Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml	N	K2
J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg	N	K2
C9089	Bupivacaine, collagen-matrix implant, 1 mg	N	K2

*Please see ASC Addenda BB for applicable proposed payment rates, OPPS Addenda D1 for proposed SI definitions, and ASC Addenda DD1 for proposed PI definitions. All are available via the internet on the CMS website.

4. Comment Solicitation Payment Policies for Separate Payment for Additional Drugs and

Biologicals and Other Products that Function as Supplies in Surgical Procedures for CY 2023

We are soliciting comment on additional non-opioid pain management drugs and biologicals that function as surgical supplies that may meet the criteria specified in § 416.174 and therefore qualify for separate payment under the ASC payment system. We encourage commenters to include an explanation of how the drug or biological meets the eligibility criteria in § 416.174, including the technical clarifications we propose to that section. In the CY 2023

OPPS/ASC final rule with comment period, we will include a summary of comments we receive and our analysis of whether these products meet the eligibility criteria in § 416.174. If we find these additional drugs or biologicals do satisfy the criteria established at § 416.174, we will finalize their separate payment status for CY 2023 in the ASC setting in the CY 2023 OPPS/ASC final rule with comment period.

We are also seeking comment on potential policy modifications and additional criteria that may help further align the ASC payment system policy for non-opioid pain management drugs and biologicals that function as surgical supplies with the intent of sections 1833(t)(22) and 1833(i)(8) of the Act. We also seek comment on non-drug or non-biological products that should qualify for separate, or modified, payment under this authority and any data regarding any such products. In addition, we solicit comments on barriers to access to non-opioid pain management products that may exist, and how our payment policies could be modified to address these barriers. We are also interested in comments and data regarding the need to expand the current ASC payment system policy for non-opioid pain management drugs and biologicals that function as surgical supplies to the OPPS, which is discussed in section XIII.E.3 of this proposed rule.

We will take comments into consideration for potential future changes to this policy.

F. Proposed New Technology Intraocular Lenses (NTIOLs)

New Technology Intraocular Lenses (NTIOLs) are intraocular lenses that replace a patient's natural lens that has been removed in cataract surgery and that also meet the requirements listed in § 416.195.

1. NTIOL Application Cycle

Our process for reviewing applications to establish new classes of NTIOLs is as follows:

- Applicants submit their NTIOL requests for review to CMS by the annual deadline.

For a request to be considered complete, we require submission of the information requested in the guidance document titled "Application Process and Information Requirements for Requests

for a New Class of New Technology Intraocular Lenses (NTIOLs) or Inclusion of an IOL in an Existing NTIOL Class” posted on the CMS website at:

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/NTIOLs.html>.

- We announce annually, in the proposed rule updating the ASC and OPSS payment rates for the following calendar year, a list of all requests to establish new NTIOL classes accepted for review during the calendar year in which the proposal is published. In accordance with section 141(b)(3) of Pub. L. 103-432 and our regulations at § 416.185(b), the deadline for receipt of public comments is 30 days following publication of the list of requests in the proposed rule.

- In the final rule updating the ASC and OPSS payment rates for the following calendar year, we—

- ++ Provide a list of determinations made as a result of our review of all new NTIOL class requests and public comments.

- ++ When a new NTIOL class is created, identify the predominant characteristic of NTIOLs in that class that sets them apart from other IOLs (including those previously approved as members of other expired or active NTIOL classes) and that is associated with an improved clinical outcome.

- ++ Set the date of implementation of a payment adjustment in the case of approval of an IOL as a member of a new NTIOL class prospectively as of 30 days after publication of the ASC payment update final rule, consistent with the statutory requirement.

- ++ Announce the deadline for submitting requests for review of an application for a new NTIOL class for the following calendar year.

2. Requests to Establish New NTIOL Classes for CY 2023

We did not receive any requests for review to establish a new NTIOL class for CY 2023 by March 1, 2022, the due date published in the CY 2022 OPPTS/ASC final rule with comment period (86 FR 63809).

3. Payment Adjustment

The current payment adjustment for a 5-year period from the implementation date of a new NTIOL class is \$50 per lens. Since implementation of the process for adjustment of payment amounts for NTIOLs in 1999, we have not revised the payment adjustment amount, and we do not propose to revise the payment adjustment amount for CY 2023.

G. Proposed ASC Payment and Comment Indicators

1. Background

In addition to the payment indicators that we introduced in the August 2, 2007 ASC final rule, we created final comment indicators for the ASC payment system in the CY 2008 OPPTS/ASC final rule with comment period (72 FR 66855). We created Addendum DD1 to define ASC payment indicators that we use in Addenda AA and BB to provide payment information regarding covered surgical procedures and covered ancillary services, respectively, under the revised ASC payment system. The ASC payment indicators in Addendum DD1 are intended to capture policy-relevant characteristics of HCPCS codes that may receive packaged or separate payment in ASCs, such as whether they were on the ASC CPL prior to CY 2008; payment designation, such as device-intensive or office-based, and the corresponding ASC payment methodology; and their classification as separately payable ancillary services, including radiology services, brachytherapy sources, OPPTS pass-through devices, corneal tissue acquisition services, drugs or biologicals, or NTIOLs.

We also created Addendum DD2 that lists the ASC comment indicators. The ASC comment indicators included in Addenda AA and BB to the proposed rules and final rules with comment period serve to identify, for the revised ASC payment system, the status of a specific

HCPCS code and its payment indicator with respect to the timeframe when comments will be accepted. The comment indicator “NI” is used in the OPPS/ASC final rule with comment period to indicate new codes for the next calendar year for which the interim payment indicator assigned is subject to comment. The comment indicator “NI” also is assigned to existing codes with substantial revisions to their descriptors such that we consider them to be describing new services, and the interim payment indicator assigned is subject to comment, as discussed in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60622).

The comment indicator “NP” is used in the OPPS/ASC proposed rule to indicate new codes for the next calendar year for which the proposed payment indicator assigned is subject to comment. The comment indicator “NP” also is assigned to existing codes with substantial revisions to their descriptors, such that we consider them to be describing new services, and the proposed payment indicator assigned is subject to comment, as discussed in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70497).

The “CH” comment indicator is used in Addenda AA and BB to the proposed rule (these addenda are available via the internet on the CMS website) to indicate that the payment indicator assignment has changed for an active HCPCS code in the current year and the next calendar year, for example if an active HCPCS code is newly recognized as payable in ASCs; or an active HCPCS code is discontinued at the end of the current calendar year. The “CH” comment indicators that are published in this final rule with comment period are provided to alert readers that a change has been made from one calendar year to the next, but do not indicate that the change is subject to comment.

In the CY 2021 OPPS/ASC final rule with comment period, we finalized the addition of ASC payment indicator “K5” – Items, Codes, and Services for which pricing information and claims data are not available. No payment made. – to ASC Addendum DD1 (which is available via the Internet on the CMS website) to indicate those services and procedures that CMS anticipates will become payable when claims data or payment information becomes available.

2. Proposed ASC Payment and Comment Indicators for CY 2023

For CY 2023, we propose new and revised Category I and III CPT codes as well as new and revised Level II HCPCS codes. Proposed Category I and III CPT codes that are new and revised for CY 2023 and any new and existing Level II HCPCS codes with substantial revisions to the code descriptors for CY 2023, compared to the CY 2022 descriptors, are included in ASC Addenda AA and BB to this proposed rule and labeled with proposed comment indicator “NP” to indicate that these CPT and Level II HCPCS codes are open for comment as part of the CY 2023 OPPI/ASC proposed rule.

We refer readers to Addenda DD1 and DD2 of this proposed rule (these addenda are available via the internet on the CMS website) for the complete list of ASC payment and comment indicators proposed for the CY 2023 update.

H. Proposed Calculation of the ASC Payment Rates and the ASC Conversion Factor

1. Background

In the August 2, 2007 ASC final rule (72 FR 42493), we established our policy to base ASC relative payment weights and payment rates under the revised ASC payment system on APC groups and the OPPI relative payment weights. Consistent with that policy and the requirement at section 1833(i)(2)(D)(ii) of the Act that the revised payment system be implemented so that it would be budget neutral, the initial ASC conversion factor (CY 2008) was calculated so that estimated total Medicare payments under the revised ASC payment system in the first year would be budget neutral to estimated total Medicare payments under the prior (CY 2007) ASC payment system (the ASC conversion factor is multiplied by the relative payment weights calculated for many ASC services in order to establish payment rates). That is, application of the ASC conversion factor was designed to result in aggregate Medicare expenditures under the revised ASC payment system in CY 2008 being equal to aggregate Medicare expenditures that would have occurred in CY 2008 in the absence of the revised system, taking into consideration the cap on ASC payments in CY 2007, as required under

section 1833(i)(2)(E) of the Act (72 FR 42522). We adopted a policy to make the system budget neutral in subsequent calendar years (72 FR 42532 through 42533; § 416.171(e)).

We note that we consider the term “expenditures” in the context of the budget neutrality requirement under section 1833(i)(2)(D)(ii) of the Act to mean expenditures from the Medicare Part B Trust Fund. We do not consider expenditures to include beneficiary coinsurance and copayments. This distinction was important for the CY 2008 ASC budget neutrality model that considered payments across the OPPS, ASC, and MPFS payment systems. However, because coinsurance is almost always 20 percent for ASC services, this interpretation of expenditures has minimal impact for subsequent budget neutrality adjustments calculated within the revised ASC payment system.

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66857 through 66858), we set out a step-by-step illustration of the final budget neutrality adjustment calculation based on the methodology finalized in the August 2, 2007 ASC final rule (72 FR 42521 through 42531) and as applied to updated data available for the CY 2008 OPPS/ASC final rule with comment period. The application of that methodology to the data available for the CY 2008 OPPS/ASC final rule with comment period resulted in a budget neutrality adjustment of 0.65.

For CY 2008, we adopted the OPPS relative payment weights as the ASC relative payment weights for most services and, consistent with the final policy, we calculated the CY 2008 ASC payment rates by multiplying the ASC relative payment weights by the final CY 2008 ASC conversion factor of \$41.401. For covered office-based surgical procedures, covered ancillary radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents, as discussed in section XIII.D.2 of this proposed rule), and certain diagnostic tests within the medicine range that are covered ancillary services, the established policy is to set the payment rate at the lower of the MPFS unadjusted nonfacility PE RVU-based amount or the amount calculated using the ASC standard ratesetting methodology. Further, as discussed in the CY 2008 OPPS/ASC final

rule with comment period (72 FR 66841 through 66843), we also adopted alternative ratesetting methodologies for specific types of services (for example, device-intensive procedures).

As discussed in the August 2, 2007 ASC final rule (72 FR 42517 through 42518) and as codified at § 416.172(c) of the regulations, the revised ASC payment system accounts for geographic wage variation when calculating individual ASC payments by applying the pre-floor and pre-reclassified IPPS hospital wage indexes to the labor-related share, which is 50 percent of the ASC payment amount based on a GAO report of ASC costs using 2004 survey data.

Beginning in CY 2008, CMS accounted for geographic wage variation in labor costs when calculating individual ASC payments by applying the pre-floor and pre-reclassified hospital wage index values that CMS calculates for payment under the IPPS, using updated Core Based Statistical Areas (CBSAs) issued by OMB in June 2003.

The reclassification provision in section 1886(d)(10) of the Act is specific to hospitals. We believe that using the most recently available pre-floor and pre-reclassified IPPS hospital wage indexes results in the most appropriate adjustment to the labor portion of ASC costs. We continue to believe that the unadjusted hospital wage indexes, which are updated yearly and are used by many other Medicare payment systems, appropriately account for geographic variation in labor costs for ASCs. Therefore, the wage index for an ASC is the pre-floor and pre-reclassified hospital wage index under the IPPS of the CBSA that maps to the CBSA where the ASC is located.

Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. On February 28, 2013, OMB issued OMB Bulletin No. 13-01, which provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published on June 28, 2010, in the **Federal Register** (75 FR 37246 through 37252) and 2010 Census Bureau data. (A copy of this bulletin may be obtained at:

<https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2013/b13-01.pdf>). In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963), we implemented the use of the CBSA delineations issued by OMB in OMB Bulletin 13-01 for the IPPS hospital wage index beginning in FY 2015.

OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. On July 15, 2015, OMB issued OMB Bulletin No. 15-01, which provides updates to and supersedes OMB Bulletin No. 13-01 that was issued on February 28, 2013. OMB Bulletin No. 15-01 made changes that are relevant to the IPPS and ASC wage index. We refer readers to the CY 2017 OPPI/ASC final rule with comment period (81 FR 79750) for a discussion of these changes and our implementation of these revisions. (A copy of this bulletin may be obtained at

<https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2015/15-01.pdf>).

On August 15, 2017, OMB issued OMB Bulletin No. 17-01, which provided updates to and superseded OMB Bulletin No. 15-01 that was issued on July 15, 2015. We refer readers to the CY 2019 OPPI/ASC final rule with comment period (83 FR 58864 through 58865) for a discussion of these changes and our implementation of these revisions. (A copy of this bulletin may be obtained at

<https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf>).

On April 10, 2018, OMB issued OMB Bulletin No. 18–03 which superseded the August 15, 2017 OMB Bulletin No. 17–01. On September 14, 2018, OMB issued OMB Bulletin 18–04 which superseded the April 10, 2018 OMB Bulletin No. 18–03. A copy of OMB Bulletin No. 18–03 may be obtained at <https://www.whitehouse.gov/wp-content/uploads/2018/04/OMB-BULLETIN-NO.-18-03-Final.pdf>. A copy of OMB Bulletin No. 18–04 may be obtained at <https://www.whitehouse.gov/wpcontent/uploads/2018/90/Bulletin-18-04.pdf>.

On March 6, 2020, OMB issued Bulletin No. 20–01, which provided updates to and superseded OMB Bulletin No. 18–04 that was issued on September 14, 2018. (For a copy of this

bulletin, we refer readers to the following website: <https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf>).

The proposed CY 2023 ASC wage indexes fully reflect the OMB labor market area delineations (including the revisions to the OMB labor market delineations discussed above, as set forth in OMB Bulletin Nos. 13-01, 15-01, 17-01, 18-03, 18-04, and 20-01). We note that, in certain instances, there might be urban or rural areas for which there is no IPPS hospital that has wage index data that could be used to set the wage index for that area. For these areas, our policy has been to use the average of the wage indexes for CBSAs (or metropolitan divisions as applicable) that are contiguous to the area that has no wage index (where “contiguous” is defined as sharing a border). For example, for CY 2023, we are applying a proxy wage index based on this methodology to ASCs located in CBSA 25980 (Hinesville-Fort Stewart, GA).

When all of the areas contiguous to the urban CBSA of interest are rural and there is no IPPS hospital that has wage index data that could be used to set the wage index for that area, we determine the ASC wage index by calculating the average of all wage indexes for urban areas in the State (75 FR 72058 through 72059). In other situations, where there are no IPPS hospitals located in a relevant labor market area, we apply our current policy of calculating an urban or rural area’s wage index by calculating the average of the wage indexes for CBSAs (or metropolitan divisions where applicable) that are contiguous to the area with no wage index.

2. Calculation of the ASC Payment Rates

a. Updating the ASC Relative Payment Weights for CY 2023 and Future Years

We update the ASC relative payment weights each year using the national OPPS relative payment weights (and PFS nonfacility PE RVU-based amounts, as applicable) for that same calendar year and uniformly scale the ASC relative payment weights for each update year to make them budget neutral (72 FR 42533). The OPPS relative payment weights are scaled to maintain budget neutrality for the OPPS. We then scale the OPPS relative payment weights again to establish the ASC relative payment weights. To accomplish this, we hold estimated

total ASC payment levels constant between calendar years for purposes of maintaining budget neutrality in the ASC payment system. That is, we apply the weight scalar to ensure that projected expenditures from the updated ASC payment weights in the ASC payment system are equal to what would be the current expenditures based on the scaled ASC payment weights. In this way, we ensure budget neutrality and that the only changes to total payments to ASCs result from increases or decreases in the ASC payment update factor.

Where the estimated ASC expenditures for an upcoming year are higher than the estimated ASC expenditures for the current year, the ASC weight scalar is reduced, in order to bring the estimated ASC expenditures in line with the expenditures for the baseline year. This frequently results in ASC relative payment weights for surgical procedures that are lower than the OPPS relative payment weights for the same procedures for the upcoming year. Therefore, over time, even if procedures performed in the HOPD and ASC receive the same update factor under the OPPS and ASC payment system, payment rates under the ASC payment system would increase at a lower rate than payment for the same procedures performed in the HOPD as a result of applying the ASC weight scalar to ensure budget neutrality.

As discussed in section II.A.1.a of this proposed rule, we are using the CY 2021 claims data to be consistent with the OPPS claims data for this proposed rule. Consistent with our established policy, we propose to scale the CY 2023 relative payment weights for ASCs according to the following method. Holding ASC utilization, the ASC conversion factor, and the mix of services constant from CY 2021, we propose to compare the total payment using the CY 2022 ASC relative payment weights with the total payment using the CY 2023 ASC relative payment weights to take into account the changes in the OPPS relative payment weights between CY 2022 and CY 2023. Additionally, in light of our proposal to provide a higher ASC payment rate through the use of new C codes for 52 primary procedures when performed with add-on packaged services, CY 2023 total payments will include spending and utilization related to these

new C codes. For this proposed rule, we estimate the additional CY 2023 spending to be \$5 million.

We propose to use the ratio of CY 2022 to CY 2023 total payments (the weight scalar) to scale the ASC relative payment weights for CY 2023. The proposed CY 2023 ASC weight scalar is 0.8474. Consistent with historical practice, we would scale the ASC relative payment weights of covered surgical procedures, covered ancillary radiology services, and certain diagnostic tests within the medicine range of CPT codes, which are covered ancillary services for which the ASC payment rates are based on OPPS relative payment weights.

Scaling would not apply in the case of ASC payment for separately payable covered ancillary services that have a predetermined national payment amount (that is, their national ASC payment amounts are not based on OPPS relative payment weights), such as drugs and biologicals that are separately paid or services that are contractor-priced or paid at reasonable cost in ASCs. Any service with a predetermined national payment amount would be included in the ASC budget neutrality comparison, but scaling of the ASC relative payment weights would not apply to those services. The ASC payment weights for those services without predetermined national payment amounts (that is, those services with national payment amounts that would be based on OPPS relative payment weights) would be scaled to eliminate any difference in the total payment between the current year and the update year.

For any given year's ratesetting, we typically use the most recent full calendar year of claims data to model budget neutrality adjustments. We propose to use the CY 2021 claims data to model our budget neutrality adjustment.

b. Updating the ASC Conversion Factor

Under the OPPS, we typically apply a budget neutrality adjustment for provider-level changes, most notably a change in the wage index values for the upcoming year, to the conversion factor. Consistent with our final ASC payment policy, for the CY 2017 ASC payment system and subsequent years, in the CY 2017 OPPS/ASC final rule with comment

period (81 FR 79751 through 79753), we finalized our policy to calculate and apply a budget neutrality adjustment to the ASC conversion factor for supplier-level changes in wage index values for the upcoming year, just as the OPPS wage index budget neutrality adjustment is calculated and applied to the OPPS conversion factor. For CY 2023, we calculated the proposed adjustment for the ASC payment system by using the most recent CY 2021 claims data available and estimating the difference in total payment that would be created by introducing the proposed CY 2023 ASC wage indexes. Specifically, holding CY 2021 ASC utilization, service-mix, and the proposed CY 2023 national payment rates after application of the weight scalar constant, we calculated the total adjusted payment using the CY 2022 ASC wage indexes and the total adjusted payment using the proposed CY 2023 ASC wage indexes. We used the 50 percent labor-related share for both total adjusted payment calculations. We then compared the total adjusted payment calculated with the CY 2022 ASC wage indexes to the total adjusted payment calculated with the proposed CY 2023 ASC wage indexes and applied the resulting ratio of 1.0010 (the proposed CY 2023 ASC wage index budget neutrality adjustment) to the CY 2022 ASC conversion factor to calculate the proposed CY 2023 ASC conversion factor.

Section 1833(i)(2)(C)(i) of the Act requires that, if the Secretary has not updated amounts established under the revised ASC payment system in a calendar year, the payment amounts shall be increased by the percentage increase in the Consumer Price Index for all urban consumers (CPI-U), U.S. city average, as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved. The statute does not mandate the adoption of any particular update mechanism, but it requires the payment amounts to be increased by the CPI-U in the absence of any update. Because the Secretary updates the ASC payment amounts annually, we adopted a policy, which we codified at § 416.171(a)(2)(ii), to update the ASC conversion factor using the CPI-U for CY 2010 and subsequent calendar years.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59075 through 59080), we finalized our proposal to apply the productivity-adjusted hospital market basket

update to ASC payment system rates for an interim period of 5 years (CY 2019 through CY 2023), during which we would assess whether there is a migration of the performance of procedures from the hospital setting to the ASC setting as a result of the use of a productivity-adjusted hospital market basket update, as well as whether there are any unintended consequences, such as less than expected migration of the performance of procedures from the hospital setting to the ASC setting. In addition, we finalized our proposal to revise our regulations under § 416.171(a)(2), which address the annual update to the ASC conversion factor. During this 5-year period, we intended to assess the feasibility of collaborating with stakeholders to collect ASC cost data in a minimally burdensome manner and could propose a plan to collect such information. We refer readers to that final rule for a detailed discussion of the rationale for these policies.

The proposed hospital market basket update for CY 2023 is projected to be 2.7 percent, as published in the FY 2023 IPPS/LTCH PPS proposed rule (86 FR 25435), based on IHS Global Inc.'s (IGI's) 2021 fourth quarter forecast with historical data through the third quarter of 2021.

Section 1886(b)(3)(B)(xi)(II) of the Act, defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP). We finalized the methodology for calculating the productivity adjustment in the CY 2011 PFS final rule with comment period (75 FR 73394 through 73396) and revised it in the CY 2012 PFS final rule with comment period (76 FR 73300 through 73301) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70500 through 70501). The proposed productivity adjustment for CY 2023 was projected to be 0.4 percentage point, as published in the FY 2023 IPPS/LTCH PPS proposed rule (86 FR 25435) based on IGI's 2021 fourth quarter forecast.

For CY 2023, we propose to utilize the hospital market basket update of 3.1 percent reduced by the productivity adjustment of 0.4 percentage point, resulting in a productivity-

adjusted hospital market basket update factor of 2.7 percent for ASCs meeting the quality reporting requirements. Therefore, we propose to apply a 2.7 percent productivity-adjusted hospital market basket update factor to the CY 2022 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the CY 2023 ASC payment amounts. The ASCQR Program affected payment rates beginning in CY 2014 and, under this program, there is a 2.0 percentage point reduction to the update factor for ASCs that fail to meet the ASCQR Program requirements. We refer readers to section XIV.E. of the CY 2019 OPSS/ASC final rule with comment period (83 FR 59138 through 59139) and section XIV.E of this proposed rule for a detailed discussion of our policies regarding payment reduction for ASCs that fail to meet ASCQR Program requirements. We propose to utilize the hospital market basket update of 3.1 percent reduced by 2.0 percentage points for ASCs that do not meet the quality reporting requirements and then reduced by the 0.4 percentage point productivity adjustment. Therefore, we proposed to apply a 0.7 percent productivity-adjusted hospital market basket update factor to the CY 2022 ASC conversion factor for ASCs not meeting the quality reporting requirements. We also propose that if more recent data are subsequently available (for example, a more recent estimate of the hospital market basket update or productivity adjustment), we would use such data, if appropriate, to determine the CY 2023 ASC update for the final rule.

For CY 2023, we propose to adjust the CY 2022 ASC conversion factor (\$49.916) by the proposed wage index budget neutrality factor of 1.0010 in addition to the productivity-adjusted hospital market basket update of 2.7 percent discussed above, which results in a proposed CY 2023 ASC conversion factor of \$51.315 for ASCs meeting the quality reporting requirements. For ASCs not meeting the quality reporting requirements, we propose to adjust the CY 2022 ASC conversion factor (\$49.916) by the proposed wage index budget neutrality factor of 1.0010 in addition to the quality reporting/productivity-adjusted hospital market basket update of 0.7 percent discussed above, which results in a proposed CY 2023 ASC conversion factor of \$50.315.

We request comments on our proposals for updating the CY 2023 ASC conversion factor.

3. Display of the Proposed CY 2023 ASC Payment Rates

Addenda AA and BB to this proposed rule (which are available on the CMS website) display the proposed ASC payment rates for CY 2023 for covered surgical procedures and covered ancillary services, respectively. The proposed payment rates included in Addenda AA and BB to this proposed rule reflect the full ASC proposed payment update and not the reduced payment update used to calculate payment rates for ASCs not meeting the quality reporting requirements under the ASCQR Program.

These Addenda contain several types of information related to the proposed CY 2023 payment rates. Specifically, in Addendum AA, a “Y” in the column titled “To be Subject to Multiple Procedure Discounting” indicates that the surgical procedure would be subject to the multiple procedure payment reduction policy. As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66829 through 66830), most covered surgical procedures are subject to a 50 percent reduction in the ASC payment for the lower-paying procedure when more than one procedure is performed in a single operative session.

For CY 2021, we finalized adding a new column to ASC Addendum BB titled “Drug Pass-Through Expiration during Calendar Year” where we flag through the use of an asterisk each drug for which pass-through payment is expiring during the calendar year (that is, on a date other than December 31st).

The values displayed in the column titled “Proposed CY 2023 Payment Weight” are the proposed relative payment weights for each of the listed services for CY 2023. The proposed relative payment weights for all covered surgical procedures and covered ancillary services where the ASC payment rates are based on OPPS relative payment weights were scaled for budget neutrality. Therefore, scaling was not applied to the device portion of the device-intensive procedures; services that are paid at the MPFS nonfacility PE RVU-based amount; separately payable covered ancillary services that have a predetermined national payment amount, such as

drugs and biologicals and brachytherapy sources that are separately paid under the OPPS; or services that are contractor-priced or paid at reasonable cost in ASCs. This includes separate payment for non-opioid pain management drugs.

To derive the proposed CY 2023 payment rate displayed in the “Proposed CY 2023 Payment Rate” column, each ASC payment weight in the “Proposed CY 2023 Payment Weight” column was multiplied by the proposed CY 2023 conversion factor. The conversion factor includes a budget neutrality adjustment for changes in the wage index values and the annual update factor as reduced by the productivity adjustment. The proposed CY 2023 ASC conversion factor uses the CY 2023 productivity-adjusted hospital market basket update factor of 2.7 percent (which is equal to the projected hospital market basket update of 3.1 percent reduced by a projected productivity adjustment of 0.4 percentage point).

In Addendum BB, there are no relative payment weights displayed in the “Proposed CY 2023 Payment Weight” column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The “Proposed CY 2023 Payment” column displays the proposed CY 2023 national unadjusted ASC payment rates for all items and services. The proposed CY 2023 ASC payment rates listed in Addendum BB for separately payable drugs and biologicals are based on ASP data used for payment in physicians' offices in 2021.

Addendum EE provides the HCPCS codes and short descriptors for surgical procedures that are proposed to be excluded from payment in ASCs for CY 2023. Addendum FF displays the device offset percentages calculated under the standard ASC ratesetting methodology for covered surgical procedures in CY 2023.

Addendum FF to this proposed rule displays the OPPS payment rate (based on the standard ratesetting methodology), the device offset percentage, and the device portion of the ASC payment rate for CY 2023 for covered surgical procedures.

XIV. Requirements for the Hospital Outpatient Quality Reporting (OQR) Program

A. Background

1. Overview

We seek to promote higher quality, more efficient, and equitable healthcare for Medicare beneficiaries. Consistent with these goals, we have implemented quality reporting programs for multiple care settings including the quality reporting program for hospital outpatient care, known as the Hospital Outpatient Quality Reporting (OQR) Program.

2. Statutory History of the Hospital OQR Program

We refer readers to the CY 2011 OPPS/ASC final rule (75 FR 72064 through 72065) for a detailed discussion of the statutory history of the Hospital OQR Program. In the CY 2021 OPPS/ASC final rule (85 FR 86179), we finalized updates to the regulations to include a reference to the statutory authority for the Hospital OQR Program. Section 1833(t)(17)(A) of the Social Security Act (the Act) states that subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act) that do not submit data required for measures selected with respect to such a year, in the form and manner required by the Secretary, will incur a 2.0 percentage point reduction to their annual Outpatient Department (OPD) fee schedule increase factor.

3. Regulatory History of the Hospital OQR Program

We refer readers to the CYs 2008 through 2022 OPPS/ASC final rules for detailed discussions of the regulatory history of the Hospital OQR Program:

- The CY 2008 OPPS/ASC final rule (72 FR 66860 through 66875);
- The CY 2009 OPPS/ASC final rule (73 FR 68758 through 68779);
- The CY 2010 OPPS/ASC final rule (74 FR 60629 through 60656);
- The CY 2011 OPPS/ASC final rule (75 FR 72064 through 72110);
- The CY 2012 OPPS/ASC final rule (76 FR 74451 through 74492);
- The CY 2013 OPPS/ASC final rule (77 FR 68467 through 68492);
- The CY 2014 OPPS/ASC final rule (78 FR 75090 through 75120);
- The CY 2015 OPPS/ASC final rule (79 FR 66940 through 66966);

- The CY 2016 OPPTS/ASC final rule (80 FR 70502 through 70526);
- The CY 2017 OPPTS/ASC final rule (81 FR 79753 through 79797);
- The CY 2018 OPPTS/ASC final rule (82 FR 59424 through 59445);
- The CY 2019 OPPTS/ASC final rule (83 FR 59080 through 59110);
- The CY 2020 OPPTS/ASC final rule (84 FR 61410 through 61420);
- The CY 2021 OPPTS/ASC final rule (85 FR 86179 through 86187); and
- The CY 2022 OPPTS/ASC final rule (86 FR 63822 through 63875).

We have codified certain requirements under the Hospital OQR Program at 42 CFR 419.46. We refer readers to section XX.X of this proposed rule for a detailed discussion of the payment reduction for hospitals that fail to meet Hospital OQR Program requirements for the CY 2025 payment determination.

B. Hospital OQR Program Quality Measures

1. Considerations in Selecting Hospital OQR Program Quality Measures

We refer readers to the CY 2012 OPPTS/ASC final rule (76 FR 74458 through 74460) for a detailed discussion of the priorities we consider for the Hospital OQR Program quality measure selection. We are not proposing any changes to these policies in this proposed rule.

2. Retention of Hospital OQR Program Measures Adopted in Previous Payment Determinations

We previously finalized and codified at 42 CFR 419.46(h)(1) a policy to retain measures from the previous year's measure set for subsequent years, unless removed (77 FR 68471 and 83 FR 59082). We are not proposing any changes to these policies in this proposed rule.

3. Removal of Quality Measures from the Hospital OQR Program Measure Set

a. Immediate Removal or Suspension

We previously finalized and codified at 42 CFR 419.46(i)(2) and (3) a process for removal or suspension of a Hospital OQR Program measure, based on evidence that the continued use of the measure as specified raises patient safety concerns (74 FR 60634 through

60635, 77 FR 68472, and 83 FR 59082).¹⁷⁴ We are not proposing any changes to these policies in this proposed rule.

b. Consideration Factors for Removing Measures

We previously finalized and codified at 42 CFR 419.46(i)(3) policies to use the regular rulemaking process to remove a measure for circumstances other than when CMS believes that continued use of a measure raises specific patient safety concerns (74 FR 60635 and 83 FR 59082).¹⁷⁵ We are not proposing any changes to these policies in this proposed rule.

4. Modifications to Previously Adopted Measures

a. Proposal to Change the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (OP-31) Measure from Mandatory to Voluntary Beginning with the CY 2027 Payment Determination

(1) Background

The OP-31 measure was adopted in the CY 2014 OPPS/ASC final rule (78 FR 75102 and 75103). During CY 2014 OPPS/ASC rulemaking, some commenters expressed concern about the burden of collecting pre-operative and post-operative visual function surveys (78 FR 75103). In response to those comments, we modified our implementation strategy in a manner that we believed would significantly minimize collection and reporting burden by applying a sampling scheme and a low case threshold exemption to address commenters' concerns regarding burden (78 FR 75113 through 75115). Shortly thereafter, we became concerned about the use of what we believed at the time were inconsistent surveys to assess visual function. The measure specifications allowed for the use of any validated survey, and we were unclear about the impact the use of varying surveys might have on accuracy, feasibility, or reporting burden. Therefore,

¹⁷⁴ We refer readers to the CY 2013 OPPS/ASC final rule (77 FR 68472 and 68473) for a discussion of our reasons for changing the term "retirement" to "removal" in the Hospital OQR Program.

¹⁷⁵ We initially referred to this process as "retirement" of a measure in the 2010 OPPS/ASC proposed rule, but later changed it to "removal" during final rulemaking.

we issued guidance¹⁷⁶ stating that we would delay the implementation of OP-31, and we subsequently finalized in the CY 2015 OP/ASC final rule (79 FR 66947) the exclusion of OP-31 from the measure set while allowing hospitals to voluntarily report measure data beginning with the CY 2015 reporting period.

(2) Considerations Concerning Previously Finalized OP-31 Measure Requirements Beginning with the CY 2025 Reporting Period/CY 2027 Payment Determination

In the CY 2022 OP/ASC proposed rule (86 FR 42247), we stated that it would be appropriate to require that hospitals report on OP-31 for the CY 2023 reporting period/CY 2025 payment determination as hospitals have had the opportunity for several years to familiarize themselves with OP-31, prepare to operationalize it, and opportunity to practice reporting the measure since the CY 2015 reporting period. Many commenters expressed concern about making this measure mandatory due to the burden of reporting the measure and the impact this additional burden would have during the COVID-19 pandemic, stating that OP-31 has not been mandatory and many facilities have not been practicing reporting it (86 FR 63845). In response to these comments, in the CY 2022 OP/ASC final rule with comment period, we finalized a delay in the implementation of this measure with mandatory reporting beginning with the CY 2025 reporting period/CY 2027 payment determination (86 FR 63845 through 63846).

Since the publication of the CY 2022 OP/ASC final rule with comment period, interested parties have expressed concern about the reporting burden of this measure given the ongoing COVID-19 public health emergency (PHE). Interested parties have indicated that they are still recovering from the COVID-19 PHE and that the requirement to report OP-31 would be burdensome due to national staffing and medical supply shortages coupled with unprecedented

¹⁷⁶ See Letter from Craig Bryant to Hospital OQR initiative discussions re: Outpatient Quality Reporting (OQR) Program - Delay of New Measures (Dec. 31, 2013), available at <https://qualitynet.cms.gov/files/5d3792e74b6d1a256059d87d?filename=2013-40-OP.pdf>; see also Letter from Craig Bryant to Hospital OQR initiative discussions re: Delayed Implementation of OP-31: Cataracts - Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery Measure (NQF #1536) to January 1, 2015; Data Collection Period for Two Endoscopy Measures OP-29 and OP-30 Begins (April 2, 2014), available at <https://qualitynet.cms.gov/files/5d3793174b6d1a256059d8e3?filename=2014-14-OP,0.pdf>.

changes in patient case volumes. Due to the continued impact of the COVID-19 PHE, such as national staffing and medical supply shortages, the 2-year delay of mandatory reporting for this measure is no longer sufficient. Based on these factors and the feedback we received from interested parties, we believe it is appropriate to change OP-31 from mandatory to voluntary beginning with the CY 2025 reporting period/CY 2027 payment determination. A hospital would not be subject to a payment reduction for failing to report this measure during the voluntary reporting period; however, we strongly encourage hospitals to gain experience with the measure. We plan to continue to evaluate this policy moving forward. To be clear, there are no changes to reporting for the CY 2023 and CY 2024, during which the measure would remain voluntary.

As the OP-31 measure uniquely requires cross-setting coordination among clinicians of different specialties (that is, surgeons and ophthalmologists), we believe it appropriate to defer mandatory reporting at this time. We will consider mandatory reporting of OP-31 after the national PHE declaration officially ends and we find it appropriate to do so given COVID-19 PHE impacts on national staffing and supply shortages. We intend to consider implementation of mandatory reporting of the OP-31 measure through future rulemaking because as we noted in the CY 2015 OPPTS/ASC final rule, this measure addresses an area of care that is not adequately addressed in our current measure set and the measure serves to drive the coordination of care (79 FR 66947). We subsequently stated in the CY 2022 OPPTS/ASC final rule with comment period that while the measure has been voluntary and available for reporting since the CY 2015 reporting period, a number of facilities have reported data for this measure and those that have reported these data have done so consistently (86 FR 63845).

We invite public comment on this proposal.

5. Previously Finalized and Proposed Hospital OQR Program Measure Sets

a. Previously Finalized Hospital OQR Program Measure Set for the CY 2024 Payment

Determination

We refer readers to the CY 2022 OPPS/ASC final rule (85 FR 63846 through 63850) for a summary of the previously adopted Hospital OQR Program measure set for the CY 2024 payment determination and subsequent years. Table 61 summarizes the previously finalized Hospital OQR Program measure set for the CY 2024 payment determination:

TABLE 61: Hospital OQR Program Measure Set for the CY 2024 Payment Determination

NQF #	Measure Name
0288	OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival*
0290	OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention*
0514	OP-8: MRI Lumbar Spine for Low Back Pain†
None	OP-10: Abdomen CT – Use of Contrast Material
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients
0499	OP-22: Left Without Being Seen†
0661	OP-23: Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival
0658	OP-29: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
1536	OP-31: Cataracts: Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery**
2539	OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
None	OP-35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy
2687	OP-36: Hospital Visits after Hospital Outpatient Surgery
None	OP-38: COVID-19 Vaccination Coverage Among Health Care Personnel
None	OP-39: Breast Cancer Screening Recall Rates

† We note that NQF endorsement for this measure was removed.

* In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63824), we finalized removal of the (Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department (ED) Arrival (OP–2) and Median Time to Transfer to Another Facility for Acute Coronary Intervention (OP–3) measures beginning with the CY 2023 reporting period/CY 2025 payment determination. We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63824) for more detail on how the OP-2 and OP-3 measures will be replaced by the STEMI-eCQM (OP-40).

**OP-31 measure voluntarily collected as set forth in the CY 2015 OPPS/ASC final rule (79 FR 66946 and 66947). In the CY 2022 OPPS/ASC final rule comment period (86 FR 63845 and 63846), we finalized mandatory reporting of this measure beginning with the CY 2025 reporting period/CY 2027 payment determination.

b. Summary of Proposed Hospital OQR Program Measure Set for the CY 2025 Payment

Determination

Table 62 summarizes the Hospital OQR Program measure set including our proposal in this proposed rule for the CY 2025 payment determination:

TABLE 62: Hospital OQR Program Measure Set for the CY 2025 Payment Determination

NQF #	Measure Name
0514	OP-8: MRI Lumbar Spine for Low Back Pain†
None	OP-10: Abdomen CT – Use of Contrast Material
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients
0499	OP-22: Left Without Being Seen†
0661	OP-23: Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival
0658	OP-29: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
1536	OP-31: Cataracts: Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery*
2539	OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
None	OP-35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy
2687	OP-36: Hospital Visits after Hospital Outpatient Surgery
None	OP-37a: Consumer Assessment of Healthcare Providers and Systems Outpatient and Ambulatory Surgery Survey (OAS CAHPS) – About Facilities and Staff**
None	OP-37b: OAS CAHPS – Communication About Procedure**
None	OP-37c: OAS CAHPS – Preparation for Discharge and Recovery**
None	OP-37d: OAS CAHPS – Overall Rating of Facility**
None	OP-37e: OAS CAHPS – Recommendation of Facility**
None	OP-38: COVID-19 Vaccination Coverage Among Health Care Personnel
None	OP-39: Breast Cancer Screening Recall Rates
None	OP-40: ST-Segment Elevation Myocardial Infraction (STEMI) electronic clinical quality measure (eCQM)***

† We note that NQF endorsement for this measure was removed.

* OP-31 measure voluntarily collected as set forth in the CY 2015 OP/ASC final rule (79 FR 66946 and 66947). In the CY 2022 OP/ASC final rule with comment period (86 FR 63845 and 63846), we finalized mandatory reporting of this measure beginning with the CY 2025 reporting period/CY 2027 payment determination. In this proposed rule, we propose that data collection and submission remain voluntary for this measure for the CY 2025 reporting period and subsequent years.

** In the CY 2022 OP/ASC final rule with comment period(86 FR 63840) we finalized voluntary reporting beginning with the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination.

*** The STEMI eCQM (OP-40) was adopted in the CY 2022 OP/ASC final rule with comment period (86 FR 63837 through 63840), beginning with voluntary reporting for the CY 2023 reporting period and for mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination.

c. Summary of Proposed Hospital OQR Program Measure Set for the CY 2026 Payment

Determination and Subsequent Years

Table 63 summarizes the proposed Hospital OQR Program measure set for the CY 2026 payment determination and subsequent years:

TABLE 63: Hospital OQR Program Measure Set for the CY 2026 Payment Determination and Subsequent Years

NQF #	Measure Name
0514	OP-8: MRI Lumbar Spine for Low Back Pain†
None	OP-10: Abdomen CT – Use of Contrast Material
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients
0499	OP-22: Left Without Being Seen†

**TABLE 63: Hospital OQR Program Measure Set for the CY 2026
Payment Determination and Subsequent Years**

NQF #	Measure Name
0661	OP-23: Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival
0658	OP-29: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
1536	OP-31: Cataracts: Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery*
2539	OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
None	OP-35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy
2687	OP-36: Hospital Visits after Hospital Outpatient Surgery
None	OP-37a: OAS CAHPS – About Facilities and Staff**
None	OP-37b: OAS CAHPS – Communication About Procedure**
None	OP-37c: OAS CAHPS – Preparation for Discharge and Recovery**
None	OP-37d: OAS CAHPS – Overall Rating of Facility**
None	OP-37e: OAS CAHPS – Recommendation of Facility**
None	OP-38: COVID-19 Vaccination Coverage Among Health Care Personnel
None	OP-39: Breast Cancer Screening Recall Rates
None	OP-40: ST-Segment Elevation Myocardial Infarction (STEMI) eCQM***

† We note that NQF endorsement for this measure was removed.

* OP-31 measure voluntarily collected as set forth in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66946 and 66947). In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63845 and 63846), we finalized mandatory reporting of this measure beginning with the CY 2025 reporting period/CY 2027 payment determination. In this proposed rule, we propose that data collection and submission remain voluntary for this measure for the CY 2025 reporting period and subsequent years.

** In the CY 2022 OPPS/ASC final rule with comment period(86 FR 63840), we finalized voluntary reporting beginning with the CY 2023 reporting period/CY 2025 payment determination and mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination.

*** The STEMI eCQM (OP-40) was adopted in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63837 through 63840), beginning with voluntary reporting for the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination.

6. Hospital OQR Program Measures and Topics for Future Considerations

a. Request for Comment on Reimplementation of Hospital Outpatient Volume on Selected Outpatient Surgical Procedures (OP–26) Measure or Adoption of Another Volume Indicator

(1) Background

Hospital care has been gradually shifting from inpatient to outpatient settings, and since 1983, inpatient stays per capita have fallen by 31 percent.¹⁷⁷ In line with this trend, outpatient services increased by 0.7 percent in 2019 while inpatient services decreased by 0.9 percent.¹⁷⁸

¹⁷⁷ Medicare Payment Advisory Commission. March 2021 Report to the Congress: Medicare Payment Policy. Chapter 3. Available at: https://www.medpac.gov/wp-content/uploads/2021/10/mar21_medpac_report_ch3_sec.pdf.

¹⁷⁸ Medicare Payment Advisory Commission. March 2021 Report to the Congress: Medicare Payment Policy. Available at: <https://www.medpac.gov/document/march-2021-report-to-the-congress-medicare-payment-policy/>.

Research indicates that volume in hospital outpatient departments will continue to grow, with some estimates projecting a 19 percent increase in patients between 2019 and 2029.¹⁷⁹

Volume has a long history as a quality metric, however, quality measurement efforts moved away from procedure volume as it was considered simply a proxy for quality rather than directly measuring outcomes.¹⁸⁰ While studies suggest that larger facility surgical procedure volume does not alone lead to better outcomes, it may be associated with better outcomes due to having characteristics that improve care (for example, high-volume facilities may have teams that work more effectively together, or have superior systems or programs for identifying and responding to complications), making volume an important component of quality.¹⁸¹ The Hospital OQR Program does not currently include a quality measure for facility-level volume data, including surgical procedure volume data, but did so previously. We refer readers to the CY 2012 OP/ASC final rule with comment period (76 FR 74466 through 74468) where we adopted the Hospital Outpatient Volume on Selected Outpatient Surgical Procedures measure (OP-26) beginning with the CY 2012 reporting period/CY 2014 payment determination. This structural measure of facility capacity collected surgical procedure volume data on eight categories of procedures frequently performed in the hospital outpatient setting: Cardiovascular, Eye, Gastrointestinal, Genitourinary, Musculoskeletal, Nervous System, Respiratory, and Skin (76 FR 74466). We adopted OP-26 based on evidence that the volume of surgical procedures, and particularly of high-risk surgical procedures, is related to better patient outcomes, including decreased medical errors and mortality (76 FR 74466).^{182,183,184} This may be attributable to

¹⁷⁹ Sg2. Sg2 Impact of Change Forecast Predicts Enormous Disruption in Health Care Provider Landscape by 2029. June 4, 2021. Available at: <https://www.sg2.com/media-center/press-releases/sg2-impact-forecast-predicts-disruption-health-care-provider-landscape-2029/>.

¹⁸⁰ Jha AK. Back to the Future: Volume as a Quality Metric. JAMA Forum Archive. Published online June 10, 2015.

¹⁸¹ Auerbach AD et al. The Relationship between Case-Volume, Care Quality, and Outcomes of Complex Cancer Surgery. *Journal of the American College of Surgery*. 2010;211(5):601-608. doi:10.1016/j.jamcollsurg.2010.07.006.

¹⁸² Livingston, E.H.; Cao, J “Procedure Volume as a Predictor of Surgical Outcomes”. Edward H. Livingston, Jing Cao *JAMA*. 2010;304(1):95–97.

¹⁸³ David R. Flum, D.R.; Salem, L.; Elrod, J.B.; Dellinger, E.P.; Cheadle, A. Chan, L. “Early Mortality Among Medicare Beneficiaries Undergoing Bariatric Surgical Procedures”. *JAMA*. 2005;294(15):1903–1908.

¹⁸⁴ Schrag, D; Cramer, L.D.; Bach, P.B.; Cohen, A.M.; Warren, J.L.; Begg, C.B ” Influence of Hospital Procedure Volume on Outcomes Following Surgery for Colon Cancer” *JAMA*. 2000; 284 (23): 3028– 3035.

greater experience or surgical skill, greater comfort with and, hence, likelihood of application of standardized best practices, and increased experience in monitoring and management of surgical patients for the particular procedure. We further stated our belief that publicly reporting volume data would provide patients with beneficial information to use when selecting a care provider (76 FR 74467).

In the CY 2018 OPSS/ASC final rule with comment period (82 FR 59429), we removed OP-26, stating that there is a lack of evidence to support this specific measure's link to improved clinical quality. Although there is evidence of a link between patient volume and better patient outcomes, we stated that we believed that there was a lack of evidence that this link was reflected in the OP-26 measure specifically. Based on this belief, we removed the OP-26 measure under the following measure removal criterion: performance or improvement on a measure does not result in better patient outcomes. At the time, many commenters supported the proposal to remove the OP-26 measure (82 FR 59429).

We are considering reimplementing the OP-26 measure or another volume measure because the shift from the inpatient to outpatient setting has placed greater importance on tracking the volume of outpatient procedures.

Over the past few decades, innovations in the health care system have driven the migration of procedures from the inpatient setting to the outpatient setting. Forty-five percent of percutaneous coronary intervention (PCI) procedures shifted from the inpatient to outpatient setting from 2004 to 2014, and more than 70 percent of patients who undergo thoracoscopic surgery can be discharged on the day of the surgery itself due to the use of innovative techniques and technologies available in the outpatient setting.¹⁸⁵ ¹⁸⁶ Given these developments, we believe that patients may benefit from the public reporting of facility-level volume measure data that

¹⁸⁵ Abrams KD, Balan-Cohen A, Durbha P. Growth in Outpatient Care: The role of quality and value incentives. Deloitte Insights. 2018. Available at: <https://www2.deloitte.com/us/en/insights/industry/health-care/outpatient-hospital-services-medicare-incentives-value-quality.html>.

¹⁸⁶ Chang AC, Yee J, Orringer MB, Iannettoni MD. Diagnostic thoracoscopic lung biopsy: an outpatient experience. *The Annals of Thoracic Surgery*. 2002;74:1942-7.

reflect the procedures performed across hospitals and provide the ability to track volume changes by facility and procedure category. Volume is an indicator for patients of which facilities are experienced with certain outpatient procedures.

OP-26 was the only measure in the Hospital OQR Program measure set that captured facility-level volume within hospitals and volume for Medicare and non-Medicare patients. As a result of its removal, the Hospital OQR Program currently does not capture outpatient surgical procedure volume in hospitals.

Furthermore, we are considering the reintroduction of a facility-level volume measure to support potential future development of a pain management measure, as described in a request for comment in the CY 2022 OPSS/ASC final rule with comment period (86 FR 63902 through 63904). When considering the need for a pain management measure, we analyzed volume data to determine the proportion of ASC procedures performed for pain management using the methodology established by ASC-7: ASC Facility Volume Data on Selected ASC Surgical Procedures, the volume measure that was included in the ASCQR Program measure set (76 FR 74507 through 74509). We found that pain management procedures were the third most common procedure in CY 2019 and 2020 and concluded that a pain management measure would provide consumers with important quality of care information. Thus, a volume measure in the Hospital OQR Program's measure set would provide information to Medicare beneficiaries and other interested parties on numbers and proportions of procedures by category performed by individual facilities, including for hospital outpatient procedures related to pain management.

We note that the OP-26 measure was adopted in the CY 2012 OPSS/ASC final rule with comment period (76 FR 4466 through 74468) and was not reviewed or endorsed by the Measure Applications Partnership (MAP), which first began its pre-rulemaking review of quality measures across Federal programs in February 2012, after the publication of the CY 2012

OPPS/ASC final rule with comment period in November 2011.¹⁸⁷ Therefore, for OP–26 to be adopted in the Hospital OQR Program measure set, the measure would need to first undergo the pre-rulemaking process specified in section 1890A(a) of the Act.

(2) Solicitation of Comments on the Readoption of the Hospital Outpatient Volume on Selected Outpatient Surgical Procedures (OP–26) Measure or Other Volume Indicator in the Hospital OQR Program

We seek comment on the potential inclusion of a volume measure in the Hospital OQR Program, either by re-adopting the Hospital Outpatient Volume on Selected Outpatient Surgical Procedures (OP–26) measure or adopting another volume indicator. We also seek comment on what volume data hospitals currently collect and if it is feasible to submit this data to the Hospital OQR Program, to minimize the collection and reporting burden of an alternative, new volume measure. Additionally, we seek comment on an appropriate timeline for implementing and publicly reporting the measure data.

Specifically, we invite comment on the following:

- The usefulness of including a volume indicator in the Hospital OQR Program measure set and publicly reporting volume data.
- Input on the mechanism of volume data collection and submission, including anticipated barriers and solutions to data collection and submission.
- Considerations for designing a volume indicator to reduce collection burden and improve data accuracy.
- Potential reporting of volume by procedure type, instead of total surgical procedure volume data for select categories, and which procedures would benefit from volume reporting.

¹⁸⁷ Measures Application Partnership. Pre-Rulemaking Report: Input on Measures Under Consideration by HHS for 2012 Rulemaking Final Report. February 2012. Available at: https://www.qualityforum.org/Publications/2012/02/MAP_Pre-Rulemaking_Report__Input_on_Measures_Under_Consideration_by_HHS_for_2012_Rulemaking.aspx.

- The usefulness of Medicare versus non-Medicare reporting versus other or additional categories for reporting.

b. Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality Programs

Significant and persistent inequities in healthcare outcomes exist in the United States. Belonging to a racial or ethnic minoritized group; being a member of a religious minority; living with a disability; being a member of lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; living in a rural area; or being near or below the poverty level is often associated with worse health outcomes.^{188,189,190,191,192,193,194,195,196}

One approach being employed to reduce inequity across our programs is the expansion of efforts to report quality measure results stratified by patient social risk factors and demographic variables. The Request for Information (RFI) included in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28479), titled “Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality Programs” describes key considerations that we might take into account across all CMS quality programs, including the Hospital OQR Program, when advancing the use of measure stratification to address healthcare disparities and advance health equity across our programs.

¹⁸⁸ Joynt KE, Orav E, Jha AK. (2011). Thirty-day readmission rates for Medicare beneficiaries by race and site of care. *JAMA*, 305(7):675–681.

¹⁸⁹ Milkie Vu et al. (2016). Predictors of Delayed Healthcare Seeking Among American Muslim Women. *J Womens Health (Larchmt)*. 2016 Jun;25(6):586-93. doi: 10.1089/jwh.2015.5517. Epub 2016 Feb 18. PMID: 26890129; PMCID: PMC5912720.

¹⁹⁰ Lindenauer PK, Lagu T, Rothberg MB, et al. (2013). Income inequality and 30-day outcomes after acute myocardial infarction, heart failure, and pneumonia: Retrospective cohort study. *British Medical Journal*, 346.

¹⁹¹ Trivedi AN, Nsa W, Hausmann LRM, et al. (2014). Quality and equity of care in U.S. hospitals. *New England Journal of Medicine*, 371(24):2298– 2308.

¹⁹² Polyakova, M., et al. (2021). Racial disparities in excess all-cause mortality during the early COVID–19 pandemic varied substantially across states. *Health Affairs*, 40(2): 307–316.

¹⁹³ Rural Health Research Gateway. (2018). Rural communities: age, income, and health status. *Rural Health Research Recap*. <https://www.ruralhealthresearch.org/assets/2200-8536/rural-communities-age-income-health-status-recap.pdf>.

¹⁹⁴ https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf.

¹⁹⁵ www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm.

¹⁹⁶ Poteat TC, Reisner SL, Miller M, Wirtz AL. (2020). COVID–19 vulnerability of transgender women with and without HIV infection in the Eastern and Southern U.S. preprint. *medRxiv*. 2020;2020.07.21. 20159327. doi:10.1101/ 2020.07.21.20159327.

We ask that readers review the full RFI in the FY 2023 IPPS/LTCH PPS proposed rule for full details on these considerations. For comments and feedback on the application of these principles to the Hospital OQR Program, please respond to this proposed rule.

7. Maintenance of Technical Specifications for Quality Measures

CMS maintains technical specifications for previously adopted Hospital OQR Program measures. These specifications are updated as we modify the Hospital OQR Program measure set. The manuals that contain specifications for the previously adopted measures can be found on the QualityNet website at: <https://qualitynet.cms.gov/outpatient/specifications-manuals>.

We refer readers to the CY 2019 OPSS/ASC final rule with comment period (83 FR 59104 and 59105), where we changed the frequency of the Hospital OQR Program Specifications Manual release beginning with CY 2019, such that we will release a manual once every 12 months and release addenda as necessary.

In the CY 2022 OPSS/ASC final rule with comment period (86 FR 63861), we finalized the adoption of eCQMs into the Hospital OQR Program measure set beginning with the CY 2023 reporting period and finalized the manner to update the technical specifications for eCQMs. Technical specifications for eCQMs used in the Hospital OQR Program will be contained in the CMS Annual Update for the Hospital Quality Reporting Programs (Annual Update). The Annual Update and implementation guidance documents are available on the eCQI Resource Center website at: <https://ecqi.healthit.gov/>. For eCQMs, we will update the measure specifications on an annual basis through the Annual Update which includes code updates, logic corrections, alignment with current clinical guidelines, and additional guidance for hospitals and electronic health record (EHR) vendors to use in order to collect and submit data on eCQMs from hospital EHRs. We are not proposing any changes to these policies in this proposed rule.

8. Public Display of Quality Measures

We refer readers to the CY 2009, CY 2014, and CY 2017 OPSS/ASC final rules (73 FR 68777 through 68779, 78 FR 75092, and 81 FR 79791, respectively) for our previously

finalized policies regarding public display of quality measures. We are not proposing any changes to these policies in this proposed rule.

C. Administrative Requirements

1. QualityNet Account and Security Official

We refer readers to the CYs 2011, 2012, 2014 and 2022 OPPTS/ASC final rules (75 FR 72099; 76 FR 74479; 78 FR 75108 through 75109; and 86 FR 639040, respectively) for the previously finalized QualityNet security official requirements, including those for setting up a QualityNet account and the associated timelines. These procedural requirements are codified at 42 CFR 419.46(b). Hospitals will be required to register and submit quality data through the Hospital Quality Reporting (HQR) System (formerly referred to as the QualityNet Secure Portal). The HQR System is safeguarded in accordance with the HIPAA Privacy and Security Rules to protect submitted patient information. See 45 CFR parts 160 and 164, subparts A, C, and E, for more information. We are not proposing any changes to these policies in this proposed rule.

2. Requirements Regarding Participation Status

We refer readers to the CYs 2014, 2016, and 2019 OPPTS/ASC final rules (78 FR 75108 through 75109; 80 FR 70519; and 83 FR 59103 through 59104, respectively) for requirements for participation and withdrawal from the Hospital OQR Program. We codified these requirements at 42 CFR 419.46(b) and (c). We are not proposing any changes to these policies in this proposed rule.

D. Form, Manner, and Timing of Data Submitted for the Hospital OQR Program

1. Hospital OQR Program Annual Submission Deadlines

We refer readers to the CYs 2014, 2016, and 2018 OPPTS/ASC final rules (78 FR 75110 through 75111; 80 FR 70519 through 70520; and 82 FR 59439, respectively) where we finalized our policies for clinical data submission deadlines. We codified these submission requirements at 42 CFR 419.46(d).

a. Proposal to Align Hospital OQR Program Patient Encounter Quarters for Chart-abstracted Measures to the Calendar Year for Annual Payment Update (APU) Determinations

(1) Background

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75110 and 75111), we specified our data submission deadlines and codified our submission requirements at 42 CFR 419.46(d)(2).¹⁹⁷ We refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70519 and 70520), where we shifted the quarters on which the Hospital OQR Program payment determinations are based, beginning with the CY 2018 payment determination. Prior to the adoption of this policy, the previous timeframe had extended from patient encounter quarter three of 2 years prior to the payment determination to patient encounter quarter two of the year prior to the payment determination. This timeframe provided less than two months between the time that the data was submitted for validation and the beginning of the payments that are affected by these data, creating compressed processing times for CMS and compressed timelines for hospitals to review their APU determination decisions. To address this issue, we changed the timeframe to begin with patient encounter quarter two of 2 years prior to the payment determination and end with patient encounter quarter one of the year prior to the payment determination.

As finalized in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70519 and 70520), the patient encounter quarters for chart-abstracted measures data submitted to the Hospital OQR Program are not aligned with the January through December calendar year. Because these quarters are not aligned with the calendar year, as other CMS quality programs' quarters are such as the Hospital Inpatient Quality Reporting (IQR) Program¹⁹⁸, this misalignment has resulted in confusion among some hospitals regarding submission deadlines and data reporting quarters.

¹⁹⁷ The CY 2014 OPPS/ASC final rule codified this standard in § 419.46(c)(2). This provision was moved to its current location in the CY 2021 OPPS/ASC final rule with comment period.

¹⁹⁸ FY 2011 IPHS/LTCH PPS final rule (75 FR 50220 and 50221).

(2) Proposal to Align Hospital OQR Program Patient Encounter Quarters for Chart-abstracted Measures to the Calendar Year Beginning with the CY 2024 Reporting Period/CY 2026 Payment Determination

Beginning with the CY 2024 reporting period/CY 2026 payment determination, we propose to align the patient encounter quarters for chart-abstracted measures with the calendar year. If this proposal is finalized as proposed, all four quarters of patient encounter data for chart-abstracted measures would be based on the calendar year two years prior to the payment determination year. We propose this change to align the patient encounter quarters for chart-abstracted measures with the calendar year schedule of the Hospital OQR Program and to further align these quarters with those of the Hospital IQR Program since some hospitals may be submitting data for both programs. The Hospital IQR Program’s patient encounter quarters all occur on the calendar year 2 years prior to the payment determination year as finalized in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50220 through 50221). We believe that the proposed alignment would also provide more time for APU determinations by increasing the length of time between the last clinical data submission deadline and APU determinations.

As an example, the current and proposed patient encounter quarters and clinical data submission deadlines for the CY 2028 payment determination are illustrated in Tables 64 and 65, respectively.

TABLE 64: Current CY 2028 Payment Determination*

Patient Encounter Quarter	Clinical Data Submission Deadline
Q2 2026 (April 1 - June 30)	11/1/2025**
Q3 2026 (July 1 – September 30)	2/1/2026**
Q4 2026 (October 1 - December 31)	5/1/2026**
Q1 2027 (January 1 - March 31)	8/1/2026**

* All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order would be extended to the first day thereafter.

**The August 1st, November 1st, February 1st, and May 1st deadlines are recurring.

TABLE 65: Proposed CY 2028 Payment Determination*

Patient Encounter Quarter	Clinical Data Submission Deadline
Q1 2026 (January 1 - March 31)	8/1/2026**

Q2 2026 (April 1 - June 30)	11/1/2026**
Q3 2026 (July 1 – September 30)	2/1/2027**
Q4 2026 (October 1 - December 31)	5/1/2027**

* All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order would be extended to the first day thereafter.

**The August 1st, November 1st, February 1st, and May 1st deadlines are recurring.

To facilitate this process, we propose to transition to the newly proposed timeframe for the CY 2026 payment determination and subsequent years and use only three quarters of data for chart-abstracted measures in determining the CY 2025 payment determination as illustrated in the tables 66, 67, and 68 below. However, we note that data submission deadlines would not change.

TABLE 66: CY 2024 Payment Determination* (Current state)

Patient Encounter Quarter	Clinical Data Submission Deadline
Q2 2022 (April 1 - June 30)	11/1/2023**
Q3 2022 (July 1 – September 30)	2/1/2024**
Q4 2022 (October 1 - December 31)	5/1/2024**
Q1 2023 (January 1 - March 31)	8/1/2024**

* All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order would be extended to the first day thereafter.

**The August 1st, November 1st, February 1st, and May 1st deadlines are recurring.

TABLE 67: Proposed CY 2025 Payment Determination*(Future state—transition period)

Patient Encounter Quarter	Clinical Data Submission Deadline
Q2 2023 (April 1 - June 30)	11/1/2023**
Q3 2023 (July 1 – September 30)	2/1/2024**
Q4 2023 (October 1 - December 31)	5/1/2024**

* All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order would be extended to the first day thereafter.

**The August 1st, November 1st, February 1st, and May 1st deadlines are recurring.

TABLE 68: Proposed CY 2026 Payment Determination* (Future state)

Patient Encounter Quarter	Clinical Data Submission Deadline
Q1 2024 (January 1 - March 31)	8/1/2024**
Q2 2024 (April 1 - June 30)	11/1/2024**
Q3 2024 (July 1 – September 30)	2/1/2025**

* All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order would be extended to the first day thereafter.

**The August 1st, November 1st, February 1st, and May 1st deadlines are recurring.

We seek public comment on our proposal.

2. Requirements for Chart-Abstracted Measures Where Patient-Level Data are Submitted

Directly to CMS

We refer readers to the CY 2013 OPPTS/ASC final rule with comment period (77 FR 68481 through 68484) and the QualityNet website available at: <https://qualitynet.cms.gov> for a discussion of the requirements for chart-abstracted measure data submitted via the HQR System (formerly referred to as the QualityNet Secure Portal) for the CY 2014 payment determination and subsequent years. We are not proposing any changes to these policies in this proposed rule.

3. Claims-Based Measure Data Requirements

We refer readers to the CY 2019 OPPTS/ASC final rule (83 FR 59106 through 59107), where we established a three-year reporting period for OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy beginning with the CY 2020 payment determination. We refer readers to the CY 2022 OPPTS/ASC final rule with comment period (86 FR 63863) where we finalized a three-year reporting period for the Breast Cancer Screening Recall Rates measure (OP-39). We are not proposing any changes to these policies in this proposed rule.

4. Data Submission Requirements for the OP-37a-e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures

We refer readers to the CYs 2017, 2018, and 2022 OPPTS/ASC final rules (81 FR 79792 through 79794; 82 FR 59432 and 59433; and 86 FR 63863 through 63866, respectively) for a discussion of the previously finalized requirements related to survey administration and vendors

for the OAS CAHPS Survey-based measures.

We refer readers to the CY 2022 OPPTS/ASC final rule with comment period (86 FR 63863 through 63866), where we reaffirmed our approach to the form, manner, and timing which OAS CAHPS information will be submitted with two additional data collection modes (web with mail follow-up of non-respondents and web with telephone follow-up of non-respondents), beginning with voluntary data collection for the CY 2023 reporting period/CY 2025 payment determination and continuing for mandatory reporting for subsequent years. For more information about the modes of administration, we refer readers to the OAS CAHPS Survey website: <https://oascahps.org/>. We are not proposing any changes to these policies in this proposed rule.

5. Data Submission Requirements for Measures Submitted via a Web based Tool

a. Data Submission Requirements for Measures Submitted via a CMS Web-based Tool

We refer readers to the CY 2014 OPPTS/ASC final rule (78 FR 75112 through 75115), the CY 2016 OPPTS/ASC final rule (80 FR 70521), and the QualityNet website available at: <https://qualitynet.cms.gov> for a discussion of the requirements for measure data submitted via the HQR System (formerly referred to as the QualityNet Secure Portal) for the CY 2017 payment determination and subsequent years. We are not proposing any changes to these policies in this proposed rule.

b. Data Submission Requirements for Measures Submitted via the CDC NHSN Website

We refer readers to the CY 2014 OPPTS/ASC final rule (78 FR 75097 through 75100) for a discussion of the previously finalized requirements for measure data submitted via the CDC NHSN website. In addition, we refer readers to the CY 2022 OPPTS/ASC final rule (86 FR 63866), where we finalized the adoption of the COVID–19 Vaccination Coverage Among Health Care Personnel measure (OP-38) beginning with the CY 2022 reporting period/CY 2024 payment determination. We are not proposing any changes to these policies in this proposed rule.

6. eCQM Reporting and Submission Requirements

a. Background

We refer readers to the CY 2014 OPSS/ASC final rule (78 FR 75106 and 75107), the CY 2015 OPSS/ASC final rule (79 FR 66956 through 66961), the CY 2016 OPSS/ASC final rule with comment period (80 FR 70516 through 70518), the CY 2017 OPSS/ASC final rule with comment period (81 FR 79785 through 79790), the CY 2018 OPSS/ASC final rule with comment period (82 FR 59435 through 59438), and the CY 2022 OPSS/ASC final rule with comment period (82 FR 63867 through 63870) for more details on previous discussion regarding future measure concepts related to eCQMs and electronic reporting of data for the Hospital OQR Program, including support for the introduction of eCQMs into the Program. Measure stewards and developers have worked to advance eCQMs that would be reported in the outpatient setting.

b. eCQM Reporting and Data Submission Requirements

In the CY 2022 OPSS/ASC final rule with comment period (86 FR 63867), we finalized the adoption of the STEMI eCQM (OP-40). In the CY 2022 OPSS/ASC final rule with comment period and a progressive increase in the number of quarters for which hospitals must report eCQM data (86 FR 63867 and 63868). For the CY 2023 reporting period, we finalized that hospitals submit STEMI eCQM (OP-40) data during this reporting period voluntarily for any quarter (86 FR 63868). Hospitals that choose to submit data voluntarily must submit in compliance with the eCQM certification requirements in sections XV.D.6.c, XV.D.6.d, and XV.D.6.e of the CY 2022 OPSS/ASC final rule with comment period. We refer readers to the CY 2022 OPSS/ASC final rule with comment period (86 FR 63867 and 63868) for additional detail on the eCQM reporting and data submission requirements.

We also refer readers to Table 69 for a summary of the previously finalized quarterly data increase in eCQM reporting beginning with the CY 2023 reporting period.

TABLE 69: Progressive Increase in eCQM Reporting Beginning with the CY 2023 Reporting Period/CY 2025 Payment Determination and for Subsequent Years

Calendar Year Period	Calendar Quarters of Reporting	Reporting
CY 2023 Reporting Period/CY 2025 Payment Determination	Any quarter(s)	Voluntary

CY 2024 Reporting Period/CY 2026 Payment Determination	One self-selected quarter	Mandatory
CY 2025 Reporting Period/CY 2027 Payment Determination	Two self-selected quarters	Mandatory
CY 2026 Reporting Period/CY 2028 Payment Determination	Three self-selected quarters	Mandatory
CY 2027 Reporting Period/CY 2029 Payment Determination and Subsequent Years	Four quarters (one calendar year)	Mandatory

c. Electronic Quality Measure Certification Requirements for eQIM Reporting

(1) Use of Cures Update

In May 2020, the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program (ONC 21st Century Cures) Act final rule (85 FR 25642 through 25961) finalized updates to the health IT certification criteria (herein after referred to as the “Cures Update”). These updates included revisions to the clinical quality measurement certification criterion at 45 CFR 170.315(c)(3) to refer to CMS Quality Reporting Data Architecture (QRDA) Implementation Guides and removal of the Health Level 7 (HL7®) QRDA standard from the relevant health IT certification criteria (85 FR 25645). The ONC 21st Century Cures Act final rule provided health IT developers with up to 24 months from May 1, 2020 to make available to their customers technology certified to the updated and/or new criteria (85 FR 25670). In November 2020, ONC issued an interim final rule (85 FR 70064) which extended the compliance deadline for the clinical quality measures-report criterion at 45 CFR 170.315(c)(3) until December 31, 2022 (85 FR 70075). These updates were finalized to reduce burden on health IT developers (85 FR 70075) and have no impact on providers’ existing reporting practices for the Hospital OQR Program.

We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63868 and 63869), where we finalized the requirement for hospitals participating in the Hospital OQR Program to utilize certified technology updated consistent with the Cures Update for the CY 2023 reporting period/CY 2025 payment determination and for subsequent years. This period includes both the voluntary reporting period and mandatory reporting periods. We noted that this requirement is in alignment with the Hospital IQR Program, which requires use of technology updated consistent with the Cures Update beginning with the CY 2023 reporting

period/FY 2025 payment determination (See 86 FR 45418). We are not proposing any changes to these policies in this proposed rule.

d. File Format for EHR Data, Zero Denominator Declarations, and Case Threshold Exemptions

(1) File Format for EHR Data

Data can be collected in EHRs and health information technology systems using standardized formats to promote consistent representation and interpretation, as well as to allow for systems to compute data without needing human interpretation. As described in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49701), these standards are referred to as content exchange standards because the standard details how data should be represented and the relationships between data elements.

We refer reader to the CY 2022 OPPS/ASC final rule with comment period (86 FR 42262), where we finalized, beginning with the CY 2023 reporting period/CY 2025 payment determination, that hospitals: (1) Must submit eCQM data via the QRDA Category I (QRDA I) file format;¹⁹⁹ (2) may use third parties to submit QRDA I files on their behalf; and (3) may either use abstraction or pull the data from non-certified sources in order to then input these data into CEHRT for capture and reporting QRDA I files. We also refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63869) for discussion on the maintenance of technical specifications including those for eCQMs. We are not proposing any changes to these policies in this proposed rule.

(2) Zero Denominator Declarations

We understand there may be situations in which a hospital does not have data to report on a particular eCQM. We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63869), where we finalized that if the hospital's EHR is certified to an eCQM, but the

¹⁹⁹ QRDA I is an individual patient-level quality report that contains quality data for one patient for one or more eCQMs. QRDA creates a standard method to report quality measure results in a structured, consistent format and can be used to exchange eCQM data between systems. For further detail on QRDA I, the most recently available QRDA I specifications and Implementation Guides (IGs) can be found at: <https://ecqi.healthit.gov/qrda>.

hospital does not have patients that meet the denominator criteria of that eCQM, the hospital can submit a zero in the denominator for that eCQM. Submission of a zero in the denominator for an eCQM counts as a successful submission for that eCQM for the Hospital OQR Program (86 FR 63869). We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63869) for additional detail on the zero denominator declarations policy. We are not proposing any changes to these policies in this proposed rule.

(3) Case Threshold Exemptions

We understand that in some cases, a hospital may not meet the case threshold of discharges for a particular eCQM. In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63869), we finalized a policy aligning the Hospital OQR Program case threshold exemption with the case threshold exemption from the Medicare Promoting Interoperability Program (77 FR 54080) and the Hospital IQR Program (79 FR 50324). Specifically, for the Hospital OQR Program we finalized that beginning with the CY 2023 reporting period/CY 2025 payment determination, if a hospital's EHR system is certified to report an eCQM and the hospital experiences five or fewer outpatient discharges per quarter or 20 or fewer outpatient discharges per year (Medicare and non-Medicare combined), as defined by an eCQM's denominator population, that hospital could be exempt from reporting on that eCQM (86 FR 63869). We also stated that the exemption would not have to be used; a hospital could report those individual cases if it would like to. We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63869) for additional detail on the case threshold exemption policy. We are not proposing any changes to these policies in this proposed rule.

e. Submission Deadlines for eCQM Data

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63870), we finalized the policy to require eCQM data submission by May 15 of the following year for the applicable CY reporting period, beginning with the CY 2023 reporting period/CY 2025 payment determination. For example, CY 2023 eCQM data would need to be reported to us by

May 15, 2024. We note the submission deadline may be moved to the next business day if it falls on a weekend or Federal holiday. We refer readers to the CY 2022 OPPTS/ASC final rule with comment period (86 FR 63870) for additional detail on submission deadlines for eCQM data.

We are not proposing any changes to these policies in this proposed rule.

7. Population and Sampling Data Requirements for the CY 2023 Payment Determination and Subsequent Years

We refer readers to the CY 2011 OPPTS/ASC final rule (75 FR 72100 through 72103) and the CY 2012 OPPTS/ASC final rule (76 FR 74482 through 74483) for discussions of our population and sampling requirements. We are not proposing any changes to these policies in this proposed rule.

8. Review and Corrections Period for Measure Data Submitted to the Hospital OQR Program

a. Chart-Abstracted Measures

We refer readers to the CY 2015 OPPTS/ASC final rule (79 FR 66964 and 67014) where we formalized a review and corrections period for chart-abstracted measures in the Hospital OQR Program. We are not proposing any changes to these policies in this proposed rule.

b. Web-Based Measures

In the CY 2021 OPPTS/ASC final rule with comment period (85 FR 86184), we finalized an expansion of our review and corrections policy to apply to measure data submitted via the CMS web-based tool beginning with data submitted for the CY 2021 reporting period/CY 2023 payment determination. We are not proposing any changes to these policies in this proposed rule.

c. Electronic Clinical Quality Measures (eCQMs)

We refer readers to the CY 2022 OPPTS/ASC final rule with comment period (86 FR 63870) where we finalized that hospitals have a review and corrections period for eCQM data submitted to the Hospital OQR Program. We finalized a review and corrections period for eCQM data which would run concurrently with the data submission period. We refer readers to

the QualityNet website (available at: <https://qualitynet.cms.gov/outpatient/measures/eCQM>) and the eCQI Resource Center (available at: <https://ecqi.healthit.gov/>) for more resources on eCQM reporting. We are not proposing any changes to these policies in this proposed rule.

d. OAS CAHPS Measures

Each hospital administers (via its vendor) the survey for all eligible patients treated during the data collection period on a monthly basis according to the guidelines in the Protocols and Guidelines Manual (<https://oascahps.org>) and report the survey data to CMS on a quarterly basis by the deadlines posted on the OAS CAHPS Survey website as stated in the CY 2022 OPSS/ASC final rule with comment period (86 FR 63870). As finalized in the CY 2017 OPSS/ASC final rule with comment period, data cannot be altered after the data submission deadline but can be reviewed prior to the submission deadline (81 FR 79793). We are not proposing any changes to these policies in this proposed rule.

9. Hospital OQR Program Validation Requirements

a. Background

We refer readers to the CY 2011 OPSS/ASC final rule (75 FR 72105 through 72106), the CY 2013 OPSS/ASC final rule (77 FR 68484 through 68487), the CY 2015 OPSS/ASC final rule (79 FR 66964 through 66965), the CY 2016 OPSS/ASC final rule (80 FR 70524), the CY 2018 OPSS/ASC final rule (82 FR 59441 through 59443), the CY 2022 OPSS/ASC final rule (86 FR 63870 through 63873), and 42 CFR 419.46(f) for our policies regarding validation.

b. Use of Electronic File Submissions for Chart-Abstracted Measure Medical Records Requests

In the CY 2022 OPSS/ASC final rule (86 FR 63870), we finalized discontinuing the option for hospitals to send paper copies of, or CDs, DVDs, or flash drives containing medical records for validation affecting the CY 2022 reporting period/CY 2024 payment determination. Hospitals must instead submit only electronic files when submitting copies of medical records for validation of chart-abstracted measures. Under this policy, hospitals are required to submit PDF copies of medical records using direct electronic file submission via a CMS-approved

secure file transmission process as directed by the CMS Data Abstraction Center (CDAC). We would continue to reimburse hospitals at \$3.00 per chart, consistent with the current reimbursement amount for electronic submissions of charts. We note that this process aligns with that for the Hospital IQR Program (See FY 2021 IPPS/LTCH PPS final rule, 85 FR 58949). We refer readers to the CY 2022 OPPI/ASC final rule (86 FR 63870) for additional information on the use of electronic file submissions for chart-abstracted measure medical records requests. We are not proposing any changes to these policies in this proposed rule.

c. Time Period for Chart-Abstracted Measure Data Validation

We refer readers to the chart-abstracted validation requirements and methods we adopted in the CY 2014 OPPI/ASC final rule (78 FR 75117 through 75118) and codified at 42 CFR 419.46(f)(1) for the CY 2025 payment determination and subsequent years.

We refer readers to the CY 2022 OPPI/ASC final rule (86 FR 63871) where we finalized the revision of 42 CFR 419.46(f)(1) to change the time period given to hospitals to submit medical records to the CDAC contractor from 45 calendar days to 30 calendar days, beginning with medical record submissions for encounters in Q1 of CY 2022 affecting the CY 2024 payment determination and for subsequent years. We are not proposing any changes to these policies in this proposed rule.

d. Targeting Criteria

(1) Background

In the CY 2012 OPPI/ASC final rule (76 FR 74485), we finalized a validation selection process in which we select a random sample of 450 hospitals for validation purposes and select an additional 50 hospitals based on specific criteria. We finalized a policy in the CY 2013 OPPI/ASC final rule (77 FR 68485 and 68486), that for the CY 2014 payment determination and subsequent years, a hospital will be preliminarily selected for validation based on targeting criteria if it fails the validation requirement that applies to the previous year's payment determination. We also refer readers to the CY 2013 OPPI/ASC final rule (77 FR 68486 and

68487) for a discussion of finalized policies regarding our medical record validation procedure requirements. In the CY 2018 OPPTS/ASC final rule (82 FR 59441), for the targeting criterion “the hospital has an outlier value for a measure based on the data it submits,” we clarified that an “outlier value” for purposes of this criterion is defined as a measure value that appears to deviate markedly from the measure values for other hospitals. In the CY 2022 OPPTS/ASC final rule (86 FR 63872), we finalized the addition of two targeting criteria: any hospital that has not been randomly selected for validation in any of the previous three years or any hospital that passed validation in the previous year and had a two-tailed confidence interval that included 75 percent. We refer readers to the CY 2022 OPPTS/ASC final rule (86 FR 63872) for additional information on the Hospital OQR Program’s previously finalized targeting criteria.

We have codified at 42 CFR 419.46(f)(3) that we select a random sample of 450 hospitals for validation purposes, and select an additional 50 hospitals for validation purposes based on the following targeting criteria:

- The hospital fails the validation requirement that applies to the previous year’s payment determination; or
- The hospital has an outlier value for a measure based on the data it submits. An “outlier value” is a measure value that is greater than five standard deviations from the mean of the measure values for other hospitals and indicates a poor score; or
- The hospital has not been randomly selected for validation in any of the previous three years; or
- The hospital passed validation in the previous year but had a two-tailed confidence interval that included 75 percent.

(2) Proposed Addition of Targeting Criterion

Beginning with validations affecting the CY 2023 reporting period/CY 2025 payment determination, we propose to add a new criterion to the four established targeting criteria at § 419.46(f)(3) used to select the 50 additional hospitals. We propose that a hospital with less

than four quarters of data subject to validation due to receiving an ECE for one or more quarters and with a two-tailed confidence interval that is less than 75 percent would be targeted for validation in the subsequent validation year. We propose this additional criterion because such a hospital would have less than four quarters of data available for validation and its validation results could be considered inconclusive for a payment determination. Hospitals that meet this criterion would be required to submit medical records to the CDAC contractor within 30 days of the date identified on the written request as finalized in the CY 2022 OPSS/ASC final rule (86 FR 63871) and codified at § 419.46(f)(1).

It is important to clarify that, consistent with our previously finalized policy, a hospital is subject to both payment reduction and targeting for validation in the subsequent year if it either: (a) has less than four quarters of data, but does *not* have an ECE for one more or more quarters and does not meet the 75 percent threshold; or (b) has four quarters of data subject to validation and does not meet the 75 percent threshold.

Specifically, we propose to revise 42 CFR 419.46(f)(3) to add the following criterion for targeting the additional 50 hospitals for validation:

- Any hospital with a two-tailed confidence interval that is less than 75 percent, and that had less than four quarters of data due to receiving an ECE for one or more quarters.

Our proposal would allow us to appropriately address instances in which hospitals that submit fewer than four quarters of data due to receiving an ECE for one or more quarters might face payment reduction under the current validation policies. We invite public comment on our proposal.

e. Educational Review Process and Score Review and Correction Period for Chart-Abstracted Measures

We refer readers to the CY 2018 OPSS/ASC final rule (82 FR 59441 through 59443) and the CY 2021 OPSS/ASC final rule (85 FR 86185) where we finalized and codified a policy to formalize the Educational Review Process for Chart-Abstracted Measures, including Validation

Score Review and Correction. We are not proposing any changes to these policies in this proposed rule.

9. Extraordinary Circumstances Exception (ECE) Process

We refer readers to the CY 2013 OPPS/ASC final rule (77 FR 68489), the CY 2014 OPPS/ASC final rule (78 FR 75119 through 75120), the CY 2015 OPPS/ASC final rule (79 FR 66966), the CY 2016 OPPS/ASC final rule (80 FR 70524), the CY 2017 OPPS/ASC final rule (81 FR 79795), the CY 2018 OPPS/ASC final rule (82 FR 59444), the CY 2022 OPPS/ASC final rule (86 FR 63873), and 42 CFR 419.46(e) for a complete discussion of our extraordinary circumstances exception (ECE) process under the Hospital OQR Program. We are not proposing any changes to these policies in this proposed rule.

10. Hospital OQR Program Reconsideration and Appeals Procedures

We refer readers to the CY 2013 OPPS/ASC final rule (77 FR 68487 through 68489), the CY 2014 OPPS/ASC final rule (78 FR 75118 through 75119), the CY 2016 OPPS/ASC final rule (80 FR 70524), the CY 2017 OPPS/ASC final rule (81 FR 79795), the CY 2021 OPPS/ASC final rule (85 FR 68185), and 42 CFR 419.46(g) for our reconsideration and appeals procedures. We are not proposing any changes to these policies in this proposed rule.

E. Payment Reduction for Hospitals That Fail To Meet the Hospital OQR Program

Requirements for the CY 2023 Payment Determination

1. Background

Section 1833(t)(17) of the Act, which applies to subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act), states that hospitals that fail to report data required to be submitted on measures selected by the Secretary, in the form and manner, and at a time, specified by the Secretary will incur a 2.0 percentage point reduction to their Outpatient Department (OPD) fee schedule increase factor; that is, the annual payment update factor. Section 1833(t)(17)(A)(ii) of the Act specifies that any reduction applies only to the payment

year involved and will not be taken into account in computing the applicable OPD fee schedule increase factor for a subsequent year.

The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data in order to receive the full payment update factor and that fail to meet the Hospital OQR Program requirements. Hospitals that meet the reporting requirements receive the full OPPS payment update without the reduction. For a more detailed discussion of how this payment reduction was initially implemented, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68769 through 68772).

The national unadjusted payment rates for many services paid under the OPPS equal the product of the OPPS conversion factor and the scaled relative payment weight for the APC to which the service is assigned. The OPPS conversion factor, which is updated annually by the OPD fee schedule increase factor, is used to calculate the OPPS payment rate for services with the following status indicators (listed in Addendum B to the proposed rule, which is available via the Internet on the CMS website): “J1”, “J2”, “P”, “Q1”, “Q2”, “Q3”, “R”, “S”, “T”, “V”, or “U”. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79796), we clarified that the reporting ratio does not apply to codes with status indicator “Q4” because services and procedures coded with status indicator “Q4” are either packaged or paid through the Clinical Laboratory Fee Schedule and are never paid separately through the OPPS. Payment for all services assigned to these status indicators will be subject to the reduction of the national unadjusted payment rates for hospitals that fail to meet Hospital OQR Program requirements, with the exception of services assigned to New Technology APCs with assigned status indicator “S” or “T”. We refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68770 through 68771) for a discussion of this policy.

The OPD fee schedule increase factor is an input into the OPSS conversion factor, which is used to calculate OPSS payment rates. To reduce the OPD fee schedule increase factor for hospitals that fail to meet reporting requirements, we calculate two conversion factors—a full market basket conversion factor (that is, the full conversion factor), and a reduced market basket conversion factor (that is, the reduced conversion factor). We then calculate a reduction ratio by dividing the reduced conversion factor by the full conversion factor. We refer to this reduction ratio as the “reporting ratio” to indicate that it applies to payment for hospitals that fail to meet their reporting requirements. Applying this reporting ratio to the OPSS payment amounts results in reduced national unadjusted payment rates that are mathematically equivalent to the reduced national unadjusted payment rates that would result if we multiplied the scaled OPSS relative payment weights by the reduced conversion factor. For example, to determine the reduced national unadjusted payment rates that applied to hospitals that failed to meet their quality reporting requirements for the CY 2010 OPSS, we multiplied the final full national unadjusted payment rate found in Addendum B of the CY 2010 OPSS/ASC final rule with comment period by the CY 2010 OPSS final rule with comment period reporting ratio of 0.980 (74 FR 60642).

We note that the only difference in the calculation for the full conversion factor and the calculation for the reduced conversion factor is that the full conversion factor uses the full OPD update and the reduced conversion factor uses the reduced OPD update. The baseline OPSS conversion factor calculation is the same since all other adjustments would be applied to both conversion factor calculations. Therefore, our standard approach of calculating the reporting ratio as described earlier in this section is equivalent to dividing the reduced OPD update factor by that of the full OPD update factor. In other words:

Full Conversion Factor = Baseline OPSS conversion factor * (1 + OPD update factor)

Reduced Conversion Factor = Baseline OPSS conversion factor * (1 + OPD update factor – 0.02)

Reporting Ratio = Reduced Conversion Factor / Full Conversion Factor

Which is equivalent to:

Reporting Ratio = $(1 + \text{OPD Update factor} - 0.02) / (1 + \text{OPD update factor})$

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68771 through 68772), we established a policy that the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies would each equal the product of the reporting ratio and the national unadjusted copayment or the minimum unadjusted copayment, as applicable, for the service. Under this policy, we apply the reporting ratio to both the minimum unadjusted copayment and national unadjusted copayment for services provided by hospitals that receive the payment reduction for failure to meet the Hospital OQR Program reporting requirements. This application of the reporting ratio to the national unadjusted and minimum unadjusted copayments is calculated according to § 419.41 of our regulations, prior to any adjustment for a hospital's failure to meet the quality reporting standards according to § 419.43(h). Beneficiaries and secondary payers thereby share in the reduction of payments to these hospitals.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68772), we established the policy that all other applicable adjustments to the OPPS national unadjusted payment rates apply when the OPD fee schedule increase factor is reduced for hospitals that fail to meet the requirements of the Hospital OQR Program. For example, the following standard adjustments apply to the reduced national unadjusted payment rates: the wage index adjustment, the multiple procedure adjustment, the interrupted procedure adjustment, the rural sole community hospital adjustment, and the adjustment for devices furnished with full or partial credit or without cost. Similarly, OPPS outlier payments made for high cost and complex procedures will continue to be made when outlier criteria are met. For hospitals that fail to meet the quality data reporting requirements, the hospitals' costs are compared to the reduced payments for purposes of outlier eligibility and payment calculation. We established this policy in the OPPS beginning in the CY 2010 OPPS/ASC final rule with comment period

(74 FR 60642). For a complete discussion of the OPPS outlier calculation and eligibility criteria, we refer readers to section II.G of this proposed rule.

2. Reporting Ratio Application and Associated Adjustment Policy for CY 2023

We propose to continue our established policy of applying the reduction of the OPD fee schedule increase factor through the use of a reporting ratio for those hospitals that fail to meet the Hospital OQR Program requirements for the full CY 2023 annual payment update factor. For this CY 2023 OPPS/ASC proposed rule, the proposed reporting ratio is 0.9805, which, when multiplied by the proposed full conversion factor of \$86.785, equals a proposed conversion factor for hospitals that fail to meet the requirements of the Hospital OQR Program (that is, the reduced conversion factor) of \$85.093. We propose to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor. We propose to continue to apply the reporting ratio, when applicable, to all HCPCS codes to which we have proposed status indicator assignments of “J1”, “J2”, “P”, “Q1”, “Q2”, “Q3”, “R”, “S”, “T”, “V”, and “U” (other than New Technology APCs to which we have proposed status indicator assignments of “S” and “T”). We propose to continue to exclude services paid under New Technology APCs. We propose to continue to apply the reporting ratio to the national unadjusted payment rates and the minimum unadjusted and national unadjusted copayment rates of all applicable services for those hospitals that fail to meet the Hospital OQR Program reporting requirements. We also propose to continue to apply all other applicable standard adjustments to the OPPS national unadjusted payment rates for hospitals that fail to meet the requirements of the Hospital OQR Program. Similarly, we propose to continue to calculate OPPS outlier eligibility and outlier payment based on the reduced payment rates for those hospitals that fail to meet the reporting requirements. In addition to our proposal to implement the policy through the use of a reporting ratio, we also propose to calculate the reporting ratio to four decimals (rather than the previously used three decimals) to more precisely calculate the reduced adjusted payment and copayment rates.

For CY 2023, the proposed reporting ratio is 0.9805, which, when multiplied by the final full conversion factor of \$86.785, equals a proposed conversion factor for hospitals that fail to meet the requirements of the Hospital OQR Program (that is, the reduced conversion factor) of \$85.093.

XV. Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

A. Background

1. Overview

We refer readers to section XIV.A.1 of the CY 2020 OPPS/ASC final rule (84 FR 61410) for a general overview of our outpatient quality reporting programs.

2. Statutory History of the ASCQR Program

We refer readers to the CY 2012 OPPS/ASC final rule (76 FR 74492 through 74494) for a detailed discussion of the statutory history of the ASCQR Program.

3. Regulatory History of the ASCQR Program

We refer readers to the CYs 2014 through 2022 OPPS/ASC final rules for an overview of the regulatory history of the ASCQR Program:

- CY 2014 OPPS/ASC final rule (78 FR 75122);
- CY 2015 OPPS/ASC final rule (79 FR 66966 through 66987);
- CY 2016 OPPS/ASC final rule (80 FR 70526 through 70538);
- CY 2017 OPPS/ASC final rule (81 FR 79797 through 79826);
- CY 2018 OPPS/ASC final rule (82 FR 59445 through 59476);
- CY 2019 OPPS/ASC final rule (83 FR 59110 through 59139);
- CY 2020 OPPS/ASC final rule (84 FR 61420 through 61434);
- CY 2021 OPPS/ASC final rule (85 FR 86187 through 86193); and
- CY 2022 OPPS/ASC final rule (86 FR 63875 through 63911).

We have codified requirements under the ASCQR Program in 42 CFR, part 16, subpart H (42 CFR 416.300 through 416.330).

B. ASCQR Program Quality Measures

1. Considerations in the Selection of ASCQR Program Quality Measures

We refer readers to the CY 2013 OPPS/ASC final rule (77 FR 68493 and 68494) for a detailed discussion of the priorities we consider for the ASCQR Program quality measure selection. We are not proposing any changes to these policies in this proposed rule.

2. Retention and Removal of Quality Measures from the ASCQR Program

a. Retention of Previously Adopted ASCQR Program Measures

We previously finalized a policy to retain measures from the previous year measure set for subsequent years, except when such measures are removed (76 FR 74494 and 74504; 77 FR 68494 and 68495; 78 FR 75122; and 79 FR 66967 through 66969). We are not proposing any changes to this policy in this proposed rule.

b. Removal Factors for ASCQR Program Measures

In the CY 2019 OPPS/ASC final rule (83 FR 59111 through 59115), we finalized and codified at 42 CFR 416.320 an updated set of factors and the process for removing measures from the ASCQR Program. We are not proposing any changes to these policies in this proposed rule.

3. Proposal to Change the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (ASC–11) Measure from Mandatory to Voluntary Beginning with the CY 2027 Payment Determination

a. Background

The ASC–11 measure was adopted in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75129). During CY 2014 OPPS/ASC rulemaking, some commenters expressed concern about the burden of collecting pre-operative and post-operative visual function surveys (78 FR 75129). In response to those comments, we modified our implementation strategy in a

manner that we believed would significantly minimize collection and reporting burden by applying a sampling scheme and a low case threshold exemption to address commenters' concerns regarding burden (78 FR 75129). Shortly thereafter, we became concerned about the use of what we believed at the time were inconsistent surveys to assess visual function. The measure specifications allowed for the use of any validated survey, and we were unclear about the impact the use of varying surveys might have on accuracy, feasibility, or reporting burden. Therefore, we issued guidance stating that we would delay the implementation of ASC-11, and we subsequently finalized in the CY 2015 OPPI/ASC final rule (79 FR 66983 through 66985) the exclusion of ASC-11 from the required measure set while allowing ASCs to voluntarily report measure data beginning with the CY 2015 reporting period.

b. Considerations Concerning Previously Finalized ASC-11 Measure Requirements Beginning with the CY 2025 Reporting Period/CY 2027 Payment Determination

In the CY 2022 OPPI/ASC proposed rule (86 FR 42272), we stated that it would be appropriate to require that ASCs report on ASC-11 for the CY 2023 reporting period/CY 2025 payment determination as ASCs have had the opportunity for several years to familiarize themselves with ASC-11, prepare to operationalize it, and to practice reporting the measure since the CY 2015 reporting period/CY 2017 payment determination. Many commenters expressed concern about making this measure mandatory due to the burden of reporting the measure and the impact this additional burden would have during the COVID-19 pandemic, stating that ASC-11 has not been mandatory and many facilities have not been practicing reporting it (86 FR 63886). In response to these comments, in the CY 2022 OPPI/ASC final rule with comment period, we finalized a delay in the implementation of this measure with mandatory reporting beginning with the CY 2025 reporting period/CY 2027 payment determination (86 FR 63885 through 63887).

We now believe it is appropriate to suspend implementation of mandatory reporting and retain continue voluntary reporting for the ASC-11 measure and not require reporting starting

with the CY 2027 payment determination. Since the publication of the CY 2022 OPPS/ASC final rule, interested parties have expressed concern about the reporting burden of this measure given the ongoing COVID-19 public health emergency (PHE). Interested parties have indicated that facilities remain impacted by the COVID-19 PHE and that the requirement to report ASC-11 would be burdensome due to national staffing and medical supply shortages coupled with unprecedented changes in patient case volumes. Due to the continued impact of the COVID-19 PHE, such as national staffing and medical supply shortages, we believe the two-year delay of mandatory reporting for this measure is no longer sufficient. Based on these factors and the feedback we received from interested parties, we believe it is appropriate to continue with voluntary reporting and delay mandatory reporting requirements for the ASC-11 measure until future rulemaking. Therefore, we propose to delay mandatory reporting of the ASC-11 measure beginning with CY 2025 reporting period/CY 2027 payment determination and maintain reporting for this measure as voluntary. ASCs would not be subject to a payment reduction for failing to report this measure during the voluntary reporting period; however, we strongly encourage ASCs to gain experience with the measure. We plan to continue to evaluate this policy moving forward. To be clear, there are no changes to reporting for the CY 2023 and CY 2024, during which the measure would remain voluntary.

As the ASC-11 measure uniquely requires cross-setting coordination among clinicians of different specialties (that is, surgeons and ophthalmologists), we believe it appropriate to defer mandatory reporting at this time. We will consider mandatory reporting of ASC-11 after the national PHE declaration officially ends and we find it appropriate to do so given COVID-19 PHE impacts on national staffing and supply shortages. As we noted in the CY 2015 OPPS/ASC final rule, this measure addresses an area of care that is not adequately addressed in our current measure set and the measure serves to drive the coordination of care (79 FR 66984). We subsequently stated in the CY 2022 OPPS/ASC final rule with comment period that while the measure has been voluntary and available for reporting since the CY 2015 reporting period, a

number of facilities have reported data consistently for this measure and those that have reported these data have done so consistently (86 FR 63886).

We invite public comment on this proposal.

4. ASCQR Program Quality Measure Set

a. Summary of Previously Finalized ASCQR Program Quality Measure Set for the CY 2023 Reporting Period/CY 2025 Payment Determination and the CY 2024 Reporting Period/CY 2026 Payment Determination

We refer readers to the CY 2022 OPPTS/ASC final rule with comment period (86 FR 63875 through 63893) for the previously finalized ASCQR Program measure set for the CY 2023 program year and subsequent years.

Table 70 summarizes the previously finalized ASCQR Program measure set for the CY 2023 reporting period/CY 2025 payment determination and the CY 2024 reporting period/CY 2026 payment determination.

TABLE 70: ASCQR Program Measure Set for the CY 2023 Reporting Period/CY 2025 Payment Determination and the CY 2024 Reporting Period/CY 2026 Payment Determination

ASC #	NQF #	Measure Name
ASC-1	0263†	Patient Burn
ASC-2	0266†	Patient Fall
ASC-3	0267†	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant
ASC-4	0265†	All-Cause Hospital Transfer/Admission
ASC-9	0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
ASC-11	1536†	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery*
ASC-12	2539	Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
ASC-13	None	Normothermia Outcome
ASC-14	None	Unplanned Anterior Vitrectomy
ASC-17	3470	Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures
ASC-18	3366	Hospital Visits after Urology Ambulatory Surgical Center Procedures
ASC-19	3357	Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers
ASC-20	None	COVID-19 Vaccination Coverage Among Health Care Personnel

† NQF endorsement was removed.

* The ASC-11 measure is voluntarily collected, as set forth in the CY 2015 OPPTS/ASC final rule (79 FR 66984 through 66985).

b. Summary of the Proposed ASCQR Program Quality Measure Set for the CY 2025 Reporting Period/CY 2027 Payment Determination and Subsequent Years

Table 71 summarizes the previously finalized ASCQR Program measure set for the CY 2025 reporting period/CY 2027 payment determination and subsequent years as would be modified by the proposal described previously in this section of this proposed rule.

TABLE 71: Proposed ASCQR Program Measure Set for the CY 2025 Reporting Period/CY 2027 Payment Determination and Subsequent Years

ASC #	NQF #	Measure Name
ASC-1	0263†	Patient Burn
ASC-2	0266†	Patient Fall
ASC-3	0267†	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant
ASC-4	0265†	All-Cause Hospital Transfer/Admission
ASC-9	0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
ASC-11*	1536†	Cataracts: Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery
ASC-12	2539	Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
ASC-13	None	Normothermia Outcome
ASC-14	None	Unplanned Anterior Vitrectomy
ASC-15a	None	OAS CAHPS - About Facilities and Staff
ASC-15b	None	OAS CAHPS - Communication About Procedure
ASC-15c	None	OAS CAHPS - Preparation for Discharge and Recovery
ASC-15d	None	OAS CAHPS - Overall Rating of Facility
ASC-15e	None	OAS CAHPS - Recommendation of Facility
ASC-17	3470	Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures
ASC-18	3366	Hospital Visits after Urology Ambulatory Surgical Center Procedures
ASC-19	3357	Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers
ASC-20	None	COVID-19 Vaccination Coverage Among Health Care Personnel

† NQF endorsement was removed.

* The ASC-11 measure was previously finalized as mandatory for the CY 2025 program year as set forth in the CY 2022 OPSS/ASC final rule with comment period (86 FR 63885 through 63887) and is being proposed as voluntary in this proposed rule.

5. ASCQR Program Measures and Topics for Future Consideration

a. Request for Comment: A Potential Future Specialty Centered Approach for the ASCQR Program

An overarching ASCQR Program goal is to have an up to date, comprehensive set of quality measures for widespread use to promote informed decision-making regarding clinical care and quality improvement efforts in the ASC setting. We recognize the clinician and clinician-group centered, specialized nature of care delivered in ASCs. We, therefore, seek comment on a potential future direction of quality reporting under the ASCQR Program that

would allow quality-related data for ASCs to be reported on a customizable measure set that more accurately reflects the care delivered in this setting and accounts for the services provided by individual facilities. ASC services for Medicare beneficiaries are concentrated in a limited number of procedures. Because of this, there could be a set of measures related to different specialties, for example, ophthalmology, from which ASCs could choose a specified number, but individualized combination of measures. Another option could include the creation of specific specialized tracks which would standardize quality measures within a specialty area. Such a reporting structure could benefit ASCs by allowing them to focus on practice-specific measures on a specialty or multispecialty basis; patients and other interested parties could benefit through the provision of more relevant information on quality and safety within ASCs.

Specialty Centered Quality Reporting Under the Merit-based Incentive Payment System (MIPS)²⁰⁰

The Merit-Based Incentive Payment System adjusts Medicare Part B payment to a clinician based on the clinician's prior performance on four performance categories.²⁰¹ The four performance categories on which clinicians are scored are quality, cost, improvement activities (IA), and Promoting Interoperability.²⁰² Under MIPS, CMS has established measure and activity inventories from which clinicians may select measures and activities to report and complete, respectively.²⁰³ While the Traditional MIPS program is being phased out over time,²⁰⁴ ²⁰⁵ we nonetheless believe that the quality performance category of the program provides an example of a specialty centered approach to quality reporting that is relevant to ASCs as clinically specialized facilities. We believe that quality reporting for ASCs would benefit from measures that:

²⁰⁰ Centers for Medicare & Medicaid Services. Quality Payment Program Overview. Available at: <https://qpp.cms.gov/about/qpp-overview>.

²⁰¹ See Social Security Act section 1848(q).

²⁰² See *id.* Section 1848(q)(2)(A)(i) and (iii).

²⁰³ See *id.* Section 1848(q)(2)(D); see also 42 CFR 414.1355(a).

²⁰⁴ CY 2022 Physician Fee Schedule final rule (86 FR 65376).

²⁰⁵ Centers for Medicare & Medicaid Services. MIPS Value Pathways. Available at: <https://qpp.cms.gov/mips/mips-value-pathways>.

- Consist of limited, connected, and complementary sets of measures and related activities that are meaningful to clinicians;
- Include measures and activities resulting in comparative performance data that are valuable to patients and caregivers in evaluating clinician performance and making choices about their care;
- Promote subgroup reporting that comprehensively reflects the services provided by multispecialty groups;
- Include measures selected using the Meaningful Measures²⁰⁶ approach and, wherever possible, include the patient voice;

b. Solicitation of Comments on a Potential Future Specialty Centered Approach for the ASCQR Program

We request comment on the following questions for the ASCQR Program:

- Is the general concept of quality reporting by specialty feasible and desirable for ASCs participating in the ASCQR Program?
- Were we to adopt a specialty centered approach to quality measure reporting for the ASCQR Program, should CMS require that ASCs report a subset of quality measures that apply broadly to all ASCs? An example of potential broadly applicable measures for ASCs based on CY 2022 performance year MIPS quality measures²⁰⁷ can be found in Table 73.
- Were we to adopt a specialty centered approach for quality measure reporting for the ASCQR Program, what would be the appropriate number and type of measures that ASCs should be required to report? Are there minimum and maximum numbers of measures required for ASCs that provide meaningful information while not being overly burdensome? What is the

²⁰⁶ Centers for Medicare & Medicaid Services. Meaningful Measures Hub. Available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page>.

²⁰⁷ Centers for Medicare & Medicaid Services. Traditional MIPS: Explore Measures & Activities. Performance Year 2022. Available at: <https://qpp.cms.gov/mips/explore-measures?tab=qualityMeasures&py=2022>.

preferred balance of required quality measures that apply broadly to all ASCs and quality measures that apply to a particular area of specialization?

TABLE 73: Potential Broadly Applicable ASCQR Program MIPS Quality Measures

MIPS MEASURE NAME	TYPE	SUMMARY OF MEASURE
Advance Care Plan	Process	Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.
Anesthesiology Smoking Abstinence	Intermediate Outcome	The percentage of current smokers who abstain from cigarettes prior to anesthesia on the day of elective surgery or procedure.
CAHPS for MIPS Clinician/Group Survey	Patient Engagement Experience	Similar measure currently in ASCQR measure set (ASC-15 a-e).
Closing the Referral Loop: Receipt of Specialist Report	Process	Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.
Documentation of Current Medications in the Medical Record	Process	Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.
Multimodal Pain Management	Process	Percentage of patients, aged 18 years and older, undergoing selected surgical procedures that were managed with multimodal pain medicine.
Patient-Centered Surgical Risk Assessment and Communication	Process	Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.
Perioperative Temperature Management	Outcome	Currently in ASCQR measure set as Normothermia (ASC-13).

Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy	Process	Percentage of patients, aged 18 years and older, who undergo a procedure under an inhalational general anesthetic, AND who have three or more risk factors for post-operative nausea and vomiting (PONV), who receive combination therapy consisting of at least two prophylactic pharmacologic antiemetic agents of different classes preoperatively and/or intraoperatively.
Surgical Site Infection (SSI)	Outcome	Percentage of patients aged 18 years and older who had a surgical site infection (SSI).
Unplanned Hospital Readmission within 30 Days of Principal Procedure	Outcome	Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure (similar to ASC-17 and ASC-18).
Unplanned Reoperation within the 30 Day Postoperative Period	Outcome	Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30 day postoperative period.
Use of High-Risk Medications in Older Adults	Process	Percentage of patients 65 years of age and older who were ordered at least two of the same high-risk medications.

- Were we to adopt a specialty centered approach for quality measure reporting for the ASCQR Program, which area(s) of specialization would benefit from such an approach and which would not?

- Were we to adopt a specialty centered approach for quality measure reporting for the ASCQR Program, should CMS define a set of measures for particular areas of specialization (for example, ophthalmology) or should measures be self-selected for individual facilities from selected categories, especially given that an ASC may be multi-specialty?

We have considered several potential measure sets for the ASC setting based on CY 2022 performance year MIPS quality measures.²⁰⁸ An example of an ophthalmology measure set using quality measures based on CY 2022 performance year MIPS quality measures²⁰⁹ can be

²⁰⁸ Centers for Medicare & Medicaid Services. Traditional MIPS: Explore Measures & Activities. Performance Year 2022. Available at: <https://qpp.cms.gov/mips/explore-measures?tab=qualityMeasures&py=2022>.

²⁰⁹ Centers for Medicare & Medicaid Services. Traditional MIPS: Explore Measures & Activities. Performance Year 2022. Available at: <https://qpp.cms.gov/mips/explore-measures?tab=qualityMeasures&py=2022>.

found in Table 73. An example of a gastroenterology measure set can be found in Table 75. We welcome comment on these specific examples as well as comment on potential future measure sets for other specialization areas.

- Were we to adopt a specialty centered approach for quality measure reporting under the ASCQR Program, should ASCs be required to report all measures in such a measure set, or should they be permitted to select a minimum number of measures from their selected measure set?

- Were we to adopt a specialty centered approach for quality measure reporting system under the ASCQR Program, what measures, if any, from the current ASCQR Program measure set should be retained and incorporated in such an approach?

TABLE 74: Example Ophthalmology ASCQR Program MVP Measures

MEASURE NAME	TYPE	SUMMARY OF MEASURE
Adult Primary Rhegmatogenous Retinal Detachment Surgery: No Return to the Operating Room Within 90 Days of Surgery	Outcome	Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment who did not require a return to the operating room within 90 days of surgery.
Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery	Outcome	Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment and achieved an improvement in their visual acuity, from their preoperative level, within 90 days of surgery in the operative eye.
Cataract Surgery: Difference Between Planned and Final Refraction	Outcome	Percentage of patients aged 18 years and older who had cataract surgery performed and who achieved a final refraction within +/- 1.0 diopters of their planned (target) refraction.
Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery	Outcome	Percentage of cataract surgeries for patients aged 18 years and older with a diagnosis of uncomplicated cataract and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved in the operative eye within 90 days following the cataract surgery.
Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	Patient Reported Outcome	Similar measure currently in ASCQR measure set (ASC-11).

Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery	Patient Engagement Experience	Percentage of patients aged 18 years and older who had cataract surgery and were satisfied with their care within 90 days following the cataract surgery, based on completion of the Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey.
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TABLE 75: Example Gastroenterology ASCQR Program MVP Measures

MEASURE NAME	TYPE	SUMMARY OF MEASURE
Age Appropriate Screening Colonoscopy	Efficiency	The percentage of screening colonoscopies performed in patients greater than or equal to 86 years of age from January 1 to December 31.
Anastomotic Leak Intervention	Outcome	Percentage of patients aged 18 years and older who required an anastomotic leak intervention following gastric bypass or colectomy surgery.
Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients	Process	Similar measure currently in ASCQR measure set (ASC-9).
Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use	Process	Percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of prior adenomatous polyp(s) in previous colonoscopy findings, which had an interval of 3 or more years since their last colonoscopy.
Photodocumentation of Cecal Intubation	Claims	The rate of screening and surveillance colonoscopies for which photodocumentation of at least two landmarks of cecal intubation is performed to establish a complete examination.

c. Request for Comment: Potential Future Reimplementation of ASC Facility Volume Data on Selected ASC Surgical Procedures (ASC –7) Measure or Other Volume Indicator

(1) Background

ASC services for Medicare beneficiaries are concentrated in a limited number of procedures. Medicare covers surgical procedures represented in about 3,500 Healthcare Common Procedure Coding System (HCPCS) codes under the ASC payment system; however, ASC volume for services covered under Medicare is concentrated in a relatively small number of

HCPCS codes. In 2019, for example, 29 HCPCS codes accounted for 75 percent of the ASC volume for surgical services provided to Medicare beneficiaries.²¹⁰

Although ASCs perform procedures under a smaller and more specialized subset of HCPCS codes, the volume within these services continues to increase. Hospital care has been gradually shifting from inpatient to outpatient settings, and since 1983, inpatient stays per capita have fallen by 31 percent.²¹¹ From 2014 to 2018, the volume of ASC services delivered per Medicare Part B Fee-for-Service (FFS) beneficiary increased by 2.1 percent.²¹² During the same time period, the number of Part B FFS beneficiaries who received ASC services increased on average by 1.4 percent annually.²¹³ Research indicates that volume in ASCs will continue to grow, with some estimates projecting a 25 percent increase in patients between 2019 and 2029.²¹⁴

Volume has a long history as a quality metric, however, quality measurement efforts had moved away from procedure volume as it was considered simply a proxy for quality rather than directly measuring outcomes.²¹⁵ More recent studies suggest that while larger facility surgical procedure volume does not alone lead to better outcomes, it may be associated with better outcomes due to having characteristics that improve care (for example, high-volume facilities may have teams that work more effectively together, or have superior systems or programs for identifying and responding to complications), making volume an important component of quality.²¹⁶ The ASCQR Program does not currently include a quality measure for facility-level

²¹⁰ Medicare Payment Advisory Commission. March 2021 Report to the Congress: Medicare Payment Policy. Available at: <https://www.medpac.gov/document/march-2021-report-to-the-congress-medicare-payment-policy/>.

²¹¹ Medicare Payment Advisory Commission. March 2021 Report to the Congress: Medicare Payment Policy. Chapter 3. Available at: https://www.medpac.gov/wp-content/uploads/2021/10/mar21_medpac_report_ch3_sec.pdf.

²¹² Medicare Payment Advisory Commission. March 2021 Report to the Congress: Medicare Payment Policy. Available at: <https://www.medpac.gov/document/march-2021-report-to-the-congress-medicare-payment-policy/>.

²¹³ Medicare Payment Advisory Commission. March 2021 Report to the Congress: Medicare Payment Policy. Available at: <https://www.medpac.gov/document/march-2021-report-to-the-congress-medicare-payment-policy/>.

²¹⁴ Sg2. Sg2 Impact of Change Forecast Predicts Enormous Disruption in Health Care Provider Landscape by 2029. June 4, 2021. Available at: <https://www.sg2.com/media-center/press-releases/sg2-impact-forecast-predicts-disruption-health-care-provider-landscape-2029/>.

²¹⁵ Jha AK. Back to the Future: Volume as a Quality Metric. JAMA Forum Archive. Published online June 10, 2015.

²¹⁶ Auerbach AD et al. The Relationship between Case-Volume, Care Quality, and Outcomes of Complex Cancer Surgery. *Journal of the American College of Surgery*. 2010;211(5):601-608. doi:10.1016/j.jamcollsurg.2010.07.006.

volume data, including surgical procedure volume data, but did so previously. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74507 through 74509) where we adopted the ASC Facility Volume Data on Selected Procedures measure (ASC-7) beginning with the CY 2013 reporting period/CY 2015 payment determination. This structural measure of facility capacity collected surgical procedure volume data on six categories of procedures frequently performed in the ASC setting: Gastrointestinal, Eye, Nervous System, Musculoskeletal, Skin, and Genitourinary (76 FR 74507). We adopted ASC-7 based on evidence that the volume of surgical procedures, and particularly of high-risk surgical procedures, is related to better patient outcomes, including decreased medical errors and mortality. We further stated our belief that publicly reporting volume data would provide patients with beneficial information to use when selecting a care provider (76 FR 74507).

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59449 and 59450), we removed ASC-7. We stated our belief at that time that measures on specific procedure types would provide patients with more valuable ASC quality of care information as these types of measures are more strongly associated with desired patient outcomes. Based on this belief, we removed the ASC-7 measure under our second criterion for removal from the program; specifically, that there are other measures available that are more strongly associated with desired patient outcomes for the particular topic. At the time, some commenters supported the proposal to remove the ASC-7 measure and agreed with CMS's rationale that the measure does not add value, however, some commenters opposed this proposal (82 FR 59449). Commenters that opposed removal of the ASC-7 measure emphasized the data's usefulness for comparative research, outcomes research, immediate consumer value, and strategic planning. Some of these commenters also expressed concerns that nonavailability of these data would interfere with the acceptance of ASC-based procedures also noting that the measure is not overly burdensome (82 FR 59449).

We are considering reimplementing the ASC–7 measure or another volume measure because, in addition to being an important component of quality, the shift from the inpatient to outpatient setting has placed greater importance on tracking the volume of outpatient procedures.

Over the past few decades, innovations in the health care system have driven the migration of procedures from the inpatient setting to the outpatient setting. Forty-five percent of percutaneous coronary intervention (PCI) procedures shifted from the inpatient to outpatient setting from 2004 to 2014, and more than 70 percent of patients who undergo thoracoscopic surgery can be discharged on the day of surgery itself due to the use of innovative techniques and technologies available in the outpatient setting.^{217 218} Given the small number of HCPCS codes utilized by most ASCs, we also believe that patients may benefit from the public reporting of facility-level volume measure data that illuminates which procedures are performed across ASCs and provides the ability to track volume changes by facility and procedure category. Volume is an indicator for patients of which facilities are experienced with certain outpatient procedures.

ASC–7 was the only measure in the ASCQR Program measure set that captured facility-level volume within ASCs and volume for Medicare and non-Medicare patients. As a result of its removal, the ASCQR Program currently does not capture outpatient surgical procedure volume in ASCs.

Furthermore, we are considering the reintroduction of a facility-level volume measure to support potential future development of a pain management measure, as described in a request for comment in the CY 2022 OPPI/ASC final rule with comment period (86 FR 63902 through 63904). When considering the need for a pain management measure, we analyzed volume data using the methodology established by ASC–7 to determine the proportion of ASC procedures performed for pain management. We found that pain management procedures were the third

²¹⁷ Abrams KD, Balan-Cohen A, Durbha P. Growth in Outpatient Care: The role of quality and value incentives. Deloitte Insights. 2018. Available at: <https://www2.deloitte.com/us/en/insights/industry/health-care/outpatient-hospital-services-medicare-incentives-value-quality.html>.

²¹⁸ Chang AC, Yee J, Orringer MB, Iannettoni MD. Diagnostic thoracoscopic lung biopsy: an outpatient experience. *The Annals of Thoracic Surgery*. 2002;74:1942–7.

most common procedure in CYs 2019 and 2020 and concluded that a pain management measure would provide consumers with important quality of care information. Thus, a volume measure would provide Medicare beneficiaries and other interested parties information on numbers and proportions of procedures by category performed by individual facilities, including for ASC procedures related to pain management.

We note that the ASC-7 measure was adopted in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74507 through 74509) and was not reviewed or endorsed by the Measure Applications Partnership (MAP), which first began its pre-rulemaking review of quality measures across Federal programs in February 2012 after the publication of the CY 2012 OPPS/ASC final rule with comment period in November 2011.²¹⁹ Therefore, for ASC-7 to be adopted in the ASCQR Program measure set, the measure would need to first undergo the pre-rulemaking process specified in section 1890A(a) of the Act.

(2) Solicitation of Comments on the Reimplementation of the ASC Facility Volume Data on Selected ASC Surgical Procedures (ASC-7) Measure or Other Volume Indicator in the ASCQR Program

We seek comment on the potential inclusion of a volume measure in the ASCQR Program, either by adopting the ASC Facility Volume Data on Selected ASC Surgical Procedures (ASC-7) measure or adopting another volume indicator. We also seek comment on what volume data ASCs currently collect and if it is feasible to submit this data to the ASCQR Program, to minimize the collection and reporting burden of an alternative, new volume measure. Additionally, we seek comment on an appropriate timeline for implementing and publicly reporting the measure data.

Specifically, we invite comment on the following:

²¹⁹ Measure Applications Partnership. Pre-Rulemaking Report: Input on Measures Under Consideration by HHS for 2012 Rulemaking Final Report. February 2012. Available at: https://www.qualityforum.org/Publications/2012/02/MAP_Pre-Rulemaking_Report_Input_on_Measures_Under_Consideration_by_HHS_for_2012_Rulemaking.aspx.

- The usefulness of including a volume indicator in the ASCQR Program measure set and publicly reporting volume data;
- Input on the mechanism of volume data collection and submission, including anticipated barriers and solutions to data collection and submission;
- Considerations for designing a volume indicator to reduce collection burden and improve data accuracy;
- Potential reporting of volume by procedure type, instead of total surgical procedure volume data for select categories, and which procedures would benefit from volume reporting; and
- The usefulness of Medicare versus non-Medicare reporting versus other or additional categories for reporting.

(3) Request for Comment: Interoperability Initiatives in ASCs

(a) Background

In 2009, under the Health Information Technology for Economic and Clinical Health Act (HITECH Act), financial incentives were authorized for hospitals and clinicians to adopt and meaningfully use certified electronic health record (EHR) technology.²²⁰ We implemented these financial incentives by establishing the Medicare and Medicaid EHR Incentive Program (now known as the Promoting Interoperability Program), to encourage health care providers to adopt and meaningfully use certified EHR technology (CEHRT) and improve health care quality, efficiency, and patient safety.²²¹ The Promoting Interoperability Program also aims to improve care coordination, reduce costs, ensure privacy and security, improve population health, and engage patients and their caregivers in their own healthcare.

²²⁰ Social Security Act section 1848(o)(2), amended by HITECH Act of 2009 section 4101 (February 2009).

²²¹ Centers for Medicare & Medicaid Services. CMS Finalizes Definition Of Meaningful Use Of Certified Electronic Health Records (EHR) Technology. July 2010. Available at: <https://www.cms.gov/newsroom/fact-sheets/cms-finalizes-definition-meaningful-use-certified-electronic-health-records-ehr-technology>.

ASCs were not included in the HITECH Act and were ineligible for the financial incentives under the Promoting Interoperability Program. This differentiation may contribute to many ASCs continuing to utilize paper-based charts while other healthcare sectors have transitioned to digital records.²²² According to an EHR utilization survey conducted by the Ambulatory Surgical Center Association (ASCA), 54.6 percent of ASCs use an EHR in their facility, indicating that ASCs have a lower adoption rate compared to the 85.9 percent of office-based physicians reported by ONC.²²³ Some EHR vendors have developed ASC-specific solutions; however, ASCs still face significant barriers to implementing EHRs as they can be expensive to implement and update, can require many staff hours for training, and may not offer ASCs a meaningful investment given the types of services provided and levels of patient follow-up required.²²⁴

We refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45460 through 45498) where we finalized changes to the Promoting Interoperability Program, and the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28576 through 28612) which proposes additional changes to the Promoting Interoperability Program. Currently, eligible hospitals and critical access hospitals (CAHs) are required to report on four scored objectives including electronic prescribing, health information exchange, provider to patient exchange, and public health and clinical data exchange, and must also attest to the following²²⁵:

- Security Risk Analysis measure.
- Safety Assurance Factors for EHR Resilience (SAFER) Guides measure.

²²² Vail, T. Electronic Health Record Adoption is Essential for Outpatient Surgery. Managed Healthcare Executive. April 2021. Available at: <https://www.managedhealthcareexecutive.com/view/electronic-health-record-adoption-is-essential-for-outpatient-surgery>.

²²³ Taira, A. ASCA Survey Shows Mixed Usage of EHR among ASCs. ASC Focus: The ASCA Journal. June 2021. Available at: <https://www.ascfocus.org/content/articles-content/articles/2021/digital-debut/asca-survey-shows-mixed-usage-of-ehr-among-ascs>.

²²⁴ Nelson, H. EHR Usability, User Satisfaction High in Ambulatory Surgery Centers. September 2021. Available at: <https://ehrintelligence.com/news/ehr-usability-user-satisfaction-high-in-ambulatory-surgery-centers>.

²²⁵ Centers for Medicare & Medicaid Services. 2022 Medicare Promoting Interoperability Program Requirements. March 2022. Available at: <https://www.cms.gov/regulations-guidance/promoting-interoperability/2022-medicare-promoting-interoperability-program-requirements>.

- Actions to limit or restrict the compatibility or interoperability of CEHRT attestation.
- Office of the National Coordinator for Health Information Technology (ONC) Direct Review Attestation.

(b) Solicitation of Comments on Interoperability in ASCs

We seek comment to explore how ASCs are implementing tools in their facilities toward the goal of interoperability. We are considering a future shift in reporting from QualityNet to eCQMs to aid in delivering effective, safe, efficient, patient-centered, equitable, and timely care²²⁶. Transitioning to eCQMs would increase alignment across quality reporting programs such as the Hospital OQR Program, which adopted the STEMI eCQM in the CY 2022 OPPTS/ASC final rule with comment period (86 FR 63822 through 63875). We are interested in learning more about capabilities for reporting such measures in the future for the ASCQR Program. Generally, we seek input on: (a) Barriers to interoperability in the ASC setting; (b) the impact of health IT, including health IT, certified under the ONC Health IT Certification Program, on the efficiency and quality of health care services furnished in ASCs; and (c) the ability of ASCs to participate in interoperability or EHR-based quality improvement activities, including the adoption of electronic clinical quality measures (eCQMs).

Specifically, we invite comment on:

- What do ASCs perceive as the benefits or risks of implementing interoperability initiatives in their facilities?
- What improvements might be possible with the implementation of interoperability initiatives in ASCs, including EHR utilization (reduced delays, efficiencies, ability to benchmark, etc.)?
- Do ASCs see interoperability initiatives as non-essential or detrimental to their business practices?

²²⁶ Centers for Medicare & Medicaid Services. 2022 Electronic Clinical Quality Measures Basics. March 2022. Available at: <https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/ClinicalQualityMeasures>

Some clinicians practicing in ASCs may voluntarily participate in the MIPS Promoting Interoperability performance category, though they are not required to do so at this time.²²⁷ We have considered several measures from the Promoting Interoperability Program and from the Traditional MIPS Promoting Interoperability measure set for the CY 2022 performance year that may be applicable for the ASC setting.^{228,229} An example of Promoting Interoperability measures potentially applicable for the ASC setting can be found in Table 76. We welcome comment on these specific measure examples, including whether ASCs believe these measures would be appropriate and feasible for use in ASCs.

TABLE 76: Example Promoting Interoperability Measures Applicable to the ASCQR Program

MEASURE NAME		SUMMARY OF MEASURE
e-Prescribing		At least one permissible prescription written by the MIPS eligible clinician is transmitted electronically using CEHRT.
Health Information Exchange(HIE) Bi-Directional Exchange		The MIPS eligible clinician or group must establish the technical capacity and workflows to engage in bi-directional exchange via an HIE for all patients seen by the eligible clinician and for any patient record stored or maintained in their EHR.
Provide Patients Electronic Access to Their Health Information		For at least one unique patient seen by the MIPS eligible clinician: (1) The patient (or the patient-authorized representative) is provided timely access to view online, download, and transmit his or her health information; and (2) The MIPS eligible clinician ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the

²²⁷ Centers for Medicare and Medicaid Services. Quality Payment Program Special Statuses. 2022. Available at: <https://qpp.cms.gov/mips/special-statuses>.

²²⁸ Centers for Medicare and Medicaid Services. 2022 Medicare Promoting Interoperability Program Requirements. Available at: <https://www.cms.gov/regulations-guidance/promoting-interoperability/2022-medicare-promoting-interoperability-program-requirements>.

²²⁹ Centers for Medicare and Medicaid Services. Traditional MIPS: Explore Measures & Activities. Performance Year 2022. Available at: <https://qpp.cms.gov/mips/explore-measures?tab=qualityMeasures&py=2022>.

		Application Programming Interface (API) in the MIPS eligible clinician's certified electronic health record technology (CEHRT).
Query of the Prescription Drug Monitoring Program (PDMP)		For at least one Schedule II opioid electronically prescribed using CEHRT during the performance period, the MIPS eligible clinician uses data from CEHRT to conduct a query of a Prescription Drug Monitoring Program (PDMP) for prescription drug history, except where prohibited and in accordance with applicable law.
Safe Use of Opioids – Concurrent Prescribing electronic clinical quality measure (eCQM)		Proportion of hospitalizations for patients 18 years of age and older prescribed, or continued on, two or more opioids or an opioid and benzodiazepine concurrently at discharge.
Security Risk Analysis		Conduct or review a security risk analysis in accordance with the requirements in 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of ePHI data created or maintained by certified electronic health record technology (CEHRT) in accordance with requirements in 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the MIPS eligible clinician's risk management process.
Support Electronic Referral Loops By Receiving and Reconciling Health Information		For at least one electronic summary of care record received for patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, or for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient, the MIPS eligible clinician conducts clinical information reconciliation for medication, medication allergy, and current problem list.
Support Electronic Referral Loops By Sending Health Information		For at least one transition of care or referral, the MIPS eligible clinician that transitions or refers their patient to another setting of care or health care provider - (1) creates a summary of care record using certified electronic health record technology (CEHRT); and (2)

		electronically exchanges the summary of care record.
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6. Maintenance of Technical Specifications for Quality Measures

We maintain technical specifications for previously adopted ASCQR Program measures. These specifications are updated as we modify the ASCQR Program measure set. The manuals that contain specifications for the previously adopted measures can be found on the QualityNet website at: <https://qualitynet.cms.gov/asc/specifications-manuals>. The policy on maintenance of technical specifications for the ASCQR Program are codified at 42 CFR 416.325. We are not proposing any changes to these policies in this proposed rule.

7. Public Reporting of ASCQR Program Data

We refer readers to the CYs 2012, 2016, 2017, and 2018 OPPS/ASC final rules (76 FR 74514 through 74515; 80 FR 70531 through 70533; 81 FR 79819 through 79820; and 82 FR 59455 through 59470, respectively) for detailed discussion of our policies regarding the public reporting of ASCQR Program data, which are codified at 42 CFR 416.315 (80 FR 70533). We are not proposing any changes to these policies in this proposed rule.

C. Administrative Requirements

1. Requirements Regarding QualityNet Account and Security Official

We refer readers to the CYs 2014, 2016, and 2021 OPPS/ASC final rules with comment period (78 FR 75132 through 75133; 80 FR 70533; and 85 FR 86189, respectively) for the previously finalized QualityNet security official requirements, including requirements for setting up a QualityNet account and the associated timelines. These procedural requirements are codified at 42 CFR 416.310(c)(1)(i). We are not proposing any changes to this policy in this proposed rule.

2. Requirements Regarding Participation Status

We refer readers to the CY 2014 OPPTS/ASC final rule (78 FR 75133 through 75135) for a complete discussion of the participation status requirements for the CY 2014 payment determination and subsequent years. In the CY 2016 OPPTS/ASC final rule (80 FR 70533 through 70534), we codified these requirements regarding participation status for the ASCQR Program at 42 CFR 416.305. We are not proposing any changes to these policies in this proposed rule.

D. Form, Manner, and Timing of Data Submitted for the ASCQR Program

1. Data Collection and Submission

a. Background

We previously codified our existing policies regarding data collection and submission under the ASCQR Program at 42 CFR 416.310.

b. Requirements for Claims-Based Measures

(1) Requirements Regarding Data Processing and Collection Periods for Claims-Based Measures Using Quality Data Codes (QDCs)

We refer readers to the CY 2014 OPPTS/ASC final rule (78 FR 75135) for a complete summary of the data processing and collection periods for the claims-based measures using QDCs for the CY 2014 payment determination and subsequent years. In the CY 2016 OPPTS/ASC final rule (80 FR 70534), we codified the requirements regarding data processing and collection periods for claims-based measures using QDCs for the ASCQR Program at 42 CFR 416.310(a)(1) and (2). We note that the previously finalized data processing and collection period requirements will apply to any future claims-based-measures using QDCs adopted in the ASCQR Program. We are not proposing any changes to these policies in this proposed rule.

(2) Minimum Threshold, Minimum Case Volume, and Data Completeness for Claims-Based Measures Using QDCs

We refer readers to the CY 2018 OPPTS/ASC final rule (82 FR 59472) (and the previous rulemakings cited therein), as well as 42 CFR 416.310(a)(3) and 42 CFR 416.305(c) for our policies about minimum threshold, minimum case volume, and data completeness for claims-based measures using QDCs. We also refer readers to section XVI.D.1.b. of the CY 2022 OPPTS/ASC final rule with comment period (86 FR 63904 through 63905), where we finalized that our policies for minimum threshold, minimum case volume, and data completeness requirements apply to any future claims-based-measures using QDCs adopted in the ASCQR Program. We are not proposing any changes to these policies in this proposed rule.

(3) Requirements Regarding Data Processing and Collection Periods for Non-QDC Based, Claims-Based Measure Data

We refer readers to the CY 2019 OPPTS/ASC final rule with comment period (83 FR 59136 through 59138) for a complete summary of the data processing and collection requirements for the non-QDC based, claims-based measures. We codified the requirements regarding data processing and collection periods for non-QDC, claims-based measures for the ASCQR Program at 42 CFR 416.310(b). We note that these requirements for non-QDC based, claims-based measures apply to the following previously adopted measures:

- ASC–12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy; and
- ASC–19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers (NQF #3357).

We are not proposing any changes to these policies in this proposed rule.

c. Requirements for Data Submitted via an Online Data Submission Tool

(1) Requirements for Data Submitted via a CMS Online Data Submission Tool

We refer readers to the CY 2018 OPPTS/ASC final rule (82 FR 59473) (and the previous rulemakings cited therein) and 42 CFR 416.310(c)(1) for our requirements regarding data submitted via a CMS online data submission tool. We are currently using the Hospital Quality

Reporting (HQR) System (formerly referred to as the QualityNet Secure Portal) to host our CMS online data submission tool, available by securely logging in at: <https://hqr.cms.gov/hqrng/login>. We note that in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59473), we finalized expanded submission via the CMS online tool to also allow for batch data submission and made corresponding changes at 42 CFR 416.310(c)(1)(i). We are not proposing any changes to these policies in this proposed rule.

The following previously finalized measures require data to be submitted via a CMS online data submission tool for the CY 2021 payment determination and subsequent years:

- ASC–9: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients;

- ASC–11: Cataracts: Improvement in Patients’ Visual Function within 90 Days Following Cataract Surgery;

- ASC–13: Normothermia Outcome; and

- ASC–14: Unplanned Anterior Vitrectomy.

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63883 through 63885), we finalized our proposal to require and resume data collection beginning with the CY 2023 reporting period/CY 2025 payment determination for the following four measures:

- ASC–1: Patient Burn;

- ASC–2: Patient Fall;

- ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant;

and

- ASC–4: All-Cause Hospital Transfer/Admission.

Measure data for these measures would be submitted via the HQR System (formerly referred to as the QualityNet Secure Portal). We are not proposing any changes to these policies in this proposed rule.

(2) Requirements for Data Submitted via a Non-CMS Online Data Submission Tool

We refer readers to the CY 2014 OPPS/ASC final rule (78 FR 75139 through 75140) and the CY 2015 OPPS/ASC final rule (79 FR 66985 through 66986) for our requirements regarding data submitted via a non-CMS- online data submission tool (specifically, the CDC's National Healthcare Safety Network (NHSN) website). We codified our existing policies regarding the data collection periods for measures involving online data submission and the deadline for data submission via a non-CMS online data submission tool at 42 CFR 416.310(c)(2). While we did not finalize any changes to those policies in the CY 2022 OPPS/ASC final rule (86 FR 63875 through 63883), we did finalize policies specific to the COVID-19 Vaccination Coverage Among Health Care Personnel measure (ASC-20), for which data will be submitted via the CDC NHSN website. We are not proposing any changes to these policies in this proposed rule.

e. ASCQR Program Data Submission Deadlines

We refer readers to the CY 2021 OPPS/ASC final rule with comment period (85 FR 86191) for a detailed discussion of our data submission deadlines policy, which we codified at 42 CFR 416.310(f). We are not proposing any changes to this policy in this proposed rule.

f. Review and Corrections Period for Measure Data Submitted to the ASCQR Program

Review and Corrections Period for Data Submitted via a CMS Online Data Submission Tool

We refer readers to the CY 2021 OPPS/ASC final rule with comment period (85 FR 86191 through 86192) for a detailed discussion of our review and corrections period policy, which we codified at 42 CFR 416.310(c)(1)(iii). We are not proposing any changes to this policy in this proposed rule.

g. ASCQR Program Reconsideration Procedures

We refer readers to the CY 2016 OPPS/ASC final rule (82 FR 59475) (and the previous rulemakings cited therein) and 42 CFR 416.330 for the ASCQR Program's reconsideration policy. We are not proposing any changes to this policy in this proposed rule.

h. Extraordinary Circumstances Exception (ECE) Process

We refer readers to the CY 2018 OPPTS/ASC final rule (82 FR 59474 through 59475) (and the previous rulemakings cited therein) and 42 CFR 416.310(d) for the ASCQR Program's extraordinary circumstance exceptions (ECE) requests policy. We are not proposing any changes to this policy in this proposed rule.

E. Proposed Payment Reduction for ASCs That Fail to Meet the ASCQR Program Requirements

1. Statutory Background

We refer readers to the CY 2012 OPPTS/ASC final rule with comment period (76 FR 74492 through 74493) for a detailed discussion of the statutory background regarding payment reductions for ASCs that fail to meet the ASCQR Program requirements.

2. Policy Regarding Reduction to the ASC Payment Rates for ASCs That Fail to Meet the ASCQR Program Requirements for a Payment Determination Year

The national unadjusted payment rates for many services paid under the ASC payment system are equal to the product of the ASC conversion factor and the scaled relative payment weight for the APC to which the service is assigned. For CY 2022, the ASC conversion factor is equal to the conversion factor calculated for the previous year updated by the productivity-adjusted hospital market basket update factor. The productivity adjustment is set forth in section 1833(i)(2)(D)(v) of the Act. The productivity-adjusted hospital market basket update is the annual update for the ASC payment system for a 5-year period (CY 2019 through CY 2023). Under the ASCQR Program, in accordance with section 1833(i)(7)(A) of the Act and as discussed in the CY 2013 OPPTS/ASC final rule with comment period (77 FR 68499), any annual increase in certain payment rates under the ASC payment system shall be reduced by 2.0 percentage points for ASCs that fail to meet the reporting requirements of the ASCQR Program. This reduction applied beginning with the CY 2014 payment rates (77 FR 68500). For a complete discussion of the calculation of the ASC conversion factor and our finalized proposal to update the ASC payment rates using the inpatient hospital market basket update for CYs 2019

through 2023, we refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59073 through 59080).

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499 through 68500), in order to implement the requirement to reduce the annual update for ASCs that fail to meet the ASCQR Program requirements, we finalized our proposal that we would calculate two conversion factors: a full update conversion factor and an ASCQR Program reduced update conversion factor. We finalized our proposal to calculate the reduced national unadjusted payment rates using the ASCQR Program reduced update conversion factor that would apply to ASCs that fail to meet their quality reporting requirements for that calendar year payment determination. We finalized our proposal that application of the 2.0 percentage point reduction to the annual update may result in the update to the ASC payment system being less than zero prior to the application of the productivity adjustment.

The ASC conversion factor is used to calculate the ASC payment rate for services with the following payment indicators (listed in Addenda AA and BB to the proposed rule, which are available via the Internet on the CMS website): “A2”, “G2”, “P2”, “R2” and “Z2”, as well as the service portion of device-intensive procedures identified by “J8” (77 FR 68500). We finalized our proposal that payment for all services assigned the payment indicators listed above would be subject to the reduction of the national unadjusted payment rates for applicable ASCs using the ASCQR Program reduced update conversion factor (77 FR 68500).

The conversion factor is not used to calculate the ASC payment rates for separately payable services that are assigned status indicators other than payment indicators “A2”, “G2”, “J8”, “P2”, “R2” and “Z2.” These services include separately payable drugs and biologicals, pass-through devices that are contractor-priced, brachytherapy sources that are paid based on the OPPS payment rates, and certain office-based procedures, radiology services and diagnostic tests where payment is based on the PFS nonfacility PE RVU-based amount, and a few other specific services that receive cost-based payment (77 FR 68500). As a result, we also finalized our

proposal that the ASC payment rates for these services would not be reduced for failure to meet the ASCQR Program requirements because the payment rates for these services are not calculated using the ASC conversion factor and, therefore, are not affected by reductions to the annual update (77 FR 68500).

Office-based surgical procedures (generally those performed more than 50 percent of the time in physicians' offices) and separately paid radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents) are paid at the lesser of the PFS nonfacility PE RVU-based amounts or the amount calculated under the standard ASC ratesetting methodology. Similarly, in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66933 through 66934), we finalized our proposal that payment for certain diagnostic test codes within the medical range of CPT codes for which separate payment is allowed under the OPPS will be at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the standard ASC ratesetting methodology when provided integral to covered ASC surgical procedures. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68500), we finalized our proposal that the standard ASC ratesetting methodology for this type of comparison would use the ASC conversion factor that has been calculated using the full ASC update adjusted for productivity. This is necessary so that the resulting ASC payment indicator, based on the comparison, assigned to these procedures or services is consistent for each HCPCS code, regardless of whether payment is based on the full update conversion factor or the reduced update conversion factor.

For ASCs that receive the reduced ASC payment for failure to meet the ASCQR Program requirements, we have noted our belief that it is both equitable and appropriate that a reduction in the payment for a service should result in proportionately reduced coinsurance liability for beneficiaries (77 FR 68500). Therefore, in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68500), we finalized our proposal that the Medicare beneficiary's national

unadjusted coinsurance for a service to which a reduced national unadjusted payment rate applies will be based on the reduced national unadjusted payment rate.

In that final rule with comment period, we finalized our proposal that all other applicable adjustments to the ASC national unadjusted payment rates would apply in those cases when the annual update is reduced for ASCs that fail to meet the requirements of the ASCQR Program (77 FR 68500). For example, the following standard adjustments would apply to the reduced national unadjusted payment rates: the wage index adjustment; the multiple procedure adjustment; the interrupted procedure adjustment; and the adjustment for devices furnished with full or partial credit or without cost (77 FR 68500). We believe that these adjustments continue to be equally applicable to payment for ASCs that do not meet the ASCQR Program requirements (77 FR 68500).

In the CY 2015 through CY 2022 OPPS/ASC final rules with comment period we did not make any other changes to these policies. We propose the continuation of these policies for CY 2023.

XVI. Requirements for the Rural Emergency Hospital Quality Reporting (REHQR) Program

A. Background

1. Overview

We refer readers to section XIV of the CY 2020 OPPS/ASC final rule with comment period (84 FR 61410) for a general overview of our Hospital Outpatient Quality Reporting (OQR) program and to the CY 2019 OPPS/ASC final rule with comment period (83 FR 58820 through 58822) where we previously discussed our Meaningful Measures Framework.

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68493 through 68494) for a detailed discussion of the priorities we consider for other

quality programs for outpatient settings including the Hospital OQR and the Ambulatory Surgical Center Quality Reporting (ASCQR) Program.

2. Statutory History of Quality Reporting for REHs

The Consolidated Appropriations Act (CAA), 2021, was signed into law in December 2020. In this legislation, Congress established a new Medicare provider type: Rural Emergency Hospitals (REHs). Section 125 of Division CC of the CAA added section 1861(kkk) to the Social Security Act (the Act). This section defines an REH as a facility that, in relevant part, was as of December 27, 2020 a Critical Access Hospital (CAH) or a subsection (d) hospital with not more than 50 beds located in a county (or equivalent unit of local government) in a rural area (defined in section 1886(d)(2)(D) of the Act) or was a subsection (d) hospital with not more than 50 beds that was treated as being in a rural area pursuant to section 1886(d)(8)(E) of the Act. Among other requirements, an REH must apply for enrollment in the Medicare program, provide emergency department services and observation care, and, at the election of the REH, provide certain services furnished on an outpatient basis, and not provide any acute care inpatient services (other than post-hospital extended care services furnished in a distinct part unit licensed as a skilled nursing facility (SNF)). Payment with respect to REH services may be made on or after January 1, 2023. Generally, a subsection (d) hospital is an acute care hospital—particularly one that receives payments under Medicare’s inpatient prospective payment system (IPPS) when providing covered inpatient services to eligible beneficiaries. Similarly, a CAH is (as defined in section 1820 of the Act) a facility with no more than 25 inpatient beds, unless operating a psychiatric and/or a rehabilitation distinct part unit which may have up to 10 beds each.

We refer readers to section XIX of this proposed rule for our proposals with respect to payment policies, conditions of participation, and provider enrollment for REHs.

Under section 1861(kkk)(7) of the Act, as added by section 125 of Division CC of the CAA also requires the Secretary to establish quality measurement reporting requirements for REHs, which may include the use of a small number of claims-based measures or patient

experience surveys. An REH must submit quality measure data to the Secretary, and the Secretary shall establish procedures to make the data available to the public on a CMS website.

3. Scope

The number of hospitals that convert to an REH and their characteristics may inform the selection of quality measures as we seek measures that are useable by REHs and that have sufficient numbers of REHs with sufficient volume of services to have meaningful measurement for individual facilities and, importantly, the public. REHs as defined by statute would be rural subsection (d) hospitals with not more than 50 beds and CAHs that convert in status to REHs. To estimate the number of facilities that are likely to consider conversion to an REH, one study²³⁰ analyzed 1,673 rural hospitals on three criteria: (1) 3-years negative total margin; (2) average daily census of acute and swing beds being less than three; and (3) net patient revenue less than \$20 million.²³¹ The analysis concluded that 68 would consider converting.²³² In contrast, an industry analysis based on estimated REH reimbursement and several financial assumptions²³³ and four simulation methods, estimated that up to 600 CAHs would benefit from conversion to REH status.²³⁴ Regardless of the exact number of facilities which convert, there may be quality measure challenges due to the low numbers of hospitals and volume of services provided by

²³⁰ Pink, G. H., et al., *How Many Hospitals Might Convert to a Rural Emergency Hospital (REH)* 8 (July 2021), available at <https://www.shepscenter.unc.edu/download/23091/>.

²³¹ *Ibid.* at 5.

²³² *Ibid.* at 1.

²³³ Estimated average facility payment, estimated outpatient fee schedule payment, estimated average skilled nursing facility payment rates by State, presence or loss of swing bed payments, and continuance or cessation of 340B eligibility.

²³⁴ <https://www.claconnect.com/resources/articles/2022/a-path-forward-clas-simulations-on-rural-emergency-hospital-designation#:~:text=Depending%20on%20resolution%20of%20key,benefit%20from%20the%20new%20designatio n> (Accessed April 8, 2022).

these facilities. We discuss possible approaches for addressing these low volume concerns in section XV.B.2.d of this proposed rule.

B. REHQR Program Quality Measures

1. Considerations in the Selection of REHQR Program Quality Measures

We seek to adopt a concise set of important, impactful, reliable, accurate, and clinically relevant measures for REHs that would inform consumer decision-making regarding care and further quality improvement efforts in the REH setting. In the CY 2022 OPPI/ASC proposed rule (86 FR 42285 through 42289), we sought comment through a Request for Information on various topics on REHs. Specifically, we sought input on the concerns of rural providers that should be taken into consideration by CMS in establishing quality measures and quality reporting requirements for REHs (86 FR 42288). We include issues raised and suggestions made from that Request for Information in this proposed rule as considerations for selecting measures for an REH quality reporting program.

a. Measure Endorsement

Under section 1861(kkk)(7)(C)(i) of the Act, unless the exception of subclause (ii) applies, a measure selected for the REHQR Program must have been endorsed by the entity with a contract under section 1890(a) of the Act. The National Quality Forum (NQF) currently holds this contract. Subclause (ii) provides that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a measure has not been endorsed by the entity with contract under section 1890(a) of the Act, the Secretary may specify a measure that is not endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. In general, we prefer to adopt measures that have been endorsed by the NQF because it is a national multi-stakeholder organization with a well-documented and rigorous approach to consensus development. However, due to lack of an endorsed measure for a given facility setting, procedure, or other aspect of care, the requirement that measures reflect consensus among affected parties can be achieved in other ways, including

through the measure development process, through broad acceptance, use of the measure(s), and through public comment.

b. Accountability and Quality

The overarching goals of this program, in line with other quality programs, are to improve the quality of care provided to beneficiaries, facilitate public transparency, and ensure accountability. We note that many subsection (d) hospitals and CAHs established on or before December 27, 2020 that are eligible for REH conversion are currently reporting outpatient quality data under the Hospital OQR Program and have publicly available data. We note that while such reporting is required for subsection (d) hospitals in order to avoid a payment penalty under the Hospital OQR Program, data submission and public reporting is voluntary for CAHs. We intend to adopt measures for the REHQR Program that are useful for REHs for their quality improvement efforts, but it is vital that measure information be of sufficient volume to meet case thresholds for facility level public reporting. See Tables 76 and 77 of this proposed rule for the current number of facilities and their current public reporting of Hospital OQR Program measure data as of January 2022 as well as the most recent data available for certain measures that have been removed from the OQR Program, but that may have continued relevance for an REHQR Program. The Medicare Beneficiary Quality Improvement Project (MBQIP) under the Medicare Rural Hospital Flexibility (Flex) program of the Health Resources and Services Administration utilizes outpatient quality data voluntarily reported by CAHs through the Hospital OQR Program. We note that per the 2020 MBQIP Quality Measures annual report, 1,353 CAHs (that is 86.5 percent of those eligible) reported data for at least one OQR measure,²³⁵ which is greater than the number of facilities having data displayed Table 77 due to the low reporting volume exclusion limitation of Care Compare, indicating a greater capacity for these facilities to report

²³⁵https://www.flexmonitoring.org/sites/flexmonitoring.umn.edu/files/media/PA_Annual%20Report_2020.pdf (Accessed June 5, 2022);

on certain Hospital OQR measures.²³⁶ Table 76 reflects data for reporting by rurally located subsection (d) hospitals with not more than 50 beds, and Table 77 reflects data for reporting by CAHs for the most recent Care Compare results available. These analyses present a starting place for assessing the extent of quality reporting by CAHs and small, rural hospitals for current or relatively recent measures with sufficient data for public reporting that could be considered for an REHQR Program.

TABLE 76: Rural* subsection (d) hospitals with not more than 50 beds Publicly Reporting Selected Hospital Outpatient Measures (Current and those Previously Removed)**

Measure Number	Measure Title	Number Reporting With Measure Displayed on Care Compare	Percent Reporting
Hospital OQR measures on Care Compare, January 2022			
	Rural subsection (d) hospitals with not more than 50 beds with publicly reported selected measures; total of 191 hospitals	188	
OP-2	Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival	4	2.13%
OP-3b	Median Time to Transfer to Another Facility for Acute Coronary Intervention	6	3.19%
OP-8	MRI Lumbar Spine for Low Back Pain	4	2.13%

²³⁶ <https://www.hrsa.gov/rural-health/grants/rural-hospitals/medicare-beneficiary-quality-improvement> (Accessed June 3, 2022).

OP-10	Abdomen CT Use of Contrast Material	124	65.96%
OP-13	Outpatients who got cardiac imaging stress tests before low-risk outpatient surgery	27	14.36%
OP-18b	Average (median) time patients spent in the emergency department before leaving from the visit	152	80.85%
OP-18c	Average (median) time patients spent in the emergency department before leaving from the visit- Psychiatric/Mental Health Patients	92	48.94%
OP-22	Left before being seen	145	77.13%
OP-23	Head CT results	13	6.91%
OP-29	Endoscopy/polyp surveillance: appropriate follow-up interval for normal colonoscopy in average risk	109	57.98%
OP-31	Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	2	1.06%
OP-32	Rate of unplanned hospital visits after colonoscopy (per 1,000 colonoscopies)	123	65.43%
OP-35-ADM	Rate of inpatient admissions for patients receiving outpatient chemotherapy	23	12.23%
OP-35-ED	Rate of emergency department (ED) visits for patients receiving outpatient chemotherapy	23	12.23%
OP-36	Ratio of unplanned hospital visits after hospital outpatient surgery	57	30.32%
	No OQR Measures Reported	8	4.26%
Hospital OQR measures on Care Compare, January 2021			
	Rural subsection (d) hospitals with not more than 50 beds with publicly reported measures	177	
OP-33	External Beam Radiotherapy for Bone Metastases	5	2.82%
Hospital OQR measures on Care Compare, January 2020			
	Rural subsection (d) hospitals with not more than 50 beds with publicly reported selected measures	175	
OP-5	Median Time to ECG	131	74.86%
OP-9	Mammography Follow-up Rates	121	69.14%
OP-11	Thorax CT Use of Contrast Material	118	67.43%
OP-14	Outpatients with brain CT scans who got a sinus CT scan at the same time	66	37.71%
OP-30	Endoscopy/polyp surveillance: colonoscopy interval for patients with a history of adenomatous polyps	110	62.86%
Hospital OQR measures on Care Compare, January 2018			
	Rural subsection (d) hospitals with not more than 50 beds with publicly reported selected measures	174	
OP-4	Aspirin at Arrival	130	74.71%
OP-20	Door to diagnostic evaluation	144	82.76%

Data sources: Hospital Compare data updated in January 2018, January 2020, January 2021, and January 2022, CMS Providers of Services File - Hospital & Non-Hospital Facilities Q1 2022, and QIO Program Resource System (PRS).

Hospitals are considered eligible to report on Hospital Compare when having a Medicare accept date prior to the latest measure end date and are identified as open as of PRS access date.

*Rural/urban location is identified by the CMS Providers of Services File - Hospital & Non-Hospital Facilities Q1 2022. Rural/urban location is based on Core Based Statistical Area (CBSA), which indicates whether the county is defined as urban or rural to limit the analysis to areas currently viewed as rural.

** A hospital is considered reporting for this data presentation if it has a Hospital OQR measure published on Care Compare; a hospital may report data to CMS, but not have data published on Care Compare due to not meeting case number requirements

TABLE 77: Critical Access Hospitals Publicly Reported Selected Hospital Outpatient Measures*

Measure Number	Measure Title	Number Reporting With Measure Displayed on Care Compare	Percent of Reporting CAHs With Measure Results Displayed
Hospital OQR measures on Care Compare, January 2022			
	CAHs with publicly reported measures; total number 1,354 plus 5 new CAHs not yet with data	1,354	
OP-2	Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival	5	0.37%
OP-3b	Median Time to Transfer to Another Facility for Acute Coronary Intervention	17	1.26%
OP-8	MRI Lumbar Spine for Low Back Pain	2	0.15%
OP-10	Abdomen CT Use of Contrast Material	838	61.89%
OP-13	Outpatients who got cardiac imaging stress tests before low-risk outpatient surgery	79	5.83%
OP-18b	Average (median) time patients spent in the emergency department before leaving from the visit	1,085	80.13%
OP-18c	Average (median) time patients spent in the emergency department before leaving from the visit- Psychiatric/Mental Health Patients	543	40.10%
OP-22	Left before being seen	775	57.24%
OP-23	Head CT results	51	3.77%
OP-29	Endoscopy/polyp surveillance: appropriate follow-up interval for normal colonoscopy in average risk	207	15.29%
OP-31	Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	7	0.52%
OP-32	Rate of unplanned hospital visits after colonoscopy (per 1,000 colonoscopies)	625	46.16%
OP-35-ADM	Rate of inpatient admissions for patients receiving outpatient chemotherapy	84	6.20%
OP-35-ED	Rate of emergency department (ED) visits for patients receiving outpatient chemotherapy	84	6.20%
OP-36	Ratio of unplanned hospital visits after hospital outpatient surgery	94	6.94%
Hospital OQR measures on Care Compare, January 2021			
	CAHs with publicly reported selected measures	1,347	
OP-33	External Beam Radiotherapy for Bone Metastases	6	0.45%
Hospital OQR measures on Care Compare, January 2020			
	CAHs with publicly reported selected measures	1,343	
OP-5	Median Time to ECG	863	64.26%
OP-9	Mammography Follow-up Rates	904	67.31%
OP-11	Thorax CT Use of Contrast Material	818	60.91%
OP-14	Outpatients with brain CT scans who got a sinus CT scan at the same time	615	45.79%
OP-30	Endoscopy/polyp surveillance: colonoscopy interval for patients with a history of adenomatous polyps	188	14.00%
Hospital OQR measures on Care Compare, January 2018			
	CAHs with publicly reported measures	1,325	
OP-4	Aspirin at Arrival	612	46.19%

OP-20	Door to diagnostic eval	726	54.79%
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Data sources: Hospital Compare data updated in January 2018, January 2020, January 2021, and January 2022, CMS Providers of Services File - Hospital & Non-Hospital Facilities Q1 2022, and QIO Program Resource System (PRS).

Hospitals are considered eligible to report on Hospital Compare when having a Medicare accept date prior to the latest measure end date and are identified as open as of PRS access date.

*Rural/urban location is identified by the CMS Providers of Services File - Hospital & Non-Hospital Facilities Q1 2022. Rural/urban location is based on Core Based Statistical Area (CBSA), which indicates whether the county is defined as urban or rural to limit the analysis to areas currently viewed as rural.

** A hospital is considered reporting for this data presentation if it has a Hospital OQR measure published on Care Compare; a hospital may report data to CMS, but not have data published on Care Compare due to not meeting case number requirements

c. Burden

We recognize REHs will be smaller hospitals that have limited resources compared with larger hospitals in metropolitan areas.²³⁷ Certain measures, particularly those that are chart-abstracted, may be more burdensome than other measures to report. Rural facilities often experience shortage of non-clinical staff to perform certain administrative duties, such as collecting and reporting quality measures.²³⁸ For the REHQR Program, we intend to seek balance between the costs associated with reporting data and the benefits of ensuring safety and quality of care through measurement and public reporting. We recognize these challenges faced by the hospitals eligible to convert to REH status may increase reporting burden and may necessitate limiting the number of quality measures in use for the REH quality reporting program to facilitate success. There are several avenues we can consider for limiting this burden (that is, reducing the costs associated with reporting the data required for quality measurement) including: (1) use of Medicare claims-based measures; and (2) use digital quality measures in place of chart-abstraction. In addition, we believe that, to the extent possible, existing quality measures should align across Medicare, Medicaid, and other payers to minimize reporting burden. The Hospital Promoting Interoperability Program, which includes a requirement to report certain eCQMs, shows that of 1,308 CAHs, 1,066 (81.5 percent) met eCQM reporting requirements for the first quarter of 2022. This indicates a relatively high level of reporting

²³⁷ American Hospital Association, *Rural Report 2019: Challenges Facing Rural Communities and the Roadmap to Ensure Local Access to High-quality, Affordable Care 3* (February 2019), available at <https://www.aha.org/system/files/2019-02/rural-report-2019.pdf>.

²³⁸ Ibid at 6 & 7.

capability for eCQMs by a hospital type that tends to be smaller and more likely to be situated in more rural areas.

d. Rural Relevance

The measures included in an REH quality program should reflect the types of services and care delivered most frequently in that setting, along with areas of care where there may be inappropriate variation or potential quality of care challenges.²³⁹ For example, an REH may provide ambulatory and outpatient procedures with supporting diagnostic services such as laboratory tests and x-rays, and be considered a low-volume emergency department (ED). Larger variation between these smaller providers due to lower case volumes could allow some topped-out measures that are no longer meaningful for larger or urban hospitals to be utilized for rural hospital quality reporting. More specifically, topped-out measures could be re-purposed for reporting the quality of their rural counterparts, which have not achieved the level of success in these measures as often as a result of low-case volumes. In addition, we believe that it may be appropriate to include some measures that would apply to all REHs, for example, measures that are tailored to ED and observation services, while instituting additional applicable measures for REHs that choose to provide additional outpatient services.

e. Low Service and Patient Volume

Section 1861(kkk)(7)(C)(iii) of the Act specifies that the Secretary shall, in the selection of measures, take into consideration ways to account for rural emergency hospitals that lack sufficient case volume to ensure that the performance rates for such measures are reliable. Effective quality measurement requires a sufficiently large patient number or services volume to account for level of measure variability. This ensures that the quality measure has the necessary reliability of an individual facility's information as well as to detect meaningful distinctions

²³⁹ National Quality Forum, *Measure Application Partnership: A Core Set of Rural Relevant Measures and Measuring and Improving Access to Care, 2018 Recommendations from the MAP Rural Health Workgroup, Final Report 24 & 26* (August 2018), available at https://www.qualityforum.org/Publications/2018/08/MAP_Rural_Health_Final_Report_-_2018.aspx.

between facilities. Possible approaches to quality measurement where low volume is expected are discussed in section XV.B.2.d of this proposed rule.

f. Health Equity

We believe methods to examine disparities in health care delivery and quality measurement should include stratified results using, for example, patient dual eligibility and other social vulnerability factors as well as patient demographic information to capture the breadth of social determinants of health in rural areas.²⁴⁰ Other factors or indicators to consider for equity measurement include access to care, disability and functional status, veteran status, health literacy, language preference, race and ethnicity, tribal membership, sexual orientation and gender identity, and religious minority status. These demographic characteristics and social determinants of health can enable a more comprehensive assessment of health equity to further identify and develop actionable strategies, including the selection of quality measures and quality improvement, to promote health equity.

One approach being considered to measure equity across our programs is the expansion of efforts to report quality measure results stratified by patient social risk factors and demographic variables. The Request for Information (RFI) included in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 19415), titled “Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality Programs” describes key considerations across all CMS

²⁴⁰ Agency for Healthcare Research and Quality, *Chartbook on Rural Healthcare: National Healthcare Quality and Disparities Report 8 & 13-14* (November 2021) available at <https://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/nhqdr/chartbooks/2019-qdr-rural-chartbook.pdf>.

quality programs, including the Hospital OQR Program, when advancing the use of measure stratification to address health care disparities and advance health equity across our programs.

We refer readers to the full RFI in the FY 2023 IPPS/LTCH PPS proposed rule for details on these considerations (87 FR 19415); for comments and feedback on the application of these principles to a quality reporting program for REHs, please respond to this RFI.

We discuss possible measures of equity for use in a REHQR Program in section XV.B.3 of this proposed rule.

2. Request for Comment on Potential Measures for an REHQR Program

a. Selected Hospital OQR Program Measures Recommended by the National Advisory Committee on Rural Health and Human Services for the REHQR Program

The National Advisory Committee on Rural Health and Human Services for the REHQR Program's measure recommendations drew from measures that were currently being reported or were recently reported under CMS' Hospital OQR Program or HRSA's MBQIP.²⁴¹ In this proposed rule, we request comment on a selection of measures from this report as we review measures for potential future inclusion in the REHQR Program. We seek to better understand how these measures may help achieve our goal of selecting measures for the REHQR Program that focus on REH areas of care, especially ED care. Measures with an OP designation represent current or past Hospital OQR measures; measure specifications are contained in program specifications manuals (current and past back to CY 2013) available on the QualityNet website.²⁴²

(1) OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival

This chart-abstracted process measure calculates the percentage of ED acute myocardial AMI patients with ST-segment elevation on the electrocardiogram (ECG) closest to arrival time receiving fibrinolytic therapy during the ED stay and having a time from ED arrival to

²⁴¹ <https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/rural/publications/2021-rural-emergency-hospital-policy-brief.pdf> (Accessed April 8, 2022).

²⁴² <https://qualitynet.cms.gov/outpatient/specifications-manuals> (Accessed May 20, 2022).

fibrinolysis of 30 minutes or less. The measure is calculated using chart-abstracted data, on a rolling, quarterly basis and is publicly reported, in aggregate, for one calendar year. We have publicly reported this measure under the Hospital OQR Program since 2012. In the CY 2022 OPP/ASC final rule (86 FR 63823 through 63824), OP-2 was finalized for removal from the Hospital OQR Program beginning with the CY 2023 reporting period/CY 2025 payment determination, with planned replacement with an electronic clinical quality measure (eCQM) that combines this measure with OP-3 Median Time to Transfer to Another Facility for Acute Coronary Intervention, the ST-Segment Elevation Myocardial Infarction (STEMI) eCQM (86 FR 63823 through 63824). The adoption of the STEMI eCQM and the measure calculation method for the Hospital OQR Program was finalized in this same final rule (86 FR 63837 through 63840). The current level of rurally located subsection (d) hospitals with not more than 50 beds (4 total) and CAHs (5 total) with data publicly displayed on Care Compare for this measure is relatively low (see Table 77 and 77 of this proposed rule). However, the MBQIP (which utilizes data reported through the Hospital OQR Program) reported that about 71 percent of CAHs reported at least one case for the OP-2 measure.

(2) OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention

Time to transfer to receiving facilities delays time to reperfusion in patients with ST segment elevation myocardial infarction (STEMI). There are multiple, critical system practices that minimize transfer time to receiving centers; however, two characteristics of the sending facility have been noted as most important: performance of a prehospital electrocardiogram and having established transfer protocols.²⁴³ The use of time-to-transfer quality measures in rural

²⁴³ Mumma, BE, Williamson, C, Diercks, DB. Minimizing transfer time to an ST segment elevation myocardial infarction receiving center: Modified Delphi Consensus. *Crit Pathw Cardiol* 2014, Mar; 13(1):20-24.

areas may raise equity concerns as the geographic isolation of many rural facilities and the lack of uniformity in geographic isolation may be outside the control of the facilities measured.

In the CY 2022 OPPTS/ASC final rule with comment period (86 FR 63458), OP-3 was finalized for removal from the Hospital OQR Program beginning with the CY 2023 reporting period/CY 2025 payment determination due to availability of a more broadly applicable measure that captures the OP-2 and OP-3 measure populations and expand beyond these populations to comprehensively measure the timeliness and appropriateness of STEMI care, with planned replacement of these measures by an eCQM. The current level of subsection (d) hospitals and CAHs with data publicly displayed on Care Compare for this chart-abstracted measure is relatively low possibly due to case numbers below the threshold to allow the data to be publicly reported (see Tables 76 and 77 of this proposed rule). About 70 percent of CAHs reported at least one case for this measure through the MBQIP program.

We invite public comment on potential future adoption of OP-3 and its replacement STEMI eCQM for the REHQR Quality Reporting Program.

(3) OP-4: Aspirin on Arrival

This chart-abstracted process measure documents the percentage of ED acute myocardial infarction (AMI) patients or chest pain patients (with probable cardiac chest pain) without aspirin contraindications who received aspirin within 24 hours before ED arrival or prior to transfer at the facility level. The early use of aspirin in patients with AMI results in a significant reduction in adverse events and subsequent mortality. OP-4 was implemented into the Hospital OQR program in CY 2008 and removed for the CY 2020 payment determination and subsequent years due to performance being sufficiently high with little variation between providers (82 FR 52570).

While being topped out at the national level and no longer useful for larger or urban providers, this measure could be useful for smaller providers, including those that may convert to REH status, due to sufficient variation between individual facilities to permit the measurement of differences. An analysis (Table 78) of the last publicly reported OP-4 data for small rurally

located hospitals and CAHs shows such variation between facilities (both urban and rural) with the lower 10th percentile. The analysis found providers with much lower percentages of proper aspirin administration across urban/rural areas for CAHs and subsection (d) hospital types and slightly higher variation as measured by standard deviation, indicating room for improvement. We note that some CAHs, while considered rural for Medicare payment purposes, are situated in areas that can be considered urban. The analysis in Table 78 is only to examine for variations by urban versus rural setting. This measure was retired and NQF endorsement removed from the Cardiovascular Project in 2013 with subsequent removal from the Hospital OQR Program for the CY 2018 reporting period/CY 2020 payment determination. A similar measure, Emergency Medicine: Aspirin at Arrival for Acute Myocardial Infarction (AMI) was also retired and NQF endorsement removed in 2017 (82 FR 59439).

TABLE 78: Urban, Rural subsection (d) Hospitals with not more than 50 beds and CAHs Reporting* OP-4: Aspirin on Arrival Reporting (Care Compare 2018)**

Hospital Type	Rural/Urban	N	Mean	Std Dev	Min	10th PCTL	25th PCTL	Median	75th PCTL	90th PCTL	Max
CAH	Rural	463	94.78	6.65	57	86	92	97	100	100	100
CAH	Urban	149	95.17	6.08	65	87	93	98	100	100	100
subsection (d) hospital	Rural	130	93.98	6.92	63	86.5	92	96	99	100	100
subsection (d) hospital	Urban	87	94.26	5.81	70	87	91	96	99	100	100

* Hospitals are considered reporting if measure data are published on Care Compare. Rural/urban location is identified by the CMS Providers of Services File - Hospital & Non-Hospital Facilities Q1 2022. Rural/urban location is based on Core Based Statistical Area (CBSA), which indicates whether the county is defined as urban or rural.

**The January 2018 release of Care Compare contained the final publicly available data for OP-4.

(4) OP-18: Median Time from ED Arrival to ED departure for Discharged ED Patients

Care provided in the ED will be a focus of REH services and we seek measures that assess the quality of care in this setting. OP-18 is a chart-abstracted measure that evaluates the time between the arrival to and departure from the ED or ED throughput time. Improving ED throughput times is important for alleviating overcrowding and reducing wait times; conditions

which can lead to potential safety events and patient dissatisfaction.²⁴⁴ OP-18 is a current measure for the Hospital OQR Program and reporting for this measure by hospitals eligible to convert to REH status is relatively high (see Table 76 of this proposed rule). Note that the OP-18 measure is calculated for varying types of patients: the OP-18b measure excludes psychiatric/mental health and transferred patients; alternatively, the OP-18c measure includes information only for psychiatric/mental health patients.

(5) OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional

This chart-abstracted, ED measure measures the mean time between patient presentation to the ED and the first moment the patient is seen by a qualified medical person for patient evaluation and management. As REH's main area of care and associated services provided will be related to their ED, and emergency services can be time-sensitive, this measure provides tailored accountability for this setting type. OP-20 was removed from the Hospital OQR Program in the CY 2018 OPPI/ASC final rule beginning with CY 2020 payment determinations (82 FR 52570). During regular measure maintenance, specific concerns were raised by a Technical Expert Panel resulting in removal of this measure from the Hospital OQR Program due to measure performance or improvement not resulting in better patient outcome (82 FR 59431)). However, while some commenters agreed with this reasoning, other commenters expressed concern that there are socioeconomic pressures that can vary by community that cause variation in performance on this measure, noted the value of this measure, and recommended that a refined version that stratifies by other factors related to measure performance, specifically mentioning hospital size which would be more effective in a specific setting (82 FR 59431). When required for the Hospital OQR Program, a significant number of hospitals eligible for REH conversion that had data publicly reported had sufficient case volumes to have publicly reported data for this measure; 70.69 percent (82) of hospitals and 51.93 percent

²⁴⁴ <https://www.healthcatalyst.com/wp-content/uploads/2021/05/Data-Driven-Operations-Improve-ED-Efficiency.pdf>.

(445) of CAHs that had any measure publicly reported indicating possible usefulness of this measure for REHs.

(6) OP-22: Left Without Being Seen

This structural measure for the ED setting is focused on reflecting staffing expertise and availability. OP-22 measures the percentage of patients who left the ED before being evaluated by a physician, advanced practice nurse (APN), or physician assistant (PA) and uses all-payer, administrative data (not Medicare claims data) to determine the measure's numerator and denominator populations. This measure is in the current Hospital OQR Program measure set with significant numbers of both hospitals and CAHs eligible for REH conversion that have publicly reported data for this measure.

We request comment on these selected Hospital OQR Program measures that were recommended by the National Advisory Committee on Rural Health and Human Services for their use in a REHQR Program.

b. Medicare Beneficiary Quality Improvement Project (MBQIP) Measure Recommended by the National Advisory Committee on Rural Health and Human Services for the REHQR Program

The MBQIP is a quality improvement activity under the Medicare Rural Hospital Flexibility (Flex) program. The MBQIP supports more than 1,350 CAHs in 45 states to improve quality of care. Measures included in the MBQIP that are also included in our selection of measures from those by the National Advisory Committee on Rural Health and Human Services for the REHQR Program (above) are OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival, OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention, OP-18: Median Time from ED Arrival to ED departure for Discharged ED Patients, and OP-22: Left Without Being Seen.

The Emergency Department Transfer Communications (EDTC) measure is a core measure in the MBQIP program for CAHs and was included in those measures recommended by the National Advisory Committee on Rural Health and Human Services for their use in a

REHQR Program. The EDTC measure assesses how well key patient information is communicated from an ED to any health care facility. The measure is applicable to patients with a wide range of medical conditions (that is, acute myocardial infarction (AMI), heart failure, pneumonia, respiratory compromise, and trauma) and is relevant for both internal quality improvement purposes and external reporting to consumers and purchasers.²⁴⁵ As REHs are expected to focus on triage and transfer, the adequate and timely sharing of information with the receiving site would be an important quality metric.

We request comment on the EDTC measure for use in a REHQR Program.

c. Other Current, Claims-Based Hospital OQR Quality Measures

Measures calculated using administrative data from Medicare claims and enrollment data limit provider burden and provide valuable information regarding Medicare beneficiary service utilization and care provision. The Hospital OQR Program has several established measures of this type that could be applicable to REHs. At this time, we are focusing on two current measures that have publicly reported data and that focus on services expected to be provided by hospitals eligible for REH conversion: OP-10 Abdomen Computed Tomography (CT) - Use of Contrast Material and OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy.

(1) OP-10: Abdomen Computed Tomography (CT) - Use of Contrast Material

This diagnostic imaging measure is based fully on Medicare fee-for-service (FFS) claims and enrollment data. It calculates the percentage of CT abdomen studies performed with and without contrast out of all CT abdomen studies performed (those without contrast, those with contrast, and those with both). A CT study performed with and without contrast doubles the radiation dose to patients, exposing them to the potential harmful side effects of the contrast material itself.²⁴⁶ Davis et al. (2020) showed that while rural facilities account for 32.2 percent

²⁴⁵ <https://www.ruralcenter.org/resource-library/edtc-measure-data-reporting-resources> (Accessed May 12 2022).

²⁴⁶ Davis M, McKiernan C, Lama, S, Parzynski C, Bruetman C, Venkatesh A. Trends in publicly reported quality measures of hospital imaging efficiency, 2011-2018. *AJR*: 215, July: 153-158), 2020.

of all facilities, they account for 46.0 percent of the outliers for the OP-10 measure. This indicates considerable variation and possible areas for targeted improvement.

(2) OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy

This outcome measure is calculated fully using Medicare FFS claims and enrollment data, estimating a facility-level rate of risk standardized, all-cause, unplanned hospital visits within 7 days of an outpatient colonoscopy among Medicare FFS patients aged 65 years and older. OP-32 captures and makes more visible to providers and patients all unplanned hospital visits following colonoscopy procedures. Under the Hospital OQR program, of the hospitals eligible for REH conversion that had sufficient case volumes to have publicly reported data for this measure, 65.43 percent (123) of hospitals and 46.16 percent (625) of CAHs had any publicly reported data. While the total numbers of hospitals with publicly reported OP-32 data is somewhat low, this could be an important measure for those REHs providing outpatient services and for patients seeking information regarding complications following this procedure. OP-32 was adopted in the CY 2015 OPSS/ASC final rule with comment period (79 FR 66963) for the CY 2018 payment determination and subsequent years using CY 2016 data for the initial year's measure calculation.

d. Request for Comment on Additional Measurement Topics and for Suggested Measures for REH Quality Reporting

Our request for information in the CY 2022 OPSS/ASC proposed rule yielded suggested additional topics for quality measures appropriate to the REH setting. We request comment on the below additional topics and request suggestions for specific measures to assess the patient experience, outcome, and processes related to these topics. In addition, we request comment on other potential topics not listed that would be applicable to an REH quality reporting program.

(1) Telehealth

REHs can utilize telehealth and other remote service capacities in serving rural communities in their vicinity. Under the COVID-19 PHE, temporary measures to facilitate the

provision and receipt of care through telehealth were federally implemented.²⁴⁷ Additionally, section 301 of Division P of the Consolidated Appropriations Act (CAA), 2022 extended certain telehealth flexibilities for Medicare patients for 151 days after the official end of the Federal public health emergency (PHE).²⁴⁸ The PHE was most recently extended on April 12, 2022, effective April 16, 2022, to July 15, 2022.²⁴⁹ Section 301 of the CAA, 2022 permits certain Medicare beneficiaries to receive telehealth services from their home. This and other flexibilities will facilitate the use of telehealth for 151 days after the expiration of the PHE in rural areas.²⁵⁰

In addition, rural emergency telehealth services present unique opportunities for access to quality care in these often time-sensitive and geographically isolated cases. For instance, utilizing provider-to-provider telehealth or telemedicine support, such as in the case of e-consultation or tele-emergency care services, in a rural emergency department could allow for critical specialist knowledge transfer and reduce patient transfers and wait times.²⁵¹ This is particularly impactful in the face of rural facility or departmental closures which can leave gaps in healthcare service access and could contribute or lead to emergency service requirements, such as in the case of obstetric challenges.²⁵²

We seek public comment on potential future quality measures development to address quality of care using telehealth services in rural and rural emergency settings; as well as, on the ways in which REHs could utilize telehealth and telemedicine to bridge both gaps in expertise and distance to render quality care services.

(2) Maternal Health

Nearly half of rural U.S. counties lack hospitals with basic capacity to provide emergency obstetric services. In New Mexico, for example, one-third of deaths during pregnancy and in the

²⁴⁷ <http://telehealth.hhs.gov> (Accessed April 8, 2022).

²⁴⁸ Pub. L. 117-103.

²⁴⁹ <https://aspr.hhs.gov/legal/PHE/Pages/COVID19-12Apr2022.aspx> (Accessed May 12, 2022).

²⁵⁰ <https://www.foley.com/en/insights/publications/2022/03/congress-extends-telehealth-flexibilities-7-things> (Accessed April 13, 2022).

²⁵¹ <https://telehealth.hhs.gov/providers/telehealth-for-emergency-departments/> (Accessed May 31, 2022).

²⁵² Centers for Medicare & Medicaid Services (CMS), *Advancing Rural Maternity Health Equity*, 10 (May 2022), available at <https://www.cms.gov/files/document/maternal-health-may-2022.pdf>.

first year postpartum are from car accidents with increasing maternal mortality and morbidities in rural areas of the State.²⁵³ Similarly, the Illinois Morbidity and Mortality Report identified 175 pregnancy-associated deaths that occurred during 2016-2017 and revealed that the number of pregnancy-associated deaths per 100,000 live births was higher in rural counties.²⁵⁴ This report identified the greatest (33 percent) underlying cause of pregnancy-associated death in rural counties was attributed to “other injuries”, most of which was the result of motor vehicle crashes, as opposed to ‘all medical’ (31 percent), drug overdose (21 percent), suicide (10 percent), or homicide (5 percent).²⁵⁵ This was in contrast with the 4 percent to 10 percent of this category’s attribution in the non-rural areas.²⁵⁶

REHs could provide valuable emergency care and other outpatient services for preserving and improving maternal health in rural areas, such as providing outpatient OB services in “OB deserts”.²⁵⁷ REHs could also leverage remote patient monitoring. This could include implementing telehealth systems to ensure engagement and timely notification and care among high-risk patients, while also reducing barriers to care, like distance and travel.²⁵⁸ In addition, REHs could possibly fill gaps in the maternity care continuum, or play a critical role in a patient’s emergency plan by being identified as their closest medical facility equipped to handle a maternal health emergency.²⁵⁹

We seek public comment on potential future quality measures for maternal health services in rural and rural emergency settings, and on the ways in which REHs could utilize

²⁵³ The Commonwealth Fund. Restoring Access to Maternity Care in Rural America. September 30, 2021. <https://www.commonwealthfund.org/publications/2021/sep/restoring-access-maternity-care-rural-america> (Accessed April 8, 2022).

²⁵⁴ Illinois Department of Public Health, *Illinois Maternal Morbidity and Mortality Report, 2016-2017* 25 (April 2021), available at <https://dph.illinois.gov/content/dam/soi/en/web/idph/files/maternalmorbiditymortalityreport0421.pdf>.

²⁵⁵ *Ibid.* at 28.

²⁵⁶ *Ibid.* at 28.

²⁵⁷ <https://telehealth.hhs.gov/providers/telehealth-for-maternal-health-services/bridging-the-gaps-with-telehealth/> (Accessed May 31, 2022).

²⁵⁸ <https://telehealth.hhs.gov/providers/telehealth-for-maternal-health-services/telehealth-and-high-risk-pregnancy/> (Accessed May 31, 2022).

²⁵⁹ <https://telehealth.hhs.gov/providers/telehealth-for-maternal-health-services/preparing-patients-and-providers/> (Accessed May 31, 2022).

telehealth and telemedicine to bridge both gaps in expertise and distance to render quality maternal health care services.

(3) Mental Health

Rural populations are disproportionately affected by mental health concerns including substance use disorders.^{260, 261} For example, suicide rates and drug overdose related deaths are especially on the rise among the rural population.^{262 263} Roughly 6.5 million individuals, or about one-fifth of the rural population, had a mental illness in 2019.²⁶⁴ While rates of mental illness and substance use disorder between rural and urban areas are comparable, serious mental illness (SMI) was found to be 1.7 percent greater for rural adults 18 and older than their urban counterparts.²⁶⁵ Contributing to this problem is the presence of contextual and cultural factors, such as stigma, isolation, and poverty, and the lack of access to trained and specialized mental health providers, with over 60 percent of rural Americans living within a designated shortage area.²⁶⁶ There are also higher reported rates of prescription opioid misuse among rural residents, but reduced availability of outpatient substance use treatment services, with nearly four times greater likelihood of availability in urban areas than in rural areas.²⁶⁷

These high rates of mental health and substance use issues, compounded by lack of access to treatment, underscores the need for an array of behavioral health crisis services in rural areas. REHs could fill this need by providing valuable emergency care and other outpatient

²⁶⁰ White B.G. (2015 January 28). Rural America's Silent Housing Crisis. The Atlantic. Retrieved from: <https://www.theatlantic.com/business/archive/2015/01/rural-americas-silent-housing-crisis/384885>.

²⁶¹ Shawnda S. (2017 November). Rural Behavioral Health. Rural Health Research RECAP. Retrieved from: <https://www.ruralhealthresearch.org/assets/658-1990/rural-behavioral-health-recap.pdf>.

²⁶² Centers for Disease Control and Prevention. (2018 February 28). Drug Overdose in Rural America. Retrieved from: <https://www.cdc.gov/ruralhealth/drug-overdose/index.html>.

²⁶³ Centers for Disease Control and Prevention. (2018 March 22). Suicide Policy Brief: Preventing Suicide in Rural America. Retrieved from: <https://www.cdc.gov/ruralhealth/suicide/policybrief.html>.

²⁶⁴ Morales, D. A., Barksdale, C. L., & Beckel-Mitchener, A. C. (2020). A call to action to address rural mental health disparities. *Journal of clinical and translational science*, 4(5), 463–467. <https://doi.org/10.1017/cts.2020.42>

²⁶⁵ Neylon, K.A. (2020). Strategies for the Delivery of Behavioral Health Crisis Services in Rural and Frontier Areas of the U.S. Alexandria, VA: National Association of State Mental Health Program Directors.

²⁶⁶ Morales, D. A., Barksdale, C. L., & Beckel-Mitchener, A. C. (2020). A call to action to address rural mental health disparities. *Journal of clinical and translational science*, 4(5), 463–467. <https://doi.org/10.1017/cts.2020.42>

²⁶⁷ In Brief: Rural Behavioral Health: Telehealth Challenges and Opportunities, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, (Nov. 2016) <https://store.samhsa.gov/product/In-Brief-Rural-BehavioralHealth-Telehealth-Challenges-and-Opportunities/SMA16-4989>

services for patients experiencing mental health and substance use crises, and possibly bridging the gaps in the continuum of care. For example, REHs could use telehealth services to reduce care delays,²⁶⁸ or offer teletherapies which can reduce stigma and privacy concerns.²⁶⁹

We seek public comment on potential future quality measures for behavioral health services in rural and rural emergency settings, and on the ways in which REHs could utilize telehealth and telemedicine to bridge both gaps in expertise and distance to render quality behavioral health care services.

(4) ED Services

Emergency departments and the services provided in this setting are expected to be a focus of REHs. OP-18: Median Time from ED Arrival to ED departure for Discharged ED Patients, OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional, and OP-22: Left Without Being Seen, for example, all measure important aspects of ED care.

ED utilization is another important aspect of ED care and quality measures for Medicare Advantage plans as well as for Medicaid beneficiaries point to this. The Emergency Department Utilization (EDU) Health Effectiveness Data and Information Set (HEDIS) measure assesses ED utilization among Medicare Advantage (18 and older) beneficiaries through an observed-to-expected ratio.²⁷⁰ For this measure, Medicare Advantage plans report observed rates of ED use and a predicted rate of ED use based on the health of their member population and factors.²⁷¹ Similarly, we recently sought stakeholder comments on a Medicaid measure under development, the All-Cause ED Utilization for Medicaid Beneficiaries measure.²⁷² This measure is defined as

²⁶⁸ <https://telehealth.hhs.gov/providers/telehealth-for-behavioral-health/tele-treatment-for-substance-use-disorders/> (Accessed May 31, 2022).

²⁶⁹ <https://telehealth.hhs.gov/providers/telehealth-for-behavioral-health/individual-teletherapy/> (Accessed May 31, 2022).

²⁷⁰ All-Cause Emergency Department (ED) Utilization for Medicaid Beneficiaries Public Comment Framing Document. <https://cmit.cms.gov/cmit/#/MeasureView?variantId=4867§ionNumber=1> (Accessed April 8, 2022).

²⁷¹ We note that we would not be seeking to propose measures that have been developed for Medicare Advantage plans or for Medicaid beneficiaries as developed for an REHQR Program; we intend only to illustrate that ED utilization is considered an important area for quality measurement.

²⁷² <https://www.cms.gov/files/document/all-cause-ed-utilization-medicaid-beneficiaries-measure-framing-document.pdf> (Accessed April 7, 2022).

the number of all-cause ED visits per 1,000 beneficiary months among Medicaid beneficiaries aged 18 years and older with at least 10 months of enrollment.

A patient who returns for an unscheduled visit to the emergency department (ED) shortly after initial discharge (that is, within 2-30 days) is called a “bounce-back”.²⁷³ ED bounce-backs are associated with ED facility and ED patient metrics, including quality of care, patient insurance status, patient age, ED overcrowding and patient satisfaction, or an unscheduled return visit. Measures for ED utilization, boarding, and unscheduled ED return visits (bounce-backs) could be useful quality metrics for the REH setting.

We seek public comment on potential future quality measures for emergency care services in rural and rural emergency settings, and on the ways in which REHs could utilize telehealth and telemedicine to bridge both gaps in expertise and distance to render quality of care.

(5) Equity

Rural populations, among others, face historic and current disproportionate health impacts that have resulted in the higher prevalence, increased risk, and greater barriers to care for medical conditions.²⁷⁴ The Hospital Commitment to Health Equity measure,²⁷⁵ which we have proposed in the FY 2023 IPPS rule for the Hospital Inpatient Quality Reporting program, has five attestation-based questions that each represent a domain of commitment to health equity: strategic planning, data collection, data analysis, quality improvement, and leadership engagement. Additionally, a potential future measure for health equity could be an attestation-based structural measure of a disparities impact statement (DIS) or organizational pledge that outlines how infrastructure supports the delivery of care that is equitable for all patient

²⁷³ Curcio J, Little A, Bolyard C, et al. (September 17, 2020) Emergency Department “Bounce-Back” Rates as a Function of Emergency Medicine Training Year. *Cureus* 12(9): e10503. <https://doi.org/10.7759/cureus.10503>

²⁷⁴ <https://www.cdc.gov/ruralhealth/about.html> (Accessed June 2, 2022).

²⁷⁵ Centers for Medicare and Medicaid Services (CMS), *Summary of Technical Expert Panel (TEP) Meeting # 1, November 16, 2021: Health Equity Quality Measurement, Hospital Commitment to Health Equity Measure, 2016-2017* (February 2022), available at <https://www.cms.gov/files/document/health-equity-quality-measurement-tep-1-summary-report-hospital-commitment-health-equity.pdf>.

populations could provide important information regarding organizational commitment to health equity.

We seek public comment on potential future quality measures for health equity in rural and rural emergency settings, and on the ways in which REHs could utilize telehealth and telemedicine to bridge both gaps in expertise and distance to render equitable, quality of care.

e. Addressing Concerns Regarding Small Case Numbers

There are significant methodological challenges with measurement in rural and low-volume settings. Measure reliability and validity often hinge on having a sufficient volume of cases to ensure the reported rates are reliable. Determining appropriate approaches to addressing low-volume measurement issues will be imperative for public reporting of REH data given expected low volume of these facilities as evidenced by the numbers of rurally located subsection (d) hospitals with not more than 50 beds and CAHs with sufficient case numbers to have data publicly available on Care Compare. The NQF most recently provided expert panel recommendations for addressing the low volume challenge for performance measurement of rural providers in 2019.²⁷⁶ The panel recommends, to the extent possible, to “borrow strength” (that is, to aggregate measured data over longer timeframes to ensure sufficient data collection for analysis) and leverage expertise and statistical methodology suited to this type of collection. These approaches have been used to model the number of facilities that could achieve sufficient measure volume to produce reliable quality measures based on Medicare Fee-For-Service (FFS) claims.

Another panel recommendation is to report exceedance probabilities as an alternate to reporting absolute performance values. An exceedance probability is the probability that a certain value will be exceeded in a predefined future time period; it is often used for predicting

²⁷⁶ National Quality Forum, *Addressing Low Case-Volume in Healthcare Performance Measurement of Rural Providers: Recommendations from the MAP Rural Health Technical Expert Panel, Final Report 3* (March 2019) available at https://www.qualityforum.org/Publications/2019/04/MAP_2019_Recommendations_from_the_Rural_Health_Technical_Expert_Panel_Final_Report.aspx.

the probability of an event. This approach would better reflect the uncertainty of observed quality measure results.²⁷⁷ For example, an exceedance probability statement might be: “We can be 84 percent sure that hospital A is performing above the mean on this particular measure.”

We request comment on these recommendations for addressing the low volume issues for performance measurement of rural providers.

C. Quality Reporting Requirements Under the REH Quality Reporting (REHQR) Program

1. Administrative Requirements

Section 1861(kkk)(7)(B)(i) of the Act provides that, with respect to each year beginning with 2023, (or each year beginning on or after the date that is 1 year after one or more measures are first specified under subparagraph (C)), a rural emergency hospital shall submit data to the Secretary in accordance with clause (ii). Clause (ii) states that, with respect to each such year, a rural emergency hospital shall submit to the Secretary data in a form and manner, and at a time, specified by the Secretary for purposes of this subparagraph. In this section of the proposed rule, we propose foundational administrative requirements for REHs participating in the REHQR Program.

2. Requirements for Registration on QualityNet and Security Official (SO)

We currently use the CMS QualityNet Secure Portal (referred to as the Hospital Quality Reporting (HQR) secure portal) to host our CMS online data submission tool. To submit quality measure data to CMS using the HQR system, a hospital must establish a secure account through the QualityNet website and designate a Security Official (SO). For more information regarding the HQR system, we refer readers to CY 2022 OPPS/ASC final rule with comment period (85 FR 86179), as well as <https://qualitynet.cms.gov>. An SO must establish user account(s) for the purpose of submitting quality measure data to the HQR system, as well as for authorized users to review and correct data submissions and preview measure information prior to public

²⁷⁷ Shwartz M, Peköz EA, Burgess JF Jr, Christiansen CL, Rosen AK, Berlowitz D. A probability metric for identifying high-performing facilities: An application for pay-for performance programs. *Med Care*. 2014 Dec; 52(2):1030-1036.

reporting. The term SO refers to the individual(s) who have responsibilities for security and account management requirements for a facility (85 FR 86182).

Hospitals that currently report quality measure data under CMS quality programs including, but not limited to, the Hospital IQR and Hospital OQR Programs have existing QualityNet accounts. For the CY 2022 payment determination under the Hospital OQR Program, 3,268 hospitals met all reporting requirements including data submission, whereas, only 30 hospitals did not meet all requirements.²⁷⁸ In addition, of 1,354 CAHs, 1,291 reported data through the Hospital OQR Program. Thus, the vast majority of all subsection (d) hospitals and CAHs have an account for reporting data via the HQR system. The QualityNet and SO registration process should therefore be familiar to many hospitals that convert to being an REH. Thus, we propose that for an REH to participate in the REHQR Program, they must: (1) have an account for the purpose of submitting data to the HQR system. If an REH already has an account for a CMS hospital quality reporting program, the REH can fulfill this requirement by updating its existing account with its new REH CMS Certification Number (CCN). If the REH does not have an account, we are proposing that it must register a new account. Once an REH has an account, it must then (2) have an SO. Since hospitals in the REHQR Program will have new REH CCNs, these hospitals would have to request SO access for the new CCN following the standard instructions posted on the QualityNet website.

From our experience, an SO typically fulfills a variety of responsibilities related to quality reporting such as creating, approving, editing, and terminating user accounts within an organization, and monitoring account usage to maintain proper security and confidentiality protocols. While an SO is initially required to enable a hospital's QualityNet account for data submission and allows the set-up of basic user accounts with capabilities including data submission, it will not be necessary or required to maintain an SO. We highly recommend that

²⁷⁸ <https://qualitynet.cms.gov/outpatient/oqr/apu>

hospitals have and maintain a Security Official; though after initial set-up, we reiterate, an SO would not be required.

We invite public comment on this proposal. We intend to propose additional administrative requirements for the REHQR Program in subsequent rulemaking.

XVII. Organ Acquisition Payment Policy

A. Background of Organ Acquisition Payment Policies

The Medicare Program supports organ transplantation by providing an equitable²⁷⁹ means of payment for the variety of organ acquisition services. Medicare excludes organ acquisition costs from the inpatient hospital prospective diagnosis-related group (DRG) payment for an organ transplant, and separately²⁸⁰ reimburses transplant hospitals²⁸¹ (THs) for their organ acquisition costs under reasonable cost principles²⁸² under section 1861(v) of the Act, based on the TH's ratio of Medicare usable organs to total usable organs. Medicare authorizes payment to designated independent organ procurement organizations (IOPOs) for kidney acquisition costs, under reasonable cost principles²⁸³ in accordance with section 1861(v) of the Act, based on the IOPO's ratio of Medicare usable kidneys to total usable kidneys (see section 1881(b)(2)(A) of the Act). In accordance with 42 CFR 413.24(f), Medicare requires THs and IOPOs to complete a Medicare cost report²⁸⁴ on an annual basis.

In the FY 2022 Inpatient Prospective Payment System (IPPS)/Long Term Care Hospital (LTCH) PPS proposed rule (86 FR 25070), which appeared in the **Federal Register** on May 10, 2021, we explained the background and history of Medicare's organ acquisition

²⁷⁹ In this context "equitable" means fair and equal to all parties. Medicare recognizes that organ acquisition costs can vary among patients due to different levels of acuity, clinical factors and genetic make-up. Some patients may require different or additional testing and care during the organ acquisition process. Payment under reasonable cost accounts for these differences and ensures that providers are paid appropriately for their share of organ acquisition costs.

²⁸⁰ 42 CFR 412.2(e)(4) and 412.113(d).

²⁸¹ Under 42 CFR 482.70, a transplant hospital is a hospital that furnishes organ transplants and other medical and surgical specialty services required for the care of transplant patients.

²⁸² See 42 CFR 412.113(d); HCFA Ruling 87-1 (April 1987); CMS Ruling 1543-R (December 2006).

²⁸³ Id. Section 1138(b)(1)(F) of the Act; 42 CFR 413.1(a)(1)(ii)(A); 413.420(a).

²⁸⁴ THs complete the hospital cost report on the CMS 2552-10 (OMB No. 0938-0050) and IOPOs complete their cost report on the CMS-216-94 (OMB No. 0938-0102).

payment policy and proposed to change, clarify, and codify Medicare organ acquisition payment policies relative to OPOs,²⁸⁵ THs, and donor community hospitals. We proposed to change the manner in which an organ is counted as a Medicare usable organ for purposes of calculating Medicare's share of organ acquisition costs by counting only organs transplanted into Medicare beneficiaries. We also proposed to codify that Medicare does not share in the costs to procure organs used for research, except where explicitly required by law. In addition, we proposed to require donor community (not transplant) hospitals to bill OPOs their customary charges reduced to costs for services provided to deceased organ donors.

In the FY 2022 IPPS/LTCH PPS final rule with comment period (86 FR 73416), which appeared in the **Federal Register** on December 27, 2021, we responded to public comments on the proposed rule, and finalized certain proposals to codify longstanding Medicare organ acquisition payment policies, with some modifications, in new subpart L of part 413. We finalized at § 413.418 proposals with respect to donor community hospitals and THs' charges for hospital services provided to deceased donors. We also finalized our proposal to move existing organ acquisition payment regulations, and portions of existing kidney acquisition regulations, within title 42 of CFR part 412, subpart G, and part 413, subpart H, to a new subpart L in part 413, so that all organ acquisition payment policies would be housed together.

We did not finalize our proposal to count as Medicare usable organs only organs transplanted into Medicare beneficiaries. We also did not finalize certain provisions of the proposed policy with respect to counting organs procured for research for purposes of calculating Medicare's share of organ acquisition costs. In the FY 2022 IPPS/LTCH PPS final rule with comment period, we stated that due to the nature of the public comments received, we would address the organ counting policy in subsequent rulemaking, as appropriate.

²⁸⁵ We refer to organ procurement organizations generally as "OPOs" throughout, unless differentiation of IOPO is required for cost reporting purposes for OPOs that file a cost report on the CMS-216-94 (OMB No. 0938-0102).

In this proposed rule, we propose additional revisions, clarifications and codifications pertaining to Medicare's organ acquisition payment policies. In section XVII.B of this proposed rule, we propose changes to how organs procured for research are counted for THs and OPOs for purposes of calculating Medicare's share of organ acquisition costs. In section XVII.C of this proposed rule, we propose that organ acquisition costs include certain hospital costs incurred for services provided to deceased donors. In section XVII.D of this proposed rule, we propose technical corrections to certain regulations. In section XVII.E of this proposed rule, we are clarifying the appropriate allocation of administrative and general costs for THs. Additionally, in section XVII.F of this proposed rule, we are soliciting comments on an alternative methodology for counting organs used in the calculation of Medicare's share of organ acquisition costs; allowing IOPOs to create a SAC for non-renal organs; and Medicare's reconciliation of non-renal organs for IOPOs.

B. Counting Research Organs to Calculate Medicare's Share of Organ Acquisition Costs

In the FY 2022 IPPS/LTCH PPS final rule with comment period (86 FR 73470), we clarified that for Medicare payment purposes, Medicare does not include in Medicare's share of organ acquisition costs the costs to procure an organ for research, except where explicitly required by law. Section 733 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 provided Medicare coverage of pancreata for islet cell transplant for beneficiaries participating in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial. An exception for Medicare cost allocation purposes for pancreata for islet cell transplant for these trials is under § 413.406(a). Under §§ 413.5(c)(2) and 413.90(a), costs incurred for research purposes, over and above usual patient care, are not includable as Medicare allowable costs.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25668), we clarified that for organ acquisition cost allocation purposes, a "research organ" is an organ procured and used for research regardless of whether it is transplanted as part of clinical care (with the exception of

certain pancreata). We proposed to codify that organs used for research are not counted as Medicare usable organs in Medicare's share of organ acquisition costs (except certain pancreata procured for islet cell transplants). We also proposed that OPOs and THs do not count organs designated for research activities prior to the time the donor entered the hospital's operating room for surgical removal of the organs as Medicare usable organs but count as total usable organs. Finally, we proposed that OPOs and THs do not count organs designated for transplant prior to the time the donor entered the hospital's operating room for surgical removal of the organs but subsequently determined to be unusable and donated to research, as Medicare usable organs or total usable organs.

In the FY 2022 IPPS/LTCH PPS final rule with comment period, we finalized our proposal to require that organs used for research be excluded from Medicare usable organs in Medicare's share of organ acquisition costs (except pancreata for islet cell transplants as specified in § 413.406(a)), and kidneys used for research be excluded from Medicare usable kidneys in Medicare's share of kidney acquisition costs under § 413.412(c). However, due to the number and nature of the comments received, we did not finalize our proposal that would have required OPOs and THs to include organs designated for research activities prior to the time the donor entered the hospital's operating room for surgical removal of the organs in the count of total usable organs or our proposal to exclude organs designated for transplant but subsequently determined to be unusable and donated to research from Medicare usable organs or total usable organs. We indicated that we may address these issues in future rulemaking.

Commenters on these proposals overall expressed concern that our proposals would negatively impact the affordability and availability of research organs and hinder the advancement of clinical research (86 FR 73494). Some commenters suggested that including research organs in the count of total usable organs reflected a change in policy for IOPOs that would require assignment of a full SAC (including administrative, general, and overhead costs) to each research organ they procured and would also result in significantly higher acquisition

costs that would be borne by the research community. One commenter suggested that our proposal to exclude organs donated for research from the count of Medicare and total usable organs would result in procurement costs being passed on to researchers, which could discourage the use of human organs in research studies. A few commenters reported that IOPOs charge researchers an agreed upon fee for furnishing an organ for use in research. They asserted that if our proposal to include organs in the count of total usable organs were finalized, IOPOs would need to charge significantly higher amounts for furnishing research organs to the research community. A few commenters noted that procuring an organ for use in research may involve less extensive testing and evaluation than is necessary when procuring an organ for transplantation. We believe that most THs and OPOs currently charge the research community agreed upon prices to procure research organs instead of charging a SAC. We have heard from some interested parties in the transplant community that THs and OPOs use agreed upon pricing because the SAC may include procurement services that are unnecessary to procure research organs.

In the time since we issued the FY 2022 IPPS/LTCH PPS final rule with comment period, we have continued to review the potential impacts of our research organ proposal on stakeholders. We agree with the comments on the FY 2022 IPPS/LTCH PPS proposed rule that suggested that including research organs in the count of total usable organs would require the assignment of a full SAC on the Medicare cost report for each research organ procured. We understand that this practice may increase the amount the research community pays for obtaining organs for research. We also recognize that procurement costs may differ for research organs and transplanted organs because organs procured for research may be subject to less extensive testing and evaluation than organs that are to be transplanted. We believe that when THs and OPOs furnish organs for research, they should charge amounts that more accurately reflect the testing and evaluation associated with procuring research organs. This amount should represent

the actual costs incurred by the TH or OPO for furnishing organs used for research instead of a token fee that does not cover the procurement cost of the organs.

In response to commenters' concerns with the research organ counting proposals in the FY 2022 IPPS/LTCH PPS proposed rule, in this proposed rule we propose to require that THs and OPOs exclude organs used for research from the numerator (Medicare usable organs) and the denominator (total usable organs) of the calculation used to determine Medicare's share of organ acquisition costs on the Medicare cost report. For the purpose of determining Medicare's share of organ acquisition costs, we intend a "research organ" to be an organ used for research (with the exception of certain pancreata), regardless of whether the organ was intended for research, or intended for transplant under § 413.412(a) and instead used for research. Including organs used for research in the count of Medicare usable organs and total usable organs results in assignment of a full SAC to each research organ. Our proposal would not require assignment of a full SAC on the Medicare cost report for each research organ procured; and therefore, would not result in a significant increase in amounts charged for research organs. We expect that when an organ, identified as a research organ, is transplanted into a patient, the organ is counted as a total usable organ and a full SAC is assigned.

Under our proposal, THs and OPOs would also be required to deduct the cost incurred in procuring an organ for research from their total organ acquisition costs. This process would ensure that research organ procurement costs are not allocated across all transplantable organs and consequently, that Medicare is not paying for non-allowable research activities.

Additionally, this practice would ensure that Medicare does not pay for non-allowable research costs in instances where the TH or OPO charges a fee that does not cover the cost it incurred to procure the organ for research.

Although TH/HOPOs are currently including research organs in the total usable organ²⁸⁶ count and assigning a full SAC to each research organ, we believe this proposal, if finalized,

²⁸⁶ CMS 2552-10 (OMB No. 0938-0050).

would not affect the TH/HOPOs ability to charge research entities a fair and accurate amount for procuring organs used for research. THs and OPOs are responsible for negotiating the amount charged for an organ used for research with the research entity receiving the research organ; however, regardless of amounts charged, the costs must be offset against total organ acquisition costs. In accordance with 42 U.S.C. 273(b)(1)(B) and § 486.303(c), OPOs are required to have accounting and other fiscal procedures necessary to assure the fiscal stability of the organization.

The availability of organs for research is important for continued innovation in transplant medicine and for the discovery of new treatments for diseases. In order to ensure the research community has access to organs for research and to lower the procurement costs associated with such organs, we propose to revise the policy set forth in § 413.412(c) for OPOs and THs for counting organs used for research. Specifically, we propose to revise § 413.412(c) as follows: first, by redesignating paragraph (c) (after the subparagraph heading) as paragraph (c)(1); second, by revising redesignated paragraph (c)(1) to specify that for Medicare cost allocation purposes, organs used for research are not counted as Medicare usable organs or as total usable organs in the ratio used to calculate Medicare's share of organ acquisition costs (except pancreata for islet cell transplants as specified in § 413.406(a) and, third, by striking the language that specifies that kidneys used for research are not counted as Medicare usable kidneys or as total usable kidneys in Medicare's share of kidney acquisition costs; (we believe this language is duplicative because the reference to "organs" includes kidneys). We also propose to amend § 413.412(c) by adding paragraph (c)(2) which would require that OPOs and THs must reduce their costs to procure organs for research from total organ acquisition costs on the Medicare cost report.

Regarding the counting of unusable organs as described in § 413.412(d), we propose to remove the specification that the determination that an organ is unusable is made by the *excising* surgeon; our proposed amendment would allow this determination to be made by any surgeon. As revised, paragraph (d) – which we propose to redesignate as paragraph (d)(1) – would provide

that an organ is not counted as a Medicare usable organ or a total usable organ in the ratio used to calculate Medicare's share of organ acquisition costs if a surgeon determines, upon initial inspection or after removal of the organ, that the organ is not viable and not medically suitable for transplant and is therefore unusable. In addition, we propose to clarify in § 413.412(d) that Medicare shares in the costs to procure unusable organs through the application of the Medicare ratio and to clarify how OPOs and THs must report these organs on their Medicare cost reports to ensure that Medicare shares in the costs to procure these organs. Specifically, we propose to add new paragraph (d)(2), which would specify that OPOs and THs include the costs to procure unusable organs, as described in § 413.412(d)(1), in total organ acquisition costs reported on their Medicare cost reports.

C. Costs of Certain Services Furnished to Potential Deceased Donors

In the FY 2022 IPPS/LTCH PPS final rule with comment period, we codified at § 413.418(a) our longstanding policy that only costs incurred after the declaration of the donor's death and consent to donate are permitted to be included as organ acquisition costs (86 FR 73500 through 73503). However, after finalizing that rule, we received feedback from some stakeholders that indicated that OPOs may incur certain costs for donor management prior to declaration of death, but when death is imminent, in accordance with OPTN donation policies.²⁸⁷ This is typical in cases of donation after cardiac death (DCD). We researched this issue further and found that these costs are for certain services that can only be performed prior to declaration of death, when death is imminent, to evaluate the organs for transplant viability and to prepare the donor for donation. Failure to provide these services to the potential donor may compromise the viability of organs, limit organ donation, and would not honor the donor or donor family's wishes to donate organs. To avoid these unintended consequences, we propose to modify § 413.418(a) to allow a donor community hospital or TH to incur costs for hospital services

²⁸⁷ OPTN Policy Manual, Policy 2, available at https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf, accessed February 4, 2022.

attributable to a deceased donor or a donor whose death is imminent. Organ acquisition costs include hospital services authorized by the OPO when there is consent to donate, and a declaration of death has been made or death is imminent and these services must be provided prior to declaration of death. These costs must not be part of medical treatment that primarily offers a medical benefit to the patient as determined by a healthcare team.

Under this proposal, hospitals would bill the OPO for these services in accordance with § 413.418(b), and the OPO would record those billed amounts as organ acquisition costs on its Medicare cost report. Because these services are intended to determine or maintain the viability of organs for transplant, the patient's health insurance would not be billed for the organ acquisition costs, and the patient or patient's family would not be responsible for those amounts. Stakeholders were concerned that without this clarification, if services authorized by the OPO and provided by the hospital could not be included as organ acquisition costs, hospitals may bill the donor's family or a third-party payor. Doing so could create a barrier to organ donation based on economic means, by forcing costs associated with organ acquisition to be borne by the donor's family or a third-party payor. Making the donor's family responsible for these costs could preclude those of lesser economic means from fulfilling their wishes to donate organs and would be inequitable. It could also be a deterrent to deceased donor organ donation and as a result reduce the supply of organs available for transplant. We are committed to supporting organ donation in an equitable fashion and view this issue as a potential barrier to organ donation. We believe our proposal supports organ donation and organ procurement costs and addresses a potential inequity in the transplant ecosystem.

D. Technical Corrections and Clarifications to 42 CFR 405.1801, 412.100, 413.198, 413.402, 413.404, 413.420 and Nomenclature Changes to 42 CFR 412.100 and 42 CFR Part 413,

Subpart L

Technical Corrections and Clarifications. In the FY 2022 IPPS/LTCH PPS final rule

with comment period, § 413.200 was reserved and redesignated as § 413.420 with revisions. In this proposed rule, we propose to make a technical correction to § 405.1801(b)(2)(ii), by removing the reference to § 413.200(g) and replacing it with a reference to § 413.420(g). We also propose to make a technical correction to § 413.198(b)(4)(ii), by removing the reference to “Section 413.200, Reimbursement of OPAs and histocompatibility laboratories” and replacing it with a reference to “Section 413.420,” and that section’s title, “Payment to independent organ procurement organizations and histocompatibility laboratories for kidney acquisition costs.”

We also propose to clarify §§ 412.100(b) and 413.402(a) by removing “as appropriate” and instead specifying that organ acquisition costs are allowable costs incurred in the acquisition of organs from a living donor or a deceased donor by a hospital, or from a deceased donor by an OPO.

We propose to revise § 413.404(c)(2)(i)(C) so that it is written in the active voice and not the passive voice. In addition, we propose to revise this provision to clarify that the kidney SAC amount is the interim payment made by the TH or other OPO to the IOPO, as set forth in § 413.420(d)(1).

We propose to amend § 413.420(a)(1) by striking “after September 30, 1978,” as we believe it is no longer necessary that the regulations specify that the reasonable cost reimbursement principles in part 413 only apply to covered services furnished after that date; and to replace the acronym “OPOs” with “IOPOs”. We propose to amend § 413.420(a)(2) to correct a typographical error by changing “HOPOs” to “IOPOs”.

We propose to amend § 413.420(c)(1)(v) to correct the statutory reference to section 1861 of the Act so that it instead refers to section 1881 of the Act; the original regulation text was in § 413.178, and was redesignated as § 413.200 in 1997²⁸⁸ before being redesignated as § 413.420 in the FY 2022 IPPS/ LTCH PPS final rule with comment period.²⁸⁹ The original

²⁸⁸ 62 FR 43668, Aug. 15, 1997.

²⁸⁹ 86 FR 73515, Dec. 27, 2021.

regulation at § 413.178 referred to section 1881 of the Act, but a typographical error changed “1881” to “1861” when other changes to the regulation were proposed in 1987 (52 FR 28674) and finalized in 1988 (53 FR 6548).

Nomenclature Changes. In this proposed rule, we propose to amend §§ 412.100(b); 413.402(a) and (b)(3), (4), (7) and (8)(ii); 413.404(a)(2), (b)(3), and (c)(1)(i) and (ii); and 413.418 (the section title and paragraph (b)), by replacing the term “cadaveric” with “deceased”, to be consistent with terminology used within the transplant community when referring to deceased donors, and to promote sensitivity regarding the process and decision of donating organs from deceased donors. In § 413.404(b)(3)(ii), we propose to replace “cadaveric SAC” with “deceased donor SAC” and “cadaveric organ(s)” with “deceased donor organ(s)”; and in § 413.404(c)(2), we propose to replace “cadaveric kidneys” with “deceased donor kidneys”.

We propose to amend § 413.404(c)(2)(i)(A), (B), and (D) and 413.414(c)(1) by replacing references to “Medicare contractor” with “contractor”, to conform to terminology changes made in the FY 2015 IPPS final rule (79 FR 49854 at 50199) and in accordance with the definition at 42 CFR 405.201(b).²⁹⁰

In this proposed rule, we also propose to remove the term “discarded” from § 413.412(d) and replace it with “unusable”, to promote sensitivity in scenarios where donated organs are unused because they are not suitable for transplantation.

Finally, in this proposed rule, we propose to amend § 413.400 by adding “TH” in parentheses after the defined term “transplant hospital”. Throughout subpart L, we propose to replace the term “transplant hospital” with “TH”.

E. Clarification of Allocation of Administrative and General Costs

When a TH procures organs for transplantation, it is required to allocate administrative

²⁹⁰ 42 CFR 405.201(b) defines contractors as Medicare Administrative Contractors and other entities that contract with CMS to review and adjudicate claims for Medicare payment of items and services.

and general (A&G) costs to the appropriate organ acquisition cost centers on its Medicare hospital cost report (MCR).²⁹¹ This practice is in accordance with Medicare's reasonable cost principles under section 1861(v) of the Act and the regulations at §§ 413.20 and 413.24. When a TH receives organs from an OPO or other TH, it makes payment to the OPO or TH that furnished the organ for the cost incurred to procure the organ. We are aware that some THs that receive organs place the "purchase cost" for the organs they receive in the accumulated cost statistic by which A&G is allocated. Under § 413.24(d)(6), including a statistical cost which does not relate to the allocation of A&G expenses causes an improper distribution of overhead and could result in improper Medicare payment. In this scenario, when the receiving TH includes the purchase cost of the organ it received in the statistical cost by which A&G is allocated, overhead is improperly distributed to the receiving TH organ acquisition cost center.

To ensure the appropriate allocation of A&G costs on a TH's MCR, we propose to clarify that when a TH receives organs from an OPO or other TH, the receiving TH must exclude from its accumulated cost statistic the cost associated with these organs because these costs already include A&G costs. In accordance with § 413.24(d)(6), purchased services for a department that are directly assigned to the department that include A&G costs result in an excessive allocation of overhead. This duplication of A&G costs results in improper Medicare payment to the provider. In accordance with MCR instructions,²⁹² if some of the costs in the department that received this direct assignment of purchased services should receive A&G costs, the TH must remove the directly assigned costs (purchased services) from its allocation statistic to assure a proper allocation of overhead. This process facilitates appropriate Medicare payment and ensures that the receiving TH's organ acquisition cost center does not receive an improper distribution of overhead costs that it did not incur. These longstanding Medicare cost finding principles are in accordance with § 413.24(d)(6), and specifically expressed in the MCR

²⁹¹ CMS 2552-10 (OMB No. 0938-0050)

²⁹² PRM 15-2, chapter 40, section 4020.

instructions for THs.²⁹³

F. Organ Payment Policy - Request for Information on Counting Organs for Medicare's Share of Organ Acquisition Costs, IOPO Kidney SACs, and Reconciliation of All Organs for IOPOs

In this proposed rule, we are requesting information on an alternative methodology for counting organs for purposes of calculating Medicare's share of organ acquisition costs; IOPOs' kidney SACs; and Medicare's reconciliation of all organs for IOPOs. While we will not be responding to specific comments submitted in response to this RFI in the CY 2023 OPSS final rule, we intend to use this input to inform future policy development.

1. Counting Organs for Medicare's Share of Organ Acquisition Costs

Medicare calculates its share of organ acquisition costs for THs/HOPOs by multiplying the allowable organ acquisition costs by the ratio of Medicare usable organs (the numerator) to total usable organs (the denominator) reported on the Medicare hospital cost report.²⁹⁴

Currently, THs/HOPOs must include the following as Medicare usable organs in the numerator of the Medicare share fraction:²⁹⁵ (1) organs transplanted into Medicare beneficiaries; (2) organs transplanted into Medicare beneficiaries that were partially paid by a primary insurance payor in addition to Medicare; (3) organs sent to other THs or OPOs; (4) kidneys transplanted into Medicare Advantage beneficiaries for dates of service on or after January 1, 2021;²⁹⁶ (5) kidneys sent to United States military renal transplant centers (MRTCs) with a reciprocal sharing agreement with the HOPO in effect prior to March 3, 1988, and approved by the contractor; and (6) pancreata procured for the purpose of acquiring pancreatic islet cells for transplantation into Medicare beneficiaries participating in a National Institute of Diabetes and Digestive and Kidney

²⁹³ Id.

²⁹⁴ CMS Pub. 15-2, chapter 40, section 4028.

²⁹⁵ Pursuant to PRM § 3115.A. and CMS Pub. 15-2, chapter 40, section 4028.3.

²⁹⁶ Section 17006 of the 21st Century Cures Act, (Pub. L. 114-255). Section 17006(c) of the Cures Act amended section 1852(a)(1)(B)(i) of the Act to exclude coverage for organ acquisitions for kidney transplants from the Medicare benefits an MA plan is required to cover for an MA enrollee, including as covered under section 1881(d) of the Act. Effective January 1, 2021, these costs are covered under the original Medicare FFS program. The MA kidney transplants are included in the numerator and denominator on the MCR to determine Medicare's share of kidney acquisition costs (85 FR 33796, 33824, June 2, 2020).

Diseases clinical trial pursuant to section 733 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108–173); 42 U.S.C 1395l (MMA).²⁹⁷ However, “(3) organs sent to other THs or OPOs” and “(5) kidneys sent to United States MRTCs with a reciprocal sharing agreement with the HOPO in effect prior to March 3, 1988, and approved by the contractor,” may include organs that are not actually transplanted into Medicare beneficiaries. Including organs that are not transplanted into Medicare beneficiaries in Medicare usable organs inflates Medicare’s share of organ acquisition costs.

Currently, THs/HOPOs must include the following as total usable organs in the denominator of the Medicare share fraction: (1) Medicare usable organs; (2) organs excised with the intention to be used for research; (3) organs excised and either transplanted or furnished to other THs or OPOs; (4) organs obtained from another TH or OPO and either transplanted or furnished to other THs or OPOs; (5) organs furnished to veterans’ hospitals or organs sent outside the United States, under § 413.203; (6) organs transplanted into non-Medicare beneficiaries, under § 413.203; (7) organs for which the transplant was totally or partially paid by primary insurance other than Medicare; (8) kidneys furnished to United States MRTCs with or without a contractor approved reciprocal sharing agreement with the HOPO in effect prior to March 3, 1988; and (9) pancreata procured on or after October 1, 2004, for the purpose of acquiring pancreatic islet cells for transplantation into participants in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial in accordance with the MMA.²⁹⁸

For IOPOs, Medicare calculates its share of kidney acquisition costs by multiplying the total allowable kidney acquisition costs by the ratio of Medicare usable kidneys (the numerator) to total usable kidneys (the denominator) reported on the Medicare IOPO cost report.²⁹⁹

Currently, IOPOs must include the following as Medicare usable kidneys: (1) kidneys sent to

²⁹⁷ Section 733 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108–173); 42 U.S.C. 1395l.

²⁹⁸ Id.

²⁹⁹ CMS Pub. 15–2, chapter 33, section 3312.

THs; (2) kidneys sent to certified OPOs; and (3) kidneys sent to United States MRTCs with a reciprocal sharing agreement with the IOPO in effect prior to March 3, 1988, and approved by the contractor. However, not all kidneys that are counted as Medicare usable kidneys are transplanted into Medicare beneficiaries.

IOPOs must currently include the following as total usable kidneys: (1) Medicare usable kidneys; (2) kidneys procured and furnished to other THs or OPOs; (3) kidneys furnished to veterans' hospitals or organs sent outside the United States in accordance with § 413.203; (4) kidneys for which the transplant was covered by a MA plan for dates of service prior to January 1, 2021; and (5) kidneys furnished to United States MRTCs with or without a contractor-approved reciprocal sharing agreement with the IOPO in effect prior to March 3, 1988.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25656), we provided a historical overview of Medicare's organ acquisition payment policy to explain why Medicare currently shares in the organ acquisition costs for some organs that are not actually transplanted into Medicare beneficiaries. When Medicare added the ESRD benefit to Medicare coverage in 1972, Medicare presumed that most kidney transplant recipients would be Medicare beneficiaries receiving the ESRD benefit, and thus Medicare would pay a larger share of kidney acquisition costs.³⁰⁰ As Medicare added benefits for transplantation of non-renal organs and included the costs to procure non-renal organs, Medicare cost reporting instructions incorporated the presumption that the ultimate transplant recipient was unknown, but likely a Medicare beneficiary. Currently, when a TH sends an organ to another TH or to an OPO, or when an OPO sends an organ to another OPO or to a TH, Medicare assumes that some of the unknown transplant recipients are Medicare beneficiaries, and permits those organs to be counted as Medicare usable organs in the numerator of the fraction for Medicare usable organs to total usable organs, to be assured that Medicare is paying its share of organ acquisition costs. Thus, some organs that are not ultimately transplanted into Medicare beneficiaries are currently being

³⁰⁰ Intermediary Letter 73-25 (July 1973) and 54 FR 5619, February 6, 1989.

included in “Medicare usable organs” or “Medicare usable kidneys”, resulting in Medicare paying more than its share of organ acquisition costs (86 FR 25665).

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25664), we stated that Medicare does not intend to share in the cost of procuring organs that are not transplanted into Medicare beneficiaries (except those organs designated for transplant but subsequently determined to be unusable). In the 1988 proposed rule titled “Medicare Program; Payment for Kidneys Sent to Foreign Countries or Transplanted in Non-Medicare Beneficiaries” (53 FR 6672, 6673), which appeared in the **Federal Register** on March 2, 1988, CMS stated that allowing all kidneys to be counted as Medicare kidneys was not aligned with anti-cross subsidization principles set forth in section 1861(v)(1)(A) of the Act. CMS (which was at that time known as the Health Care Financing Administration, or HCFA) observed that the Medicare Program had been paying the cost of procuring kidneys transplanted into non-Medicare beneficiaries and stated it was necessary to amend the regulations in order to effectuate the statutory principles embodied in section 1861(v)(1)(A), including that the cost of services be borne by the appropriate payor. We stated that the cost associated with the kidneys not used by Medicare beneficiaries must be borne by the responsible individual or third-party payor and that Medicare is precluded from paying any costs associated with kidneys not used by Medicare beneficiaries. We proposed to establish in the regulations at Part 413 a requirement for OPOs to reduce their acquisition costs for kidneys furnished to foreign transplant centers and kidneys transplanted in non-Medicare patients, which would be achieved by including these kidneys in total usable kidneys and excluding them from Medicare usable kidneys. This proposal was finalized in the final rule titled “Medicare Program; Payment for Kidneys Sent to Foreign Countries or Transplanted in Patients Other Than Medicare Beneficiaries” (54 FR 5619) and currently appears at § 413.202.³⁰¹

³⁰¹ The requirement in § 413.202 (titled “Organ procurement organization (OPO) cost for kidneys sent to foreign countries or transplanted in patients other than Medicare beneficiaries” (titled “Organ procurement agencies’ (OPAs’) or transplant centers’ costs for kidneys sent to foreign countries or transplanted in non-Medicare beneficiaries”), was originally codified under § 413.179 (54 FR 5619, February 6, 1989). Section 413.179 was subsequently redesignated as § 413.202 (62 FR 43665, August 15, 1997)).

Similarly, under § 413.203, THs are required to reduce their acquisition costs for organs they furnish to foreign transplant centers and organs transplanted in non-Medicare patients. This is achieved by including these organs in total usable organs and excluding them from Medicare usable organs.

In the FY 2022 IPPS/LTCH PPS proposed rule, we proposed to require that THs count the number of organs, and IOPOs count the number of kidneys, actually transplanted into Medicare beneficiaries on their Medicare cost reports to more accurately calculate Medicare's share of organ acquisition costs. Our proposal used the current methodology to calculate Medicare's share where for THs, organs furnished to other THs or OPOs are included in the numerator and denominator of the Medicare fraction, and for IOPOs, kidneys furnished to other OPOs or THs are included in the numerator and denominator of the Medicare fraction. Under our proposal, THs and IOPOs would have been required to track organs they furnish to other facilities and to determine and report on their Medicare cost reports, the number of those organs that were transplanted into Medicare beneficiaries.

In the FY 2022 IPPS/LTCH PPS final rule with comment period, we stated that we were not finalizing the organ counting proposals included in the FY 2022 IPPS/LTCH PPS proposed rule, due to the number and nature of the comments received, and we indicated we may revisit this issue in future rulemaking. Many commenters expressed acknowledgment and understanding of CMS' objective to pay for organ acquisition costs for only organs transplanted into Medicare beneficiaries. However, commenters expressed concerns over potential operational challenges and increases in burden for THs and OPOs if CMS were to finalize the proposal and require tracking of organs furnished to other THs and OPOs, from donors to recipients. Commenters also expressed concern over the revenue reductions that OPOs and THs, particularly THs that are children's hospitals, were expected to experience under the proposal to count only organs transplanted into Medicare beneficiaries as Medicare usable organs. Many commenters indicated that because of their traditionally very low Medicare utilization, THs that

are children's hospitals would experience a greater financial burden under the proposed organ counting methodology than would be experienced by THs that are not children's hospitals. Commenters indicated that THs that are children's hospitals would have difficulty in making up for the loss of Medicare revenue from other payor sources. Commenters indicated that stakeholders would need more time to renegotiate contracts with other payors, including Medicaid payments from states. Commenters expressed concern over the potential impact on the transplantation ecosystem and suggested the proposed policy would result in a decreased organ supply, although they did not explain how the proposed policy might cause this to occur. Commenters asked CMS to either withdraw the proposal or delay its implementation. Commenters also requested that CMS conduct additional analyses.

In the FY 2022 IPPS/LTCH PPS final rule with comment period, we indicated that we would conduct additional analyses of impacts upon THs, children's hospitals, and OPOs before considering a possible re-proposal in future rulemaking of a policy that would only count organs transplanted into Medicare beneficiaries for purposes of calculating Medicare's share of organ acquisition costs. We examined the states where the children's transplant hospitals are located and how often their State legislatures meet. We found that all children's hospitals that are certified as THs are in states where legislatures meet annually, except for four children's hospitals located in Texas, where the legislature meets biennially.

Due to the comments received on the FY 2022 IPPS/LTCH PPS proposed rule, in this RFI we are seeking information as we consider an alternative methodology for counting organs that will not require THs and OPOs to track exported organs but would require TH/HOPOs and OPOs to report only organs transplanted into Medicare beneficiaries for purposes of calculating Medicare's share of organ acquisition costs. Under such methodology, TH/HOPOs would include as Medicare usable organs only organs transplanted within their TH into Medicare beneficiaries. In this regard, we would exclude organs that a TH furnishes to other THs or OPOs from its Medicare share fraction, in both the numerator (Medicare usable organs) and

denominator (total usable organs), and require revenue offsets against total organ acquisition costs for these organs. Such a methodology would result in an apportionment of costs and redistribution of reasonable organ acquisition costs to only organs transplanted into Medicare beneficiaries within the recipient TH, but it would not require TH/HOPOs to track organs they furnish to other THs and OPOs, removing a burden that was concerning to many commenters on the FY 2022 IPPS/LTCH PPS proposed rule.

For OPOs, we are considering an alternative methodology for counting organs where OPOs would count all organs, not just kidneys, and calculate Medicare's share of organ acquisition costs using a ratio of Medicare usable organs to total usable organs. OPOs would include in Medicare usable organs only organs transplanted into Medicare beneficiaries, using recipient payor data provided to OPOs by the OPTN. Under such a methodology, OPOs would also be required to offset total organ acquisition costs with revenue received for Medicare usable organs. Under the methodology, IOPOs would not be required to track organs they furnish to other OPOs or THs to determine whether the organ recipient is a Medicare beneficiary, removing a burden that was concerning to many commenters on the FY 2022 IPPS/LTCH PPS proposed rule. Such a methodology would result in an apportionment of costs and redistribution of reasonable organ acquisition costs to only organs transplanted into Medicare beneficiaries.

We would like to better understand and obtain more detailed information on the extent to which THs, OPOs, and other interested parties would be impacted under these alternative organ counting methodologies used to calculate Medicare's share of organ acquisition costs.

Specifically, CMS seeks public comment on the following:

1. What proportion of organs used for transplant are acquired by your hospital, received from other THs directly, or received from OPOs? Does this vary by type of organ, age category, or insurance status of the potential recipient and if so, how?

2. Of all the transplants performed in your hospital in the past 5 years, what percentage were for:

a) Medicare beneficiaries; b) Medicaid patients; c) private pay patients; d) patients who receive financial assistance for services provided at a free or reduced rate?

3. Describe how THs and OPOs currently support organ acquisition costs financially. What revenue and income streams (for example, grants, fundraising, etc.) support these activities?

4. Are you able to quantify the revenue your facility has received over the past 5 years resulting from Medicare's organ counting policy because acquisition costs were assigned to Medicare usable organs for THs, or Medicare usable kidneys for IOPOs, that were transplanted into non-Medicare beneficiaries? If so, what are the amounts?

5. Describe the impact of the revenue reduction resulting from an alternate organ counting methodology, both in absolute terms and relative to your IOPO, or transplant program and hospital as a whole.

6. Should children's hospitals be treated differently under an alternate organ counting methodology, and if so, why and how?

7. In your State, does Medicaid cover organ transplants and acquisition costs? If so, explain the Medicaid payment methodology. Would an alternative organ counting methodology to calculate Medicare's share of organ acquisition costs impact your payments received from Medicaid for transplants and/or organ acquisition costs? Additionally, would a potential change in organ counting affect access to care, and if so, how?

8. Do other payors pay equitably to share in the costs to acquire organs for transplant for their patients? If so, under an alternate organ counting methodology for Medicare would all payors, including Medicaid, continue to equitably share in the cost to acquire organs for transplant? By "equitably", we mean other payors pay their share of organ acquisition costs for organs transplanted into their respective patients.

9. If an alternate organ counting methodology were implemented, are there any timing issues for implementation that we should consider regarding other payors, including State Medicaid Agencies, to address their organ acquisition and/or transplant payment methodologies?

10. Describe what services your TH or IOPO may need to reduce or change to accommodate a reduction in revenue from Medicare stemming from an alternate organ counting methodology to count only organs transplanted into Medicare beneficiaries to calculate Medicare's share of organ acquisition costs.

11. Will your facility perform less transplants if revenue is eliminated from Medicare under an alternate organ counting methodology? If so, why and how? Will your facility perform less organ acquisitions if revenue is eliminated from Medicare under an alternate organ counting methodology? If so, why and how?

12. Is the cost to acquire an organ for transplantation into a Medicare beneficiary different than the cost to acquire an organ for transplantation into a non-Medicare beneficiary? If so, what factors contribute to the difference in organ acquisition costs?

13. Describe how clinical decision-making affects organ allocation and transplantation. Are there other factors that affect organ allocation and transplantation that we should be aware of?

2. IOPO Kidney Standard Acquisition Charges

Currently, the contractor³⁰² establishes each IOPO's kidney SAC, and adjusts it if necessary, in accordance with § 413.404(c)(2). IOPOs must bill their kidney SAC for the costs of Medicare and non-Medicare kidneys procured for transplant, and are paid their SAC amount by the entity receiving the kidney (§ 413.404(c)(3)). At the end of the cost reporting period, the contractor reconciles the IOPO's Medicare kidney acquisition costs with the revenue the IOPO received for those kidneys, and settles with the IOPO to

³⁰² "contractor" refers to the Medicare Administrative Contractor (MAC) and conforms to terminology changes made in the FY 2015 IPPS final rule (79 FR 50199) and with the definition given at 42 CFR 405.201(b).

ensure it is paid the reasonable costs of Medicare kidney acquisition

(§ 413.420(e)(2)).³⁰³

Currently, IOPOs count almost all of the kidneys they procure as Medicare usable kidneys. (Kidneys sent outside of the United States are not counted as Medicare usable kidneys.) Consequently, Medicare's current share of kidney acquisition costs is nearly 100 percent, and the reconciliation process currently makes the IOPO whole for nearly all its kidney acquisition costs, on a reasonable cost basis. However, not all kidneys that are counted as Medicare usable kidneys are transplanted into Medicare beneficiaries; some of those kidneys are transplanted into patients with Medicaid, private insurance, etc. As discussed in the Request for Information (RFI) in section XVII.F.1 of this proposed rule, we are considering an alternative organ counting methodology that would require IOPOs to count as Medicare usable organs only those organs that are actually transplanted into Medicare beneficiaries, including renal and non-renal organs. Such a methodology would result in IOPOs' organ acquisition costs being reconciled and settled for all organ acquisition costs for organs actually transplanted into Medicare beneficiaries.

Additionally, for kidneys, such an alternative organ counting methodology would limit the kidney revenue IOPOs receive from THs and other OPOs to the kidney SAC amount. Longstanding policy currently requires the contractor to establish the kidney SAC amount (§ 413.404(c)(2)). To ensure that an IOPO's kidney SAC appropriately covers its costs, we are considering a methodology under which IOPOs, rather than the Medicare contractor, would establish their kidney SACs, similar to how they establish their SACs for non-renal organs. This alternative methodology would place the fiscal responsibility on the IOPOs for kidneys, similar to non-renal organs, by placing the IOPO in control of its kidney acquisition revenue stream through control of its kidney SAC.

³⁰³ Section 1861(v) of the Act requires that certain Medicare services, including organ acquisition costs, must be paid based on reasonable cost.

Specifically, we are considering an alternative methodology where an IOPO would estimate the reasonable and necessary costs it expects to incur for services furnished to procure deceased donor kidneys during its cost reporting period and divide that estimated amount by the projected number of deceased donor kidneys the IOPO expects to procure within its cost reporting period. We are also considering a potential policy approach that would permit an IOPO to adjust its kidney SAC during the year, if necessary, to account for cost changes. We believe these alternative policy approaches are in alignment with section 371(b)(1)(B) of the Public Health Service Act and the conditions of participation at § 486.303(c), which require OPOs to have accounting and other fiscal procedures necessary to assure the fiscal stability of the organization, including procedures to obtain payment for kidneys and non-renal organs provided to THs.

We are requesting information on these alternative policy approaches that we are considering related to the IOPO kidney SAC. Specifically, we are seeking information pertaining to the following questions:

1. Do IOPOs have any concerns with establishing (and where necessary, adjusting) their own kidney SAC, in accordance with the potential policy approach under consideration? Do IOPOs have any concerns with the potential methodology under consideration for calculating the kidney SAC amount?

2. We have heard from stakeholders that some IOPOs have lengthy internal processes to adjust their SACs. Do IOPOs have the ability to respond quickly to cost changes that might necessitate a SAC adjustment? How frequently do IOPOs currently need to adjust their SACs due to cost changes that are higher or lower than usual?

3. Are there specific high cost items or services associated with organ procurement that potentially could increase a SAC? If yes, please explain. What rules or parameters should CMS consider to account for these items or services when developing a potential methodology for how IOPOs calculate their SACs?

4. Do IOPOs believe that being in control of their kidney SAC, as they are of their non-renal organ SACs, would improve their fiscal stability?

5. Do stakeholders have concerns about IOPOs establishing their kidney SACs?

3. Reconciliation for All Organs for IOPOs

Currently, the contractor is required to review IOPOs' kidney acquisition costs and reconcile and settle those costs to ensure that Medicare pays its share on a reasonable cost basis. However, there is no similar requirement for the contractor to review, reconcile and settle IOPOs' non-renal organ acquisition costs. Over the years, through various rulings and national coverage determinations (NCDs), Medicare has added coverage for transplantation of non-renal organs such as heart, liver, or lungs. Non-renal organs were covered for transplantation through a CMS Ruling (for heart transplants) and through NCDs (for other non-renal organs),³⁰⁴ and payment policies were subsequently implemented through notice-and-comment rulemaking.³⁰⁵ We modeled our reimbursement for non-renal organ acquisition costs on our earlier kidney acquisition policies. In addition, the OIG³⁰⁶ and Congress³⁰⁷ have expressed concerns regarding some OPOs' financial practices. As such, we believe there is a need to provide more contractor review of non-renal organ acquisition costs to protect the Medicare Trust Fund and the transplant ecosystem. Therefore, we are considering a requirement that the contractor review, reconcile and settle Medicare's share of costs to acquire non-renal organs for IOPOs under reasonable cost principles, similar to the current practice for kidneys.

³⁰⁴See CMS Ruling 87-1, April 1987; National Coverage Determinations Manual, IOM 100-03, chapter 1, Part 4, section 260 (available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part4.pdf).

³⁰⁵ 52 FR 33034, September 1, 1987 (heart); 55 FR 8545, March 8, 1990 and 56 FR 15013, April 12, 1991 (liver); 60 FR 6537, February 2, 1995 (lung); 64 FR 41497, July 30, 1999 (pancreas); 66 FR 39828, August 1, 2001 (intestine, with reasonable cost coverage of acquisition costs beginning October 1, 2001).

³⁰⁶ <https://oig.hhs.gov/oas/reports/region9/90800033.pdf>; <https://oig.hhs.gov/oas/reports/region9/90900087.pdf>; <https://oig.hhs.gov/oas/reports/region9/90500034A.pdf>; <https://oig.hhs.gov/oas/reports/region9/91102039.pdf>.

³⁰⁷ <https://oversight.house.gov/news/press-releases/oversight-subcommittee-launches-investigation-into-poor-performance-waste-> and <https://www.young.senate.gov/newsroom/press-releases/young-joins-finance-committee-members-to-probe-us-organ-transplant-system>; <https://www.congress.gov/117/chr/CHRG-117hrg44569/CHRG-117hrg44569.pdf>.

To reconcile Medicare's share of non-renal organ acquisition costs, the contractor would review the Medicare cost report to determine if the costs are reasonable. This would entail the contractor's review of all IOPO organ acquisition costs, and would ensure that IOPOs' costs that are reported as organ acquisition costs are appropriate, in accordance with § 413.402, and are reasonable and necessary, in accordance with section 1861(v) of the Act and §§ 413.5 and 413.9.

If an IOPO establishes a non-renal SAC that is higher than its reasonable costs, that higher charge becomes an inflated non-renal organ acquisition cost to the TH or other OPO receiving the organ. Medicare shares in these inflated costs as a portion are ultimately paid by Medicare when Medicare reconciles THs' organ acquisition costs. Without reconciliation and settlement of IOPOs' non-renal organ acquisition costs, Medicare cannot recover those inflated costs, resulting in Medicare paying more than reasonable costs for Medicare's share of organ acquisitions. Conversely, if an IOPO establishes a non-renal SAC that is less than its reasonable costs, the charge becomes an organ acquisition cost to the TH receiving the organ. The lower costs are ultimately paid to the TH by Medicare when reconciled through the TH's Medicare cost report. Without reconciliation and settlement of IOPOs' non-renal organ acquisition costs, Medicare is unable to make IOPOs whole for Medicare's share of the reasonable costs. If IOPOs are consistently underpaid for their non-renal Medicare organ acquisitions costs because IOPOs establish SACs that are too low, their fiscal stability could be compromised.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25675), we proposed regulatory changes to § 413.200, and a commenter expressed concern that CMS did not make a proposal to reconcile and settle an IOPO's non-renal organ acquisition costs. The commenter noted that not reconciling and settling IOPO non-renal organ acquisition costs could result in fewer non-renal organs being made available for transplant when an IOPO's total non-renal organ acquisition costs exceed the total revenue the IOPO receives for organs it provides to other OPOs or THs. In the FY 2022 IPPS/LTCH PPS final rule with comment period, we responded that we would consider this issue in future rulemaking (86 FR 73479). While the inconsistency in reconciliation

and settlement of renal and non-renal organ acquisition costs may compromise fiscal stability if costs consistently exceed revenue, we do not know the extent to which this inconsistency might also affect equity in organ procurement or patient access to transplants. We are committed to identifying and addressing Medicare payment inequities for organ acquisition costs in the transplant ecosystem.

Another commenter on the FY 2022 IPPS/LTCH PPS proposed rule suggested that the contractor review, approve, and publish IOPO non-renal SACs to provide needed oversight. We responded that we would consider our options for future rulemaking (86 FR 73479). We believe it is important that IOPOs continue their responsibility for establishing their non-renal SACs to maintain financial stability and control over their operating revenue and cash flow, which is based upon the SACs they bill (42 U.S.C. 273(b)); however, requiring reconciliation and settlement of IOPOs' non-renal organ acquisition costs would provide needed contractor review to ensure alignment with Medicare's reasonable cost principles while still encouraging IOPOs' fiscal responsibility.

Our authority to reconcile and settle non-renal organ acquisition costs exists under section 1138(b) of the Act. Medicare payment for organ procurement costs may be made only if an OPO has been designated by the Secretary as the OPO for its service area (§ 486.301(a)(1)). An OPO must enter into an agreement with CMS in order for the organ procurement costs attributable to the OPO to be reimbursed under Medicare and Medicaid (§ 486.304(c)). Consequently, all OPOs wishing to receive Medicare and Medicaid reimbursement for the procurement of organs must have a signed agreement with CMS.³⁰⁸

For these reasons, we are considering a potential policy approach under which Medicare would reconcile and settle for its share of an IOPO's non-renal organ acquisition costs, in accordance with section 1861(v) of the Act and §§ 413.60 and 413.64(f). Under this potential policy approach, Medicare-certified IOPOs would submit a Medicare cost report for review,

³⁰⁸ See form CMS 576-A, expires January 31, 2023; OMB No. 0938-0512.

reconciliation, and settlement of non-renal organ acquisition costs to determine Medicare's reasonable costs. This potential policy approach would mirror our current approach for determining Medicare's reimbursement of IOPOs' kidney acquisition costs. In addition, as part of this potential policy approach, we would require IOPOs to provide their non-renal SACs to the contractor, similar to how IOPOs are currently required to share their renal SACs with the contractor (*see* § 413.420(d)(4)). This potential policy approach that we are considering would provide needed contractor oversight to protect the Medicare Trust Fund and the transplant ecosystem, and would ensure that non-renal organ acquisition costs are paid on a reasonable cost basis. Such an approach would promote fiscal responsibility for IOPOs, and would also create a more equitable, consistent process for billing and reimbursing organ acquisition costs for non-renal versus renal organs. We are requesting information on the alternative policy approach under consideration, and on the following questions:

1. Does the current policy of not reconciling and settling IOPOs' non-renal organ acquisition charges lead to excessive non-renal SACs? If yes, please explain.
2. How often and to what extent do IOPOs have non-renal organ acquisition costs that exceed the revenue they receive for those non-renal organs procured? Are there particular situations or items or services where an IOPO's non-renal organ costs would exceed the non-renal SAC amount received from the TH (or other IOPO) for the organ(s) procured?
3. Does the current lack of reconciliation and settlement of non-renal organ acquisition costs disincentivize IOPOs from procuring non-renal organs? Does it create an inequity in organ procurement for renal vs. non-renal organs? Would a potential policy approach that included a requirement to reconcile and settle non-renal organ acquisition costs better support the transplant ecosystem?
4. How would contractor review, reconciliation, and settlement of IOPOs' non-renal organ acquisition costs affect the transplant ecosystem? Would there be any effect on those waiting for a non-renal transplant or on transplant hospitals?

5. Would CMS's adoption of a policy approach that required reconciliation and settlement of non-renal organ acquisition costs cause IOPOs to procure fewer organs, more organs, or about the same number of organs for transplant? If so, how and why?

XVIII. Rural Emergency Hospitals (REH): Payment Policies, Conditions of Participation, Provider Enrollment, Use of the Medicare Outpatient Observation Notice, and Physician Self-Referral Law Updates

A. Rural Emergency Hospitals (REH) Payment Policies

1. Introduction

Americans who live in rural areas of the nation make up about 20 percent of the United States (U.S.) population, and they often experience shorter life expectancy, higher all-cause mortality, higher rates of poverty, fewer local doctors, and greater distances to travel to see health care providers, compared to their urban and suburban counterparts.³⁰⁹ In addition, one in five rural residents identifies as Black, Hispanic, American Indian/Alaska Native (AI/AN), Asian American/Pacific Islander (AA/PI), or a combination of ethnic backgrounds. Compared to the non-Hispanic White rural population, these rural minority groups often and regularly experience several disadvantageous social determinants of health.³¹⁰

The health care inequities that many rural Americans face raise serious concerns that the trend for poor health care access and worse outcomes overall in rural areas will continue unless the potential causes of such health care inequities are addressed.

There have been growing concerns over the closures of rural hospitals and critical access hospitals (CAHs). Between 2010 and February 2022, 138 rural hospitals stopped providing inpatient services, 44 of which were Critical Access Hospitals. There were 75 complete hospital closures where all services ended and 63 hospital conversions where inpatient services ended but

³⁰⁹ Rural Health Research Gateway. (2018). Rural Communities: Age, Income, and Health Status. <https://www.ruralhealthresearch.org/assets/2200-8536/rural-communities-age-income-health-status-recap.pdf>

³¹⁰ Health Resources & Services Administration (2021). Rural Hospital Programs. <https://www.hrsa.gov/rural-health/rural-hospitals/>

some type of health care service continued.³¹¹ Rural hospitals report they continue to face the threat of closure because they lack sufficient patient volume to offer traditional hospital inpatient acute care services required for Medicare payment; however, the demand still exists for emergency and outpatient services in areas served by these hospitals. Rural hospitals are essential to providing health care to their communities and the closure of these hospitals limits access to care for the communities they once served and reduces employment opportunities, further impacting local economies. Barriers such as workforce shortages can impact health care access in rural communities and can lead to unmet health needs, delays in receiving appropriate care, inability to get preventive services, financial burdens, and preventable hospitalizations.³¹²

The Consolidated Appropriations Act (CAA), 2021, was signed into law on December 27, 2020. In this legislation, Congress established a new rural Medicare provider type: Rural Emergency Hospitals (REHs). These providers will furnish emergency department and observation care, and other specified outpatient medical and health services, if elected by the REH, that do not exceed an annual per patient average of 24 hours. Hospitals may convert to REHs if they were CAHs or rural hospitals with not more than 50 beds participating in Medicare as of the date of enactment of the CAA.

REHs are expected to help address the barriers in access to health care, particularly emergency services and other outpatient services that result from rural hospital closures, and by doing so, may help address observed inequities in health care in rural areas.

On January 20 and 21, 2021, President Biden issued three executive orders related to issues of health equity: Executive Order 13985 “Advancing Racial Equity and Support for Underserved Communities Through the Federal Government;”³¹³ Executive Order 13988,

³¹¹ UNC: Cecil G. Sheps Center for Health Services Research. (2022). Rural Hospital Closures. <https://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/>

³¹² Healthy People 2020 (n.d.) Access to Health Services. <https://www.healthypeople.gov/2020/topics-objectives/topic/Access-to-Health-Services>

³¹³ The White House. (2021). Briefing Room: Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/>.

“Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation;”³¹⁴ and Executive Order 13995 “Ensuring an Equitable Pandemic Response and Recovery.”³¹⁵

Executive Order 13985, “Advancing Racial Equity and Support for Underserved Communities Through the Federal Government” requires the Federal Government to pursue a comprehensive approach to advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality by recognizing and working to redress inequities in its policies and programs that serve as barriers to equal opportunity. In accordance with this executive order, persons who live in rural areas are identified as belonging to underserved communities that have been adversely affected by inequality.

Executive Order 13988, “Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation” requires the Federal Government to prevent and combat discrimination, including when accessing health care, on the basis of gender identity or sexual orientation, and to fully enforce Title VII of the Civil Rights Act. This executive order also requires the Federal Government to fully enforce other laws that prohibit discrimination on the basis of gender identity or sexual orientation, all of which impact all persons, including those in rural communities.

In accordance with Executive Order 13995, “Ensuring an Equitable Pandemic Response and Recovery,” the Federal Government must identify and eliminate health and social inequities resulting in disproportionately higher rates of exposure, illness, and death related to COVID-19 and take swift action to prevent and remedy differences in COVID-19 care and outcomes within

³¹⁴ The White House. (2021). Briefing Room: Executive Order on Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation. <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-preventing-and-combating-discrimination-on-basis-of-gender-identity-or-sexual-orientation/>.

³¹⁵ The White House. (2021). Briefing Room: Executive Order on Ensuring an Equitable Pandemic Response and Recovery. <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/21/executive-order-ensuring-an-equitable-pandemic-response-and-recovery/>.

communities of color and other underserved populations. The executive order highlights the observed inequities in rural and Tribal communities, territories, and other geographically isolated communities. We believe the services furnished by REHs, could be one means of addressing some of the issues raised in these orders, particularly, barriers to access health care in rural communities.

Consistent with these executive orders, in implementing the new REH provider type, we are committed to advancing equity for all, including racial and ethnic minorities, members of the lesbian, gay, bisexual, transgender, and queer/questioning (LGBTQ) community, people with limited English proficiency, people with disabilities, rural populations, and people otherwise adversely affected by persistent poverty or inequality.

2. Statutory Authority and Establishment of Rural Emergency Hospitals as a Medicare Provider Type

Section 125 of Division CC of the CAA was signed into law on December 27, 2020 and establishes REHs as a new Medicare provider type. Section 125 of the CAA added section 1861(kkk) to the Social Security Act (the Act), which sets forth the requirements for REHs. Section 1861(kkk)(2) of the Act defines an REH as a facility that is enrolled in the Medicare program as an REH; does not provide any acute care inpatient services (other than post-hospital extended care services furnished in a distinct part unit licensed as a skilled nursing facility (SNF)); has a transfer agreement in effect with a level I or level II trauma center; meets certain licensure requirements; meets requirements of a staffed emergency department; meets staff training and certification requirements established by the Secretary of the Department of Health and Human Services (the Secretary); and meets certain conditions of participation (CoPs) applicable to hospital emergency departments and CAHs with respect to emergency services.

Additionally, section 125(a)(1) of the CAA added section 1861(kkk)(1) of the Act, which requires that REHs provide emergency department services and observation care and, at the election of the REH, other medical and health services furnished on an outpatient basis, as

specified by the Secretary through rulemaking. The REH must also have a staffed emergency department 24 hours a day, 7 days a week, have a physician, nurse practitioner, clinical nurse specialist, or physician assistant available to furnish rural emergency hospital services in the facility 24 hours a day, and meet applicable staffing requirements similar to those for CAHs.³¹⁶

In order to become an REH, section 1861(kkk)(3) of the Act requires that the facility, on the date of enactment of the CAA, 2021 (December 27, 2020), was a CAH or a rural hospital with not more than 50 beds. For the purpose of REH designation, section 1861(kkk)(3)(B) defines rural hospital as a subsection (d) hospital (as defined in section 1886(d)(1)(B) with not more than 50 beds located in a county (or equivalent unit of local government) in a rural area (as defined in section 1886(d)(2)(D) of the Act)), or treated as being located in a rural area pursuant to section 1886(d)(8)(E) of the Act. In addition, the REH must meet certain other requirements under section 1861(kkk) of the Act, including, but not limited to the following:

- An annual per patient average of 24 hours or less in the REH;
- Staff training and certification requirements established by the Secretary;
- Emergency services CoPs applicable to CAHs;
- Hospital emergency department CoPs determined applicable by the Secretary;
- The applicable SNF requirements (if the REH includes a distinct part SNF);
- A transfer agreement with a level I or level II trauma center; and
- Any other requirements the Secretary finds necessary in the interest of the health and

safety of individuals who are furnished services by an REH.

Starting on January 1, 2023, an REH that provides rural emergency hospital services (as defined in section 1861(kkk)(1) of the Act) will receive a Medicare payment for those services pursuant to section 1834(x)(1) of the Act, as added by section 125 of the CAA, that is equal to the amount of payment that would otherwise apply under the Medicare Hospital Outpatient

³¹⁶ Congress.gov. (2020). H.R.133 - Consolidated Appropriations Act, 2021. <https://www.congress.gov/116/bills/hr133/BILLS-116hr133enr.pdf>

Prospective Payment System (OPPS) for covered outpatient department (OPD) services increased by 5 percent. The beneficiary co-payments for these services will be calculated the same way as under the OPPS for the service, excluding the 5 percent payment increase. In addition, section 1834(x)(2) of the Act provides an additional monthly facility payment to an REH.

To participate in the Medicare program and receive payment for services furnished to Medicare beneficiaries, providers of services such as hospitals, home-health agencies, hospices, SNFs, and now REHs must enter into a provider agreement with CMS, in accordance with section 1866 of the Act. Medicaid providers, likewise, must enter into provider agreements with State Medicaid agencies to be eligible for participation in that program as described in section 1902(a)(27) of the Act. By entering into a provider agreement, a facility agrees that it will comply with the applicable requirements of the Medicare and Medicaid statutes and the regulations that the Secretary issues under the respective statute.

Section 1861(kkk)(7) of the Act requires the Secretary to establish quality measurement reporting requirements for REHs, which may include claims-based outcome measures and/or patient experience surveys. An REH must submit quality measure data to the Secretary with respect to each year beginning in 2023 (or each year beginning on or after the date that is one year after one or more measures are first specified), and the Secretary is required to establish procedures to make the data available to the public on the CMS website. At this time, CMS is requesting information on certain quality measures and quality reporting requirements for REHs as discussed further in section XVI of this proposed rule.

The Quality Improvement Organization requirements of the Act shall apply to REHs in the same manner that they apply to hospitals and CAHs, in accordance with section 1866(a) of the Act (as amended by section 125(b)(1) of the CAA). In addition, the requirements established at section 1864 of the Act for hospitals and CAHs to be surveyed for compliance with the CoPs

shall apply to REHs in the same manner as other hospitals and CAHs, in accordance with section 125(d)(2) of the CAA.

In accordance with section 1864 of the Act, CMS uses State surveyors to determine whether a provider or supplier subject to certification qualifies for an agreement to participate in Medicare. Additionally, under section 1865 of the Act, some providers or suppliers subject to certification have the option to instead elect to be accredited by private accrediting organizations (AOs) whose Medicare accreditation programs have been approved by CMS as having standards and survey procedures that meet or exceed all applicable Medicare requirements. The survey process for Medicare and Medicaid participating providers and suppliers provides an opportunity for these providers and suppliers to demonstrate compliance with all of the applicable CoPs, conditions for coverage (CfCs) or requirements. The methods used by CMS to determine compliance with the regulations include surveys conducted by a State survey agency, surveys conducted by AOs that have deeming authority for Medicare providers and suppliers, and self-attestation. CMS would require REHs participating in Medicare to demonstrate and maintain compliance with the provisions included in the CY 2023 OPPI final rule with comment period.

3. Summary of Comments by Interested Parties in Response to REH Request for Information

In preparation for developing these proposed standards and to gain a clear understanding of the challenges faced by facilities providing health care services in rural communities, we published a Request for Information (RFI) on REHs in the proposed rule, “Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals” (86 FR 42018) on August 4, 2021. CMS sought public input on a broad range of issues to inform our policymaking in establishing this new provider type. The RFI solicited public input on the concerns of rural providers, including in the areas of health and safety standards, health equity, payment policies,

quality measures and quality reporting, and additional considerations and unintended consequences that should be considered during the development of standards for REHs.

Commenters on the RFI generally noted that CMS should take into consideration the challenges associated with the provision of health care services in rural communities. Some commenters noted that, while Congress did not specify the exact steps that CMS should take to calculate the annual facility payment, CMS should do so in a manner that maximizes potential payment to REHs to ensure these hospitals can continue to operate. Other commenters cautioned CMS against calculating the monthly facility payment in a way that leads to excessive payment. Commenters also encouraged CMS to set forth the details of the payment calculation in rulemaking, so that interested parties could replicate the calculation. With regard to the services provided by REHs, commenters recommended that REHs should provide maternal health, behavioral/mental health services, and telehealth services to further support the communities that they will serve. Commenters recommended that CMS pay for all REH services at the OPPS rate plus 5 percent. A few commenters also suggested that CMS should pay for all services furnished by an REH, including those that are not designated as REH services, at the applicable rate plus 5 percent. With regard to health equity, several interested parties commented that REHs could have significant value for underserved, rural populations by maintaining local access to care, reducing travel times for care, and serving as leaders for community health improvement efforts including efforts to address the social determinants of health. We note that CMS is committed to reducing inequities in rural communities and we are considering the best approach to address health equity in the standards for all Medicare and Medicaid participating providers and suppliers, including REHs.

We have reviewed all comments from interested parties and have taken them into consideration while drafting this proposed rule. We appreciate the interested parties' input and responses to our outreach efforts thus far.

During the development of the policies to implement this new provider type, we reviewed the public comments received on the REH RFI, and held public listening sessions with national stakeholder organizations as well as tribal communities. We also gave presentations at CMS' hospital, rural health, and SNF open door forums and sought public feedback.

4. Payment for Services performed by REHs

a. Covered Outpatient Department (OPD) services performed by REHs

(1) Defining "REH Services"

Section 1861(kkk)(1)(A) defines the term "REH services" as emergency department and observation services as well as, at the election of the REH, other medical and health services furnished on an outpatient basis as specified by the Secretary through rulemaking.

We considered how to determine what other covered outpatient medical and health services should be considered "REH services" for purposes of payment under section 1834(x)(1). Section 1834(x)(1) provides that the amount of payment for REH services shall be equal to the amount of payment that would otherwise apply under section 1833(t) of the Act for covered OPD services (as defined in section 1833(t)(1)(B) (other than clause (ii) of such section, which are inpatient hospital services paid under the OPPI)), increased by 5 percent. We interpret this statutory language to mean that the scope of covered OPD services as defined in 1833(t)(1)(B) of the Act (excluding 1833(t)(1)(B)(ii)) represents the outer limit of services that CMS may specify as "REH services." 1834(x)(1) frames the services that may receive the 5 percent increase provided under the statute for "REH services" exclusively in terms of covered OPD services, which we believe precludes including any services that are not "covered OPD services" in this definition. Although we interpret 1834(x)(1) to limit the potential scope of REH services to what is included within the definition of "covered OPD services," we are not suggesting that REHs would be unable to furnish, and receive payment for, other services. Rather, we are stating that only services that are covered OPD services can be paid as specified under Section 1834(x)(1). For further discussion of CMS's proposals pertaining to payment for other services performed by

REHs, please see discussion in the below section titled “Services performed by REHs that are not specified REH services.”

Within the universe of covered OPD services, in its broadest interpretation, “REH services” could be defined to encompass all services included in the definition of “covered OPD services,” as provided in section 1833(t)(1)(B) of the Act, when furnished by an REH, with the exception of services described in clause (ii) of such section, which are hospital inpatient services, as REHs are precluded by section 1861(kkk)(2)(B) of the Act from providing acute inpatient services. Alternatively, CMS could define “REH services” to include only a smaller subset of services. For instance, we considered limiting “REH services” to services that are emergent in nature, such as those services described by the specific HCPCS codes describing emergency department visits and observation services.

We have some concerns, however, about narrowly defining the covered OPD services for which REHs may receive payment as REH services to only services that are emergent in nature. For one, if CMS were to limit the definition of REH services to strictly emergency services, this might cause REHs to cease to furnish other covered OPD services previously provided by the facility upon conversion of the facility to an REH, which could limit access to such services for some beneficiaries. This would seem antithetical to the purpose of section 125 of the CAA, which was created with the goal of ensuring greater access to outpatient services in rural areas. Further, a narrower definition could exclude services that may be desirable for REHs to provide in order to expand or maintain access to outpatient services in rural areas, including behavioral health, routine imaging, or clinic visits.

In light of our concerns with narrowly defining “REH services” and our interest in allowing maximum flexibility for REHs to tailor the services provided to the needs of their individual communities, for purposes of payment, we are proposing to define “REH services,” at 42 CFR 419.91, as all covered outpatient department services, as defined in section 1833(t)(1)(B) of the Act, excluding services described in section 1833(t)(1)(B)(ii), furnished by an REH that

would be paid under the OPSS when provided in a hospital paid under the OPSS for outpatient services, provided that the REH meets the various applicable REH CoPs. In other words, all services that are paid under the OPSS when furnished in an OPSS hospital, with the exception of acute inpatient services, would be REH services when furnished in a REH. We note that this definition of REH services excludes services described in section 1833(t)(1)(B)(ii) of the Act, which cannot be considered REH services because they are inpatient services, which REHs are not permitted to furnish pursuant to section 1861(kkk)(2)(B) of the Act.

Additionally, we are soliciting comments on whether CMS should adopt a narrower definition of REH services than the definition we are proposing, and if so, how commenters believe we should define these services and what methodology commenters suggest CMS use to determine whether a service meets this definition.

(2) Payment for REH Services

Section 1834(x)(1) of the Act states that payment for REH services "...shall be equal to the amount of payment that would otherwise apply under section 1833(t) for covered OPD services (as defined in section 1833(t)(1)(B) (other than clause (ii) of such section)), increased by 5 percent to reflect the higher costs incurred by such hospitals, and shall include the application of any copayment amount determined under section 1833(t)(8) as if such increase had not occurred." As a result, we propose that payments for REH services would be calculated using existing OPSS payment policies and rules. The only differences between the payment for a covered OPD service furnished by an OPSS provider and the payment for an REH service furnished by an REH provider would be that the service payment to the REH would be equal to the applicable OPSS payment for the same service plus an additional 5 percent. Accordingly, we propose to codify, at 42 CFR 419.92(a)(1), that the payment rate for an REH service would be calculated using the OPSS prospective payment rate for the equivalent covered OPD service increased by 5 percent.

Because we are proposing to utilize OPSS payment policies and rules to effectuate payment rates for REH services equivalent to the OPSS payment rates plus five percent, we believe it would be most efficient from a claims processing perspective for the REHs to utilize the OPSS claims processing system to process REH payments. We propose updating the OPSS claims processing logic to include an REH-specific payment flag, which an REH provider would utilize to indicate that the provider is an REH and should not be paid at the OPSS payment rates, but should instead be paid at the REH payment rates. Claims from REH providers for REH services would be processed within the OPSS claims processing system. However, when a REH submits a facility claim with the REH-specific payment flag, this payment flag would trigger payment for REH services on the claim at the REH services payment rate, which is the OPSS payment rate plus 5 percent.

We also propose, consistent with the requirement in section 1834(x)(1) of the Act, that the copayment amount for a REH service would be determined as if the 5 percent payment increase had not occurred. That is, the additional 5 percent payment for REH services, above the amount that would be paid for covered OPD services, would not be subject to a copayment. Therefore, we propose to codify in the REH payment regulation, at 42 CFR 419.92(a)(2), that the beneficiary copayment amounts for REH service would be the amounts determined under the OPSS for the equivalent covered OPD service, pursuant to section 1833(t)(8) of the Act, and would exclude the 5 percent payment increase that applies to the REH service payment.

Finally, we note that section 1834(x)(5)(A) of the Act states that "...except as provided in subparagraph (B), payments under this subsection shall be made from the Federal Supplementary Medical Insurance Trust Fund under section 1841." The statute makes clear that payments for services rendered by REHs receive payment from the Federal Supplementary Medical Insurance Trust Fund under section 1841. We note, however, that payments for REH services would have no impact on OPSS budget neutrality because REH services are not covered OPD services under section 1833(t) of the Act to which the OPSS budget neutrality requirements apply. This also

means that REH claims would not be used for OPPS rate setting purposes. Consistent with section 1834(x)(5)(A) of the Act, REH service payments will be paid from the Federal Supplementary Medical Insurance Trust Fund under section 1841 of the Act.

b. Services performed by REHs that are not specified REH services

Section 1834(x)(1) specifically addresses the payment rate that applies for “REH services,” which, as discussed above, include at most the full range of covered OPD services for which payment can be made under the OPPS. Likewise, as discussed further below, sections 1834(x)(3) and 1834(x)(4) of the Act specifically address payment for ambulance services and post-hospital extended care services that are furnished by an REH. However, section 125 of the CAA is silent on how CMS should pay for other services furnished by an REH, such as services paid under the Clinical Laboratory Fee Schedule (CLFS) or outpatient therapy services, that may be provided on an outpatient basis by hospital outpatient departments, but that are not covered OPD services, as defined under section 1833(t)(1)(B) of the Act, and thus, pursuant to the limiting language in 1834(x)(1) of the Act, would not be payable as REH services when furnished by an REH.

In order for a REH to fulfill the statutory requirements set forth in section 1861(kkk)(2) of the Act, as well as the proposed CoPs for REHs described in the proposed rule “Medicare and Medicaid Programs; Conditions of Participation (CoPs) for Rural Emergency Hospital (REH) and Critical Access Hospital CoP Updates,” which appeared in the **Federal Register** on July 6, 2022 (87 FR 40350), REHs must be capable of providing certain types of outpatient services that are not covered OPD services, such as basic laboratory services and certain diagnostic services. Additionally, the proposed REH CoPs state that the REH may provide outpatient and medical health diagnostic and therapeutic items and services that are commonly furnished in a physician's office or at another entry point into the health care delivery system that include, but are not limited to, radiology, laboratory, outpatient rehabilitation, surgical, maternal health, and behavioral health services.

As discussed above, section 1834(x)(1) of the Act provides that the amount CMS shall pay for REH services furnished by an REH shall be the same amount that would otherwise apply under section 1833(t) of the Act for covered OPD services plus five percent. However, section 125 of the CAA does not indicate that the additional 5 percent payment described in 1834(x)(1) of the Act would apply to any services other than those within the definition of “REH services.” While some of the services described by the proposed REH CoPs would meet the definition of an REH service because they are also covered OPD services under section 1833(t)(1)(B) of the Act and would therefore be eligible for the 5 percent additional payment specified in 1834(x)(1) of the Act, others—such as laboratory services paid off of the CLFS, and outpatient rehabilitation services—are outside the scope of covered OPD services and therefore, for the reasons previously discussed, could not meet the definition of a REH service. However, CMS believes that it is consistent with the statutory requirements for rural emergency hospitals set forth in section 1861(kkk)(2) of the Act for these services to be paid when they are furnished in an REH. As a result, we are proposing that any outpatient service furnished by an REH consistent with the statutory requirements governing this provider type and the proposed REH CoPs, that does not meet the proposed definition of REH services, would be paid at the same rate the service would be paid if performed in a hospital outpatient department and paid under a fee schedule other than the OPDS, provided the requirements for payment under that system are met.

As noted above, section 1834(x)(3) of the Act states that “...for provisions relating to payment for ambulance services furnished by an entity owned and operated by a rural emergency hospital, see section 1834(l).” Section 1834(l) of the Act establishes the Medicare ambulance fee schedule. Therefore, consistent with section 1834(x)(3) of the Act, we propose to codify, at 42 CFR 419.92(c)(1), that an entity that is owned and operated by an REH that provides ambulance services will receive payment for such services under the ambulance fee schedule as described in section 1834(l) of the Act and, as described in section VIII.A.7.b of this proposed

rule, to revise § 410.40(f) to include an REH as a covered origin and destination for ambulance transport.

Section 1861(kkk)(6)(A) of the Act provides discretion for REHs to include a unit that is a distinct part of the facility licensed as a skilled nursing facility to furnish post-hospital extended care services. Further, section 1834(x)(4) of the Act states that “...for provisions relating to payment for post-hospital extended care services furnished by a rural emergency hospital that has a unit that is a distinct part licensed as a skilled nursing facility, see section 1888(e).” Section 1888(e) of the Act establishes the skilled nursing facility prospective payment system. Consistent with section 1834(x)(4), we therefore propose to codify, at 42 CFR 419.92(c)(2), that post-hospital extended care services provided by an REH in such a unit receive payment through the skilled nursing facility prospective payment system as described at section 1888(e) of the Act.

c. Payment for an Off-Campus Provider-Based Department of an REH

As discussed above, section 1834(x)(1) of the Act sets forth the amounts that shall be paid for REH services in terms of amounts that would be otherwise apply for “covered OPD services” under 1833(t). Section 1833(t)(1)(B)(v) of the Act, which was added by section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74), enacted on November 2, 2015, (“BBA”), specifically excludes from the definition of “covered OPD services” applicable items and services furnished by an off-campus outpatient department of a provider as defined by sections 1833(t)(21)(A) and (B) of the Act. In light of the exclusion contained in 1833(t)(1)(B)(v) of the Act, CMS has carefully considered how an REH will be paid for items and services furnished by in an off-campus outpatient department of the REH. Section 1861(kkk)(8) of the Act appears to speak to this issue, stating that nothing in that provision, section 1833(a)(10), or section 1834(x) shall affect the application of paragraph (1)(B)(v) of section 1833(t), relating to applicable items and services (as defined by 1833(t)(21)(A)) that are furnished by an off-campus outpatient department of a provider (as defined by 1833(t)(21)(B)). For the reasons discussed in this

section, CMS is proposing to interpret this language as stipulating that the new provisions governing payments for services furnished by REHs are not intended to change the existing scope and applicability of the section 603 amendments to section 1833(t) of the Act, and that, as a result, the section 603 amendments would not apply to the determination of the payment rates for services furnished by an off-campus outpatient department of a REH.

Section 603 of the BBA amended section 1833(t)(1)(B) of the Act by adding a new clause (v), which excludes from the definition of “covered OPD services” applicable items and services (defined in paragraph (21)(A) of the section) that are furnished on or after January 1, 2017, by an off-campus outpatient department of a provider, as defined in paragraph (21)(B) of the section. Section 603 also added a new paragraph (21) to section 1833(t) of the Act, which defines the terms “applicable items and services” and “off-campus outpatient department of a provider,” and requires the Secretary to make payments for such applicable items and services furnished by an off-campus outpatient department of a provider under an applicable payment system (other than the OPPS). In defining the term “off-campus outpatient department of a provider,” section 1833(t)(21)(B)(i) of the Act specifies that the term means a department of a provider (as defined at 42 CFR 413.65(a)(2) as that regulation was in effect on November 2, 2015) that is not located on the campus (as defined in § 413.65(a)(2)) of the provider, or within the distance (as described in the definition of campus) from a remote location of a hospital facility (as defined in section § 413.65(a)(2)). We note that, in order to be considered part of a hospital, an off-campus department of a hospital must meet the provider-based criteria established under 42 CFR 413.65. Accordingly, in this proposed rule, we refer to an “off-campus outpatient department of a provider,” which is the term used in section 603, as an “off-campus outpatient provider-based department” or an “off-campus PBD.”

Sections 1833(t)(21)(B)(ii) through (vi) of the Act except from the definition of “off-campus outpatient department of a provider,” for purposes of paragraphs (1)(B)(v) and (21)(B) of the section, an off-campus PBD that was billing under section 1833(t) of the Act with respect

to covered OPD services furnished prior to November 2, 2015, as well as off-campus PBDs that meet the “mid build” requirement described in section 1833(t)(21)(B)(v) of the Act and the departments of certain cancer hospitals. Likewise, the department of a provider located on the campus of such provider or within the distance (described in the definition of campus at § 413.65(a)(2)) from a remote location of a hospital facility (as defined in § 413.65(a)(2)), is also excepted from the definition of “off-campus outpatient department of a provider” pursuant to section 1833(t)(21)(B)(i). The items and services furnished on or after January 1, 2017 (or during 2018 or a subsequent year for off-campus PBDs that qualify for the mid-build exception), by the various types of excepted off-campus PBDs described in 1833(t)(21)(B) continue to be paid under the OPPS. In addition, we note that in defining “applicable items and services,” section 1833(t)(21)(A) of the Act specifically excludes items and services furnished by a dedicated emergency department as defined at 42 CFR 489.24(b).

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79720), we established a number of policies to implement the section 603 amendments. Broadly, we: (1) defined applicable items and services in accordance with section 1833(t)(21)(A) of the Act for purposes of determining whether such items and services are covered OPD services under section 1833(t)(1)(B)(v) of the Act or whether payment for such items and services will instead be made under the applicable payment system designated under section 1833(t)(21)(C) of the Act; (2) defined off-campus PBD for purposes of sections 1833(t)(1)(B)(v) and (t)(21) of the Act; and (3) established policies for payment for applicable items and services furnished by an off-campus PBD (nonexcepted items and services) under section 1833(t)(21)(C) of the Act. We specified the Medicare Physician Fee Schedule (PFS) as the applicable payment system for most nonexcepted items and services furnished by nonexcepted off-campus PBDs. Nonexcepted items and services furnished by nonexcepted off-campus PBDs are generally paid under the PFS at the applicable OPPS payment rate adjusted by the PFS Relativity Adjuster of 40 percent (82 FR 53030).

Section 125(a)(1) of the CAA added the following language, at section 1861(kkk)(8) of the Act, regarding the application of the section 603 amendments to REHs:

“(8) CLARIFICATION REGARDING APPLICATION OF PROVISIONS RELATING TO OFF-CAMPUS OUTPATIENT DEPARTMENT OF A PROVIDER.— Nothing in this subsection, section 1833(a)(10), or section 1834(x) shall affect the application of paragraph (1)(B)(v) of section 1833(t), relating to applicable items and services (as defined in subparagraph (A) of paragraph (21) of such section) that are furnished by an off-campus outpatient department of a provider (as defined in subparagraph (B) of such paragraph).”

While we are proposing to define REH services as the covered OPD services furnished by an REH, REHs are not paid under the OPSS; we do not interpret the language in section 1861(kkk)(8) to indicate that the section 603 amendments to section 1833(t) should apply to off-campus PBDs of a REH. Rather, we believe section 1861(kkk)(8) can reasonably be interpreted as demonstrating an intent that the creation of the REH provider type would not change the existing scope and applicability of the section 603 amendments, such that the exclusion of items and services furnished by non-expected off-campus PBDs from the definition of covered outpatient department services under the section 603 amendments continues to apply only to items and services furnished by the non-expected off-campus PBDs of subsection (d) hospitals paid under the OPSS and does not apply to items and services furnished by an off-campus PBD of an REH, because REHs are a different provider type and are not paid under the OPSS.

We note that interpreting section 1861(kkk)(8) of the Act to instead mean that the section 603 amendments should apply to items and services furnished by off-campus PBDs of REHs appears to be contrary to the Congressional intent for creating this new provider type, as this interpretation would potentially disincentivize some otherwise eligible facilities from choosing to convert to REHs. Specifically, we note that section 603 does not apply to items and services furnished by the off-campus PBDs of CAHs. However, if the section 603 amendments applied to the off-campus PBDs of a former CAH that becomes an REH, these off-campus PBDs would

appear to meet the statutory definition of “off-campus outpatient department of a provider,” and items and services furnished by these entities would be excluded from the definition of “covered OPD services” and paid at the alternative applicable payment system as provided under section 1833(t)(21)(C). Thus, if a CAH becomes an REH and as a result becomes subject to the section 603 amendments, it would experience a significant decrease in payment for items and services furnished by its off-campus PBDs, relative to the amount paid for such services when the entity was a CAH (where it is generally paid at 101 percent of reasonable cost). This would create a financial disincentive for CAHs to convert to REHs and would seem to be contrary to the Congressional intent for creating this new provider type.

We propose to codify in the REH payment regulation, at 42 CFR 419.93(a), that items and services furnished by off-campus PBDs of REHs are not applicable items and services under sections 1833(t)(1)(B)(v) or (t)(21) of the Act, and thus that items and services furnished by these off-campus PBDs that otherwise meet the definition of “REH services” will receive the REH services payment amount of the OPDS payment plus 5 percent, as provided in section 1834(x)(1) of the Act and described in the proposed regulation text at 42 CFR 419.92(a)(1). Likewise, items and services furnished by the off-campus PBD of a REH that do not meet the definition of “REH services” would be paid under the payment system applicable to that item or service, provided the requirements for payment under the relevant system are met, as described in the proposed regulation text at 42 CFR 419.92(c).

We seek comment on alternative payment approaches for items and services furnished by the off-campus PBDs of REHs that may be supported by the REH statute, including section 1861(kkk)(8). For example, CMS seeks comment on whether application of the section 603 amendments to an off-campus PBD of an REH should depend on whether that provision applied to the entity before it converted to an REH. Under that framework, if a CAH converts to a REH, because section 1833(t)(1)(B)(v) did not apply to the CAH before converting, REH services furnished by any existing off-campus PBDs of the CAH would be paid at 105 percent of the

OPPS rate, rather than at the PFS-equivalent rate required by section 1833(t)(1)(B)(v) and (t)(21). However, because sections 1833(t)(1)(B)(v) and (t)(21) would have applied to any non-excepted off-campus PBDs of small rural hospital paid under the OPPS before that entity converted to an REH, any existing non-excepted off-campus PBDs of the small rural hospital would continue to be considered non-excepted off-campus PBDs and would continue to receive the PFS-equivalent rate under section 1833(t)(21)(C). Under this framework, any new off-campus PBDs created by the REH would be subject to the section 603 amendments. We are seeking comment on our proposed approach for paying for items and services furnished by the off-campus PBDs of REHs, as well as any alternative approaches to this issue that interested parties may have.

5. Monthly REH Facility Payment

a. Overview of the Monthly REH Facility Payment

Section 1834(x)(2) of the Act establishes an additional facility payment that is paid monthly to an REH. Section 1834(x)(5)(B) specifies that this monthly facility payment shall be made from the Federal Hospital Insurance Trust Fund under section 1817. Sections 1834(x)(2)(B) and 1834(x)(2)(C) of the Act require that, for 2023, the monthly payment is determined by first calculating the total amount that CMS determines was paid to all CAHs under Title 18 of the Act in 2019 minus the estimated total amount that would have been paid under Title 18 to CAHs in 2019 if payment were made for inpatient hospital, outpatient hospital, and skilled nursing facility services under the applicable prospective payment systems for such services during 2019. The difference is divided by the number of CAHs enrolled in Medicare in 2019 to calculate the annual amount of this additional facility payment per individual REH for 2023. The annual payment amount is then divided by 12 to calculate the monthly facility payment that each REH will receive. For 2024 and subsequent years, the monthly facility payment will be the amount of the monthly facility payment for the previous year increased by

the hospital market basket percentage increase as described under section 1886(b)(3)(B)(iii) of the Act.

We interpret the references to the year 2019 in sections 1834(x)(2)(C)(i) and 1834(x)(2)(C)(ii) of the Act to mean calendar year 2019 (CY 2019) rather than fiscal year 2019 (FY 2019) because, in the absence of language implicitly or explicitly denoting the year as fiscal, we believe calendar year is the most logical reading. The REH payment system is based on the OPSS, which sets its payment rates and rules on a CY schedule. Additionally, section 1834(x)(1) of the Act states that payments for REH services will begin on January 1, 2023, which is the first day of the CY. Accordingly, we propose to codify the calculation of the REH monthly facility payment, under 42 CFR 419.92(b)(1), to specifically refer to the amounts that were and would have been paid to CAHs in calendar year 2019. Under this proposal, we would apply the CY schedule even when the sections refer to the inpatient hospital prospective payment system or the skilled nursing facility prospective payment system where substantial policy changes are implemented on a fiscal year schedule. Therefore, when we calculate the total amount that would have been paid to CAHs if inpatient hospital services, outpatient hospital services, and skilled nursing facility services were paid under their respective prospective payment systems, we would use claims data from the last nine months of FY 2019 and the first three months of FY 2020 to calculate payment data for CY 2019 for both inpatient hospital services and skilled nursing facility services and claims data from CY 2019 for outpatient hospital services.

When determining “the total amount that . . . was paid under this title to all critical access hospitals,” as described in section 1834(x)(2)(C)(i)(I) of the Act, we propose to include both amounts paid to CAHs from the Medicare program and from beneficiary copayments. Likewise, we propose to include both projected payments from the Medicare program and projected beneficiary copayments when determining the estimated total amount that would have been paid to CAHs had they been paid on a prospective basis, as described in section 1834(x)(2)(C)(i)(II). By including both Medicare trust fund payments and beneficiary copayments, we believe that the

resulting calculations will reflect the actual payments CAHs received for services provided in CY 2019 and ensure that the full amount of additional payments made to CAHs are reflected in the determination of the monthly REH facility payment. Because CAHs are generally paid at 101 percent of reasonable cost, a 2014 report found that in 2012 beneficiary copayments consisted of around 47 percent of the total Medicare-related spending for CAHs.³¹⁷

Excluding around 47 percent of the payment CAHs received in 2019 for Medicare services from the REH monthly facility payment calculation would generate a monthly facility payment that would cover a substantially smaller share of the costs REHs face. We believe that if the calculation of the monthly facility payment does not reflect payments from beneficiaries, CAHs and small rural hospitals could be discouraged from converting into REHs because the monthly facility payment would be too small.

Using our calculations, which we will discuss in more detail in sections XVIII.A.5.b and XVIII.A.5.c of this proposed rule, we have determined that the estimated prospective payment for CAHs in 2019 is 58.2 percent of total CAH spending in 2019 when copayments are included for both total CAH spending and the estimated prospective payment for CAHs. The aggregate REH monthly facility payment would be 72 percent of the estimated prospective payment for CAHs in 2019. The combination of the estimated prospective payment for CAHs and the aggregate REH monthly facility payment where copayments are included in the calculation for an REH would be close to the amount that REH would have received from Medicare if it had decided to stay as a CAH and not convert to an REH. Therefore, it is less likely that a CAH would lose revenue if it converted to an REH in the future, which may encourage a CAH to convert to an REH. If copayments are removed from both the total amount of CAH spending in 2019 and the estimated prospective payment for CAHs in 2019, the aggregate monthly facility payment for all providers only would be 11.1 percent of the estimated prospective payment for CAHs in 2019

³¹⁷ Office of Inspector General, Department of Health and Human Services. 2014. Medicare beneficiaries paid nearly half of the costs for outpatient services at critical access hospitals. OEI-05-12-00085. Washington, DC: OIG.

where the estimated prospective payment amount includes copayments. That means a CAH converting to an REH would face a substantial reduction in Medicare payment if it converted to an REH. Please review the detailed calculations below:

Step 1: Total estimated CAH spending in CY 2019 with copayments: \$12,083,666,636

Total estimated prospective payment for CAHs in CY 2019 with copayments:

\$7,033,248,418

Difference: $\$12,083,666,636 - \$7,033,248,418 = \$5,050,418,218$

Aggregate REH monthly facility payment with copayments: \$5,050,418,218

Share of the aggregate REH monthly facility payment with copayments of the total estimated prospective payment for CAHs in CY 2019 with copayments:

$\$5,050,418,218 / \$7,033,248,418 = 72$ percent

Step 2: Total estimated CAH spending in CY 2019 removing copayments:

$\$12,083,666,636 \times 0.53 = \$6,404,343,317$

Total estimated prospective payment for CAHs in CY 2019 removing copayments: \$5,626,598,734

Difference: $\$6,404,343,317 - \$5,626,598,734 = \$777,744,583$

Aggregate REH monthly facility payment without copayments: \$777,744,583

Total estimated prospective payment for CAHs in CY 2019 with copayments:

\$7,033,248,418

Share of the aggregate REH monthly facility payment without copayments of the total estimated prospective payment for CAHs in CY 2019 with copayments:

$\$777,744,583 / \$7,033,248,418 = 11.1$ percent

We believe that including both Medicare trust fund payments and beneficiary copayments in the calculation of the monthly facility payment reflects the intent of the statute to provide incentives for CAHs and small rural hospitals that might otherwise close to convert to REHs and continue to provide outpatient hospital care in rural communities. We propose to

codify including payments from the Medicare program and beneficiary copayments for CAHs to calculate the monthly facility payment under 42 CFR 419.92(b)(1)(i) and (ii).

Finally, section 1834(x)(2)(D) of the Act states that “[a] rural emergency hospital receiving the additional facility payment under this paragraph shall maintain detailed information as specified by the Secretary as to how the facility has used the additional facility payments. Such information shall be made available to the Secretary upon request.” Accordingly, we are proposing to codify this reporting requirement, under 42 CFR 419.92(b)(3), to state that an REH receiving the additional monthly facility payment must maintain detailed information as to how the facility has used the monthly facility payments and must make this information available upon request. We believe that this requirement can be met using existing cost reporting requirements for outpatient hospital facilities that would include REHs. The cost reports track spending on outpatient hospital services as a part of overall provider spending. This information will show if a sufficient share of revenue to the REH, which includes the monthly facility payment, is being directed to outpatient care. For CY 2023, we therefore do not propose to establish any new reporting or data collection requirements for REHs related to their use of the REH monthly facility payments. However, we will monitor this issue in CY 2023 to see if we may need to propose new reporting or data collection requirements for REHs in future rulemaking.

b. Proposed Methodology to Estimate Medicare CAH Spending in CY 2019

Section 1834(x)(2)(C)(i)(I) requires that CMS use “the total amount that the Secretary determines was paid under this title to all critical access hospitals in 2019” as part of the calculation used to determine the monthly facility payment that each REH will receive in 2023. Although the statute provides that this amount shall be an amount determined by the Secretary, the statute is silent regarding what data source the Secretary should use in making such determination. We considered whether CAH claims or cost reports would be the most appropriate data source from which to determine the payments made to CAHs in 2019.

Because CAHs are generally paid at 101 percent of their reasonable costs in furnishing services to Medicare beneficiaries and receive an annual cost settlement for all services covered by Medicare, we did not initially believe that CAH claims would reflect all payments that Medicare may have made to CAHs under Title 18 of the Act. We were most concerned about modelling the annual cost settlement using CAH claims data, because the cost settlement is an accounting action that is not linked to payments reported on individual claims. It was not clear how we would identify the payment or recoupment performed for the cost settlement. By contrast, hospital cost reports track not only payments for claims when they are first submitted to Medicare but also track the annual cost settlements made with CAHs. However, some hospital cost report data can take up to 3 years to be received and processed which raises concerns whether the cost report data for CY 2019 is fully complete. We compared our calculation of Medicare CAH spending in CY 2019 using CAH claims data to our calculation of Medicare CAH spending in CY 2019 using CAH cost report data.

We found that CAH claims data reported approximately \$450 million more in CAH Medicare spending (\$12,083,666,636) compared to CAH cost report data (\$11,631,762,706). Also, the CAH claims data identified 42 more CAHs than the CAH hospital cost report data. Both findings indicated that the CAH claims data may have a more complete report of CAH spending than the CAH cost report data. Finally, we would need to use CAH claims data to estimate prospective Medicare spending for CAHs. CAH claims data is the only payment data source that allows service-specific payment rates to be linked to individual services, which is necessary to estimate Medicare prospective spending. When comparing data for two different sets of calculations, it is generally preferred to use the same data source for both calculations unless an alternate source is clearly superior. Since we are using CAH claims data to estimate prospective Medicare spending for CAHs, we determined that CAH claims data are the best available resource to fulfill the requirements of section 1834(x)(2)(C)(i)(I) of the Act to determine the amount of Medicare payments to all CAHs in CY 2019.

We propose to use CAH claims data with service dates in CY 2019 to calculate the actual Medicare spending for CAHs for CY 2019 as required under section 1834(x)(2)(C)(i)(I) of the Act. Our calculation of CAH Medicare spending will include CAH claims data for inpatient hospital services, inpatient rehabilitation services, inpatient psychiatric services, outpatient hospital services, and skilled nursing services including both hospital-based and swing bed services. As discussed above, we interpret the references to the year 2019 in sections 1834(x)(2)(C)(i) of the Act to mean calendar year 2019 (CY 2019) rather than fiscal year 2019 (FY 2019) because, in the absence of language implicitly or explicitly denoting the year as fiscal, we believe calendar year is the most logical reading. Additionally, section 1834(x)(1) of the Act states that payments for REH services will begin on January 1, 2023, which is the first day of the CY. Therefore, we are using CY 2019 CAH claims data to align with our interpretation of the statute that references to the year 2019 are for the calendar year, and to avoid unintended discrepancies by combining calendar year and fiscal year data. Once we identify the claims that we will use for the calculation, we will calculate the total CAH Medicare spending for CY 2019 by getting the total of the provider payment, coinsurance amounts, and deductible amounts for all of the claims. We propose to codify the calculation of total CAH Medicare spending in CY 2019 to create the monthly facility payment for CY 2023 under 42 CFR 419.92(b)(1)(i).

c. Proposed Methodology to Estimate the Projected Prospective Medicare Payment for CAHs for CY 2019

Section 1834(x)(2)(C)(i)(II) of the Act directs CMS to use “the estimated total amount that the Secretary determines would have been paid under this title to such hospitals in 2019 if payment were made for inpatient hospital, outpatient hospital, and skilled nursing facility services under the applicable prospective payment systems for such services during such year” as part of the calculation used to determine the monthly facility payment that each REH will receive in 2023. The statute clearly directs us to use policy and payment rules from the IPPS, the IRF-PPS, the IPF-PPS, the OPSS, and the Skilled Nursing Facility PPS (SNF PPS) as they

applied in CY 2019 to determine the projected prospective Medicare payment for CAHs for CY 2019.

To determine the estimated prospective Medicare payment that CAHs would have received for CY 2019, CMS will need to use data reflecting the Medicare-covered services rendered by CAHs in CY 2019. However, the statute does not specify what data source should be used for generating this estimation. We researched this issue and determined that CAH claims would be the only resource available to estimate projected prospective payment as directed by section 1834(x)(2)(C)(i)(II). We are aware of no other data sources that report individual services received by Medicare beneficiaries in CAHs, and the amounts paid to CAHs for those services, that could be used to estimate projected prospective payment for Medicare CAH services. To estimate Medicare CAH spending if CAHs were paid on a prospective basis, we therefore propose to use CAH claims for inpatient hospital, inpatient rehabilitation, inpatient psychiatric, skilled nursing facilities, and outpatient hospital services. We also propose to include services and items that are paid through other payment subsystems including clinical lab services; physician services; ambulance services; parenteral and enteral nutrition services; durable medical equipment, prosthetics/orthotics; and supplies; and vaccines and Medicare Part B drugs if those services and items are reported on an inpatient CAH claim, an outpatient CAH claim, or a skilled nursing CAH claim. We propose to model prospective Medicare payment for CAHs by processing the CAH claims data through the IPPS, IRF-PPS, IPF-PPS, OPPS, or SNF-PPS in a test environment as appropriate following the detailed methodologies described in either XVIII.A.5.c.(1) for all claims except for skilled nursing facility claims or XVIII.A.5.c.(2) for skilled nursing facility claims.

In response to our request for information in the CY 2022 OPPS/ASC proposed rule which discussed REH payment policies (86 FR 42288 through 42289), MedPAC expressed concerns that, since CAHs are paid based on procedure cost for inpatient hospital services, they have less incentive to fully document a patient's comorbidities than if the inpatient hospital

services were paid prospectively where only documented diagnoses can generate payment for a provider. MedPAC was concerned that if the claims used to document CAH inpatient hospital services do not fully report all relevant patient diagnoses, the amount of projected Medicare prospective payment assigned to CAHs under the IPPS could be underestimated, which would cause the monthly REH facility payment to be larger than the amount that would be paid if CMS made this calculation using a projected Medicare prospective payment that more accurately reflected all relevant diagnoses of patients that received inpatient hospital services from CAHs assuming CAHs have the same distribution of reported primary diagnoses as hospitals receiving prospective payment.³¹⁸

However, we have concerns about adopting a methodology that assigns additional diagnoses for CAH inpatient hospital claims so that these claims are consistent with the distribution of reported primary diagnoses for hospitals receiving prospective payment. The relative health levels of CAH patients compared to patients of hospitals receiving prospective payment would be needed to be able to confirm MedPAC's hypothesis that CAH inpatient hospital claims may be missing some primary diagnosis information because the information is not required for CAHs to receive full payment for the services they render.

We do not have immediately available data describing in aggregate whether Medicare patients receiving care at CAHs are healthier, less healthy, or have a similar level of health compared to Medicare patients receiving care in facilities receiving prospective payment. Also, it is not feasible to gather these data before the implementation of the REH provider type. Obtaining such data would likely involve identifying a representative sample of the patients of CAHs and hospitals receiving prospective payment to determine if there are similar or different distributions of patients based on health status, age, income, and race, which is beyond the scope of this rulemaking process. Therefore, when calculating the projected prospective Medicare

³¹⁸ Medicare Payment Advisory Commission. September 10, 2021. Comment Letter. https://www.medpac.gov/wp-content/uploads/2021/10/09102021_OPPS_ASC_2022_MEDPAC_COMMENT_SEC.pdf. Accessed April 4, 2022.

payment for CAHs, we are not proposing to adjust the distribution of reported primary diagnoses on the CAH inpatient hospital claims to reflect the distribution of reported primary diagnoses for hospitals receiving prospective payment.

Another issue with relying on inpatient hospital and outpatient hospital CAH claims to estimate the prospective Medicare payment that CAHs would have received in CY 2019 is that these claims do not report the Medicare supplemental payments that hospitals receive through the inpatient and outpatient prospective payment systems. Supplemental payments include IPPS new technology payments, outlier claims payments, clotting factor payments, indirect medical education (IME) payments, disproportionate-share hospital (DSH) payments, including uncompensated care payments under section 1886(r) of the Act, low-volume hospital payments, hospital value-based purchasing program (VBP) payments, and hospital readmissions reduction program (HRRP) adjustments. However, to accurately model how much CAHs would have received if they had instead been paid for applicable services under the inpatient and outpatient prospective payment systems, as provided by section 1834(x)(2)(C)(i)(II) of the Act, we must estimate the various supplemental payments that CAHs would have received under these prospective payment systems.

We therefore propose, in addition to medical claims service data, that CAH payment information used to calculate the projected Medicare prospective payment for CAHs include IPPS new technology payments, outlier claims payments in both the IPPS and the OPSS, clotting factor payments, indirect medical education (IME) payments, DSH payments, uncompensated care payments, and low-volume hospital payments. We chose these supplemental payments because these payments are used to determine the payment amount for claims in either the IPPS or the OPSS.

We are able to estimate new technology add-on payments, outlier payments, and clotting factor payments from the existing CAH claims data.

For IME and DSH adjustments, CAHs generally do not have up-to-date entries in the Provider Specific File. Therefore, the IME and DSH adjustments would be almost always zero in the actual calculation. We are estimating an aggregate projected prospective payment amount for CAHs, and therefore, we do not need to calculate IME and DSH for each individual CAH. Instead, we will estimate an aggregate amount of IME and DSH spending for all CAHs. Our approach is the following:

- First, identify all IPPS hospitals that are classified as rural and calculate the average percentage of additional DSH payment and the average percentage of IME payment for these rural hospitals. We use rural IPPS hospitals as a proxy to estimate the percentage of additional DSH payment and the average percentage of IME payment. Rural IPPS hospitals are more likely to have complete and timely data to allow the calculation of DSH and IME payments than CAHs, because rural IPPS hospitals need to report their data to receive payment. CAHs, where all services are paid at 101 percent of cost, do not have an incentive to report data to generate DSH and IME payments.

- Second, for each CAH, find the closest IPPS hospital to that CAH, even if the IPPS hospital is located in an urban area, and link the additional DSH payment percentage and additional IME payment percentage of the nearby IPPS hospital to the CAH.

- Finally, average the overall rural IPPS DSH payment percentage and IME payment percentage with the modelled DSH payment percentage and IME payment percentage for each individual CAH. These individual average additional DSH and IME payments for each CAH can be aggregated to get a national estimate of DSH and IME spending for CAHs.

We will use the methodology described in the CY 2019 IPPS/LTCH PPS final rule to estimate the low-volume hospital adjustment for CAHs (83 FR 41399). For discharges occurring in FYs 2019 through 2022, the low-volume hospital payment adjustment is determined using a continuous, linear sliding scale ranging from an additional 25 percent payment adjustment for low-volume hospitals with 500 or fewer discharges (both Medicare and non-Medicare

discharges) to a zero percent additional payment for low-volume hospitals with more than 3,800 discharges in the fiscal year.

For uncompensated care payments, we will use a similar approach to the approach we have described earlier in this section for calculating estimated DSH and IME payments for CAHs. The difference will be that, for uncompensated care payments, we will estimate the share of uninsured patients in each CAH receiving uncompensated care based on a nearby IPPS hospital and adjusted by the average share of uncompensated care patients for all rural IPPS hospitals. These calculations will be performed in addition to calculating the percentage of Medicare inpatient days attributed to patients eligible for both Medicare Part A and Supplemental Security Income (SSI) and the percentage of total inpatient days attributable to patients eligible for Medicaid but not Medicare Part A. We will then aggregate the estimated uncompensated care payments for individual CAHs into a national estimate and include that estimate in the CAH estimated projected prospective payment amount.

We also considered modelling hospital value-based purchasing program (VBP) payments, hospital readmissions reduction program (HRRP) adjustments, and hospital-acquired condition (HAC) reduction program. However, we have identified no feasible way to estimate these adjustments for either individual CAHs or for all CAHs in aggregate. These payments are made based on the actions of individual hospitals, and there are no trends regarding these payments based on whether the hospital is located in a rural or urban area or on the size of the hospital. CAHs do not participate in the VBP, HRRP, or HAC reduction program themselves. So, the only way to model these payments would be to identify trends in comparable hospitals. Since there are no payment trends with the VBP, HRRP, and HAC reduction program, we decided to not include these adjustments in the estimate of projected prospective payment for CAHs.

We propose to codify our proposal to estimate the prospective spending for CAHs in 2019 under 42 CFR 419.92(b)(1)(ii).

(1) Detailed Proposed Methodology to Estimate CY 2019 Prospective Payment for CAHs for Inpatient Hospital and Outpatient Hospital Services

This section provides a proposed methodology using inpatient hospital and outpatient hospital CAH claims and estimated supplemental payments to estimate the projected Medicare prospective payment for CAHs for inpatient hospital and outpatient hospital services. For more detailed information regarding the methodology for estimating the projected aggregate prospective payment for inpatient and outpatient CAH services, please refer to the supplementary document “Calculation of Rural Emergency Hospital (REH) Monthly Additional Facility Payment for 2023” on the CMS website (<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices>).

Step 1: Proposed CAH Inpatient Prospective Payment (IPPS) Calculation

Preparing Inpatient Claims for CAHs:

- Identify CAH inpatient hospital claims by using the provider CCN number.
- Exclude Medicare Advantage encounter claims and claims where Medicare is not the primary payer from the analysis file.
- Feed CAH claims through MS-DRG grouper software to assign MS-DRG code. If the DRG code field on the claim is empty, take the grouper-assigned MS-DRG code as input to calculate payment. Otherwise, take the claim MS-DRG code as input.
- Group CAH claims that have the same Provider CCN, Admission Date, and Beneficiary ID combination into inpatient stays.³¹⁹ Take the benefit exhaust date (if present and earlier than discharge date) or discharge date of the last claim in the grouping as the discharge date of the stay. Take the calendar year of the stay discharge date as the calendar year of the stay (and claims making up the stay).

³¹⁹ PPS payment is made at the stay level instead of the claim level, that is, there will be up to one final claim per inpatient stay. CAHs can split-bill an inpatient stay, that is, multiple claims that make up one stay can have positive payment. In order to calculate PPS payment for CAH claims, stay grouping is necessary.

- Identify paid CAH stays by checking if there is at least one paid claim (Type-of-Bill not being “110”) within the stay. The non-paid stays or non-discharging claims will be assigned zero payment, and the discharging claim (last claim) will be assigned total PPS payment for the stay.

Calculating PPS Payment for Each Component

The Medicare PPS payment includes the components described in the following sections.

1. DRG Payment

DRG payment is calculated as the sum of operating base rate and capital base rate multiplied by DRG weight and Transfer Fraction and their respective geographic adjustment factor.

- The **operating** and **capital base rates** and **DRG weight** are taken from the relevant Final Rule/Correction Notice for either FY 2019 or FY 2020;
- **Transfer Fraction** is calculated by the covered days of stay and the **Geometric Mean Length of Stay** of the DRG code, per post-acute-care transfer adjustment policy;
- **Operating geographic adjustment factor** is calculated as the weighted sum of wage index and operation cost-of-living adjustment, the weights being the labor share and one minus labor share;
- **Capital geographic adjustment** for inpatient hospital services is the wage index raised to the power of 0.6848³²⁰, multiplied by capital cost-of-living adjustment;
- **Wage index** is taken from the CMS provider wage index file or impact file. If not found, take wage index from CBSA wage index file or inpatient provider specific file;
- The **covered length of stay** is calculated as the maximum of utilization days and cost report days. If either is 0, take the discharge date minus admission date plus one as the covered days.

³²⁰ This value is set by statute and is the same value every year.

2. New Technology Add-On Payments

- Check the applicable relevant Diagnosis, Procedure, and Drug code on the claim to determine if the claim is eligible to receive new-tech add-on payment.
- Calculate the new-tech payment as the maximum amount for the new-tech or the operating loss multiplied by the new-tech factor, whichever is smaller.
- The operating loss is defined as operation cost minus operating DRG payment (defined in the “DRG Payment” section above).
- Perform New-Tech add-on calculation for all applicable new technologies found on claim and sum all eligible New-Tech add-ons as total new-tech add-on.

3. Outlier Payments

- Calculate outlier payment as the excess cost over outlier threshold multiplied by the cost sharing factor. **Cost** is defined as the sum of operating cost and capital cost;
- **Operating cost** is estimated by total covered charges multiplied by operating cost-to-charge ratio;
- **Capital cost** is estimated by total covered charges multiplied by capital cost-to-charge ratio, divided by wage index of provider raised to the power of 0.6848.

4. Clotting Factor Payments

- Calculate the clotting factor payment as the multiplication of revenue unit of clotting factor line and the clotting factor payment rate from the Part B drug ASP file.

5. Adjusting PPS Payment

The following sections describe adjustments to the payment calculation. This methodology includes Disproportionate Share Hospital (DSH) payment, Uncompensated Care Payment (UCP), Indirect Medical Education (IME) payment, and Low-Volume Adjustment (LVA) payment. Performance-based payment adjustments, such as Value-based Purchasing, Hospital Readmission Reduction Program, and Hospital-Acquired Condition Reduction Program, are not included. These performance programs typically exclude CAHs and are of

smaller magnitude than IME, DSH, UCP and LVA. As stated previously, there are no payment trends with the VBP, HRRP, and HAC reduction program in the rural IPPS hospital data, and we decided to not include these adjustments in the estimate of projected prospective payment for CAHs.

a. Disproportionate Share Hospital (DSH) and Uncompensated Care Payment (UCP)

The DSH payment adjustment and UCP are both provider-specific add-on payments for IPPS claims. In order to apply these two adjustments to CAHs, we must assess how they are calculated for IPPS hospitals. DSH is a percentage-based adjustment to the IPPS DRG payment that is determined by the sum of: (1) the percentage of Medicare inpatient days attributed to patients eligible for both Medicare Part A and Supplemental Security Income (SSI), and (2) the percentage of total inpatient days attributable to patients eligible for Medicaid but not Medicare Part A. UCP is determined by the percent of individuals under 65 who are uninsured, and hospitals' amounts of uncompensated care. These calculations are performed in addition to calculating the percentage of Medicare inpatient days attributed to patients eligible for both Medicare Part A and Supplemental Security Income (SSI), and the percentage of total inpatient days attributable to patients eligible for Medicaid but not Medicare Part A. All of the factors used in determining DSH/UCP are ultimately determined by the demographics of the patient populations hospitals serve. Operationally, CMS collects and calculates these factors from hospitals' cost report data from prior years. If CAHs' cost report data were as complete and timely as that of IPPS hospitals, DSH and UCP could be calculated for CAHs in the same way. However, because CAHs are reimbursed based on reasonable cost, they do not have the same incentives to complete their cost reports as IPPS hospitals. Because of the data availability and validity concerns, we do not propose to calculate DSH/UCP directly from cost report data.

To simplify the calculations, define the DSH UCP ratio as the ratio of a hospital's total DSH and UCP payment amount over its core payment (i.e., inpatient hospital DRG payment before the inclusion of supplemental payments) for 2019. The goal is to calculate a reasonable

DSH UCP ratio for CAHs. Starting from the premise that DSH/UCP are determined by the demographics the hospitals serve, we take the following steps:

- Select IPPS hospitals that are located in rural areas.
- For each CAH, identify the IPPS hospital that is closest based on distance from the CAH.
- Identify the closest rural IPPS hospital and then calculate the average DSH UCP ratio for that hospital.

As a validation, we run a linear regression model that predicts an IPPS hospital's DSH UCP ratio using urban/rural indicator, the percentage of population below the poverty line (at zip code level, obtained from American Community Survey) and the percentage of dually enrolled inpatient beneficiaries (calculated from claims and enrollment data). Then, apply the parameter estimates of the model to the CAHs (i.e., out of sample prediction) and calculate the average predicted DSH UCP ratio. The results show all the covariates are significant predictors of DSH UCP ratio. Furthermore, the validation produces very similar DSH UCP ratios for CAHs as the proposed method.

After we calculate and validate the DSH UCP ratios for the CAHs, we multiply the ratios by the core payment amount for each CAH to determine the estimate amount of DSH and UCP payments the CAH would receive. We then add the DSH and UCP payment amounts to the estimated prospective payment for the CAH.

b. Indirect Medical Education (IME)

The IME payment is a provider-specific add-on payment for IPPS claims. The IME adjustment factor is determined by a hospital's ratio of residents to beds. Operationally, CMS collects and calculates the adjustment from hospitals' cost report data from prior years. Because of the data availability and validity concerns (stated above), we do not propose to calculate IME payment directly from cost report data.

Instead, we propose to define the IME ratio as the ratio of a hospital's total IME payment over its core payment (i.e. DRG payment) for 2019. The goal is to calculate a reasonable IME ratio for CAHs. We take the following steps:

- Select IPPS hospitals that are located in rural areas.
- For each CAH, identify the IPPS hospital that is closest to it.
- Identify the closest rural IPPS hospital and then calculate the IME ratio for the rural IPPS hospital for 2019.

As validation, run a linear regression model that predicts an IPPS hospital's IME ratio using urban/rural indicator and the average IPPS DRG weight per discharge (calculated from claims data). The urban/rural indicator is assumed to be correlated to the likelihood of a hospital to run an approved graduate medical education (GME) program and attractiveness of such program to medical school graduates; the average IPPS DRG weight is a measurement of level of complexity of inpatient care a hospital provides and is assumed to be correlated to the size of and need for GME. The results show both urban/rural indicator and average IPPS DRG weight per discharge are significant predictors of IME ratio.

c. Low Volume Adjustment

The Low-Volume Hospital Payment Adjustment is an additional payment adjustment based on the per discharge amount (including capital, DSH, IME, and outlier payments) to the qualifying IPPS hospitals during CY 2019. For discharges occurring in FYs 2019 through 2022, the qualifying criteria are: (1) the hospital is more than 15 road miles from another subsection (d) hospital, and (2) the hospital has less than 3,800 total discharges during the fiscal year. If these qualifying criteria for the Low-Volume Hospital payment adjustment were also applied to CAHs, they meet the first criterion, as CAHs must be located either more than 35-miles from the nearest hospital or more than 15 miles in areas with mountainous terrain or with only secondary roads. We then check the number of total discharges from each CAH to determine if the CAH has less

than 3,800 total discharges. The adjustment factor is calculated using the following formula for hospitals between 500 and 3,800 total discharges:

$$\text{Low-Volume Hospital Payment Adjustment} = 0.25 - [0.25/3300] \times (\text{number of total discharges} - 500) = (95/330) - (\text{number of total discharges} / 13,200)$$

If a hospital has less than 500 total discharges, then the low-volume hospital payment adjustment is 25 percent. The number of total discharges of CAHs is obtained from Hospital Cost Report Data, Worksheet S-3, Part I, Line 14, and Column 15.

6. Other Adjustments

- Device credit (if applicable) is deducted from the claims payment.
- Sequestration:
 - ++ Subtract the actual coinsurance and deductible amount from PPS payment, and
 - ++ Remove 2 percent as sequester reduction.
- Subtract the sequester reduction from the PPS payment.

Step 2: Proposed CAH Inpatient Rehabilitation Facility (IRF) and Inpatient Psychiatric Facility (IPF) PPS Payment Calculation

- IRF PPS rules that applied in FY 2019 or FY 2020 based on date of service to claims furnished by the rehabilitation units of CAHs.
- IPF PPS rules that applied in FY 2019 or FY 2020 based on date of service to claims furnished by the psychiatric units of CAHs.
- The Rehabilitation and Psychiatric Units of CAH are actually paid by IRF PPS and IPF PPS payment rules; therefore, we calculate their PPS payment by summing up their actual payment.

Step 3: Proposed Outpatient PPS Payment Calculation

Preparing Outpatient Claims for CAHs

Identify CAH outpatient hospital claims. Feed CAH claim lines to the IOCE grouper software to assign Status Indicator, Ambulatory Payment Classification (APC) code,³²¹ and Discount Formula Indicator.

Calculating OPPS Payment for CAHs

- Flag claim lines that have OPPS payable status indicator.³²² For claim lines that have APC assignment, obtain relevant APC payment rate from the OPPS Final Rule/Correction Notice data files. Apply the following APC adjustments, as applicable:

- ++ Device Credit, taken from value code “FD”, is deducted from payment;
- ++ Off-campus Provider Based Department deduction indicated by modifier PO;
- ++ Computed tomography reduction (indicated by modifier CT and HCPCS code);
- ++ Reduction of X-rays taken with film (indicated by modifier FX);
- ++ 22.5 percent ASP rate reduction for Part B drugs (indicated by modifier JG and status indicator K).

- Adjust APC payment rate with OPPS discount factor based on the Discount Formula Indicator.

- Multiply adjusted APC payment rate with the number of revenue units to get APC payment.

- Adjust APC payment with geographic adjustment factor.

- ++ Geographic adjustment factor is the sum of labor share multiplied by wage index and non-labor share;

- ++ Wage index is determined by the wage index file, CBSA code, and provider specific record of the provider.

³²¹ Since CAH outpatient claims have type of bill “85x”, the IOCE software will not assign status indicator or APC code. In order to use the software properly, change the type of bill to “131” (the same bill type OPPS hospitals use to bill) before feeding the claims to the software.

³²² First digit of status indicator to be “F”, “G”, “H”, “J”, “K”, “L”, “P”, “Q”, “R”, “S”, “T”, “U”, “V”, and “X”.

- Calculate line outlier payment by multiplying excess line cost over line multiple threshold with OPPS loss share ratio, if line estimated cost is greater than line multiple threshold and line fixed threshold.

- ++ Estimate claim line cost by adding line covered charge and charges from packaged services;

- ++ Line fixed threshold is the line OPPS payment plus the OPPS fix threshold of the calendar year

- ++ Line multiple threshold is line OPPS payment multiplied by the OPPS outlier factor of the calendar year

- Aggregate claim line level payment to claim level and apply sequester reduction to calculate final PPS payment for CAHs.

Calculating Payment for Other Claim Lines

Calculate payment for other claim lines with applicable fee schedule rules (OPPS Status Indicator “A”).

- Clinical Lab Fee Schedule lines.
- Physician Fee Schedule lines.
- Ambulance Fee Schedule lines.
- Parenteral and Enteral Nutrition Fee Schedule lines.
- Durable Medical Equipment, Prosthetics/Orthotics, and Supplies Fee (DMEPOS) Schedule lines.
- Vaccine and Part B drug lines.

(2) Detailed Proposed Methodology to Estimate CY 2019 Prospective Payment for CAHs for Provision of Skilled Nursing Facility Services

We also propose to use CAH claims to make estimates of the prospective payment amounts for skilled nursing swing bed payments. Under the SNF PPS, facilities are paid a pre-determined daily rate for each day of SNF care for each individual provided services, adjusted by

each patient's unique medical needs and diagnoses. In order to calculate PPS payment for CAH claims that were not paid under PPS, we propose to assign a PPS equivalent daily rate to CAH claims factoring in patient case mix. CAH swing bed claims generally do not have minimum data set (MDS) records (that is, assessment data), which are the critical input to the Grouper software for Resource Utilization Group (RUG)/Patient Driven Payment Model (PDPM) code assignment. Therefore, RUG/PDPM codes for the CAH claims cannot be generated by the RUG/PDPM Grouper software. The RUG codes (which have been phased out of the SNF PPS, to be replaced by the PDPM) are determined mainly by the number of therapy minutes provided or expected to be provided to the beneficiary. However, the therapy minute variable is reported only through the MDS and not recorded on claims. Because of the lack of MDS data, RUG/PDPM rates cannot be directly obtained from the CAH swing bed claims. However, RUG/PDPM rates of CAH swing-bed claims can be predicted by modeling the RUG/PDPM per-diem-rates of claims that were actually paid under PPS rules. Under the statute, the SNF benefit must generally be qualified by a preceding inpatient stay. The information on the qualifying inpatient claim can be used to predict the RUG/PDPM per-diem-rate.

On October 1, 2019, a new case-mix classification model, the PDPM, under SNF PPS began. The use of RUG coding assignments ended, and the use of PDPM coding assignments started. We propose to apply RUG PPS rules for claims with service dates between January 1, 2019, and September 30, 2019, and we propose to apply PDPM rules for those with service dates between October 1, 2019, and December 31, 2019. The primary steps to estimate the projected prospective skilled nursing payment for CAHs are as follows:

Step 1: Use the PPS payment calculation formula to estimate payment for skilled nursing facility PPS claims.

Step 2: Process claims using the RUG/PDPM rate prediction model.

Step 3: Use the PPS payment calculation formula to estimate payment for CAH swing-bed claims.

For more detailed information regarding the methodology for each of the steps listed to estimate the aggregate projected prospective payment for CAH skilled nursing services, please refer to the supplementary document “Calculation of Rural Emergency Hospital (REH) Monthly Additional Facility Payment for 2023” on the CMS website.

d. Proposal to determine the total number of CAHs in CY 2019

We propose to use the CAH claims data to determine the total number of CAHs in CY 2019, which is required to determine the amount of the monthly facility payment pursuant to section 1834(x)(2)(C)(ii) of the Act. We propose that the number of CAHs in 2019 should be calculated as the distinct count of CAH CMS certification numbers (CCNs) that have any paid Medicare FFS claims from January 1, 2019 to December 31, 2019, based on service date. We propose that the number of distinct CAH CCNs includes providers that may have either been open or closed during CY 2019. We propose that CAHs that were open for only part of the year in CY 2019 will be reported as full providers in our count of distinct CAHs and will not be weighted in the count by the portion of the year they were open. Section 1834(x)(2)(C)(ii) of the Act requires that we use the number of CAHs that were in existence during 2019 and does not make any provision for counting CAHs only open for a part of the year differently from CAHs open the entire year. We propose to check the CCNs to ensure that if a CAH reports claims data from rehabilitation, psychiatric, skilled nursing facility or swing bed units in addition to the primary hospital unit, that only one facility is included in the count of total CAHs. We propose to codify our methodology to calculate the number of CAHs in CY 2019 under 42 CFR 419.92(b)(1)(iii).

e. Proposed Calculation of the Monthly REH Facility Payment for CY 2023

As stated above, section 1834(x)(2) of the Act requires an additional facility payment be paid monthly to an REH. For CY 2023, we propose that this facility payment be determined, per the requirements of the CAA and consistent with our proposed regulation text at 42 CFR 419.92(b)(1), using the following calculation:

Step 1: The total amount of Medicare spending for CAHs in CY 2019 (as described in section 1834(x)(2)(C)(i)(I) of the Act) minus the projected Medicare spending for CAHs in CY 2019 if inpatient hospital services, outpatient hospital services, and skilled nursing services had been paid on a prospective basis rather than at 101 percent of total cost (as described in section 1834(x)(2)(C)(i)(II) of the Act) and calculated according to the methodology described above.

Total Amount of Medicare Spending for CAHs in CY 2019: \$12.08 billion

Total Projected Amount of Medicare Spending for CAHs if Paid Prospectively in CY 2019: \$7.68 billion

Step1 Difference: \$12.08 billion – \$7.68 billion = \$4.40 billion

Step 2: The difference in Step 1 would be divided by the number of CAHs enrolled in Medicare in CY 2019 to calculate the annual payment per individual REH. The annual payment amount would be divided by 12 to calculate the monthly REH facility payment. Each REH would receive the same facility payment.

Step 1 Difference: \$ 4,404,308,465

Number of Medicare CAHs in CY 2019: 1,368

REH Monthly Facility Payment: $(\$4,404,308,465 / 1,368) / 12 = \$268,294$

Using this calculation, we propose that the monthly facility payment for REHs for CY 2023 would be \$268,294. We are seeking public comments on our methodology to determine the total amount was paid by Medicare to all critical access hospitals in 2019, our methodology to estimate the total amount that would have been paid to CAHs in 2019 for inpatient hospital, outpatient hospital, and skilled nursing facility services under the applicable prospective payment systems, and our overall methodology to calculate the monthly REH facility payment for CY 2023.

f. Proposed Calculation of the Monthly REH Facility Payment for CY 2024 and Subsequent Calendar Years

Section 1834(x)(2)(B) of the Act states that “[t]he annual additional facility payment amount specified in this subparagraph is... for 2024 and each subsequent year, the amount determined under this subparagraph for the preceding year, increased by the hospital market basket percentage increase.” Accordingly, we are proposing to codify, at 42 CFR 419.92(b)(2), that for CY 2024 and each subsequent calendar year, the amount of the additional annual facility payment is the amount of the preceding year’s additional annual facility payment, increased by the hospital market basket percentage increase as described under section 1886(b)(3)(B)(iii) of the Act.

6. Preclusion of Administrative or Judicial Review

Section 1861(kkk)(9) of the Act explicitly precludes administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of (1) the establishment of requirements by the Secretary under subsection 1861(kkk) of the Act; (2) the determination of payment amounts under section 1834(x) of the Act, including the determination of additional facility payments; and (3) the determination of whether a rural emergency hospital meets the requirements of subsection 1861(kkk) of the Act.

Consequently, we propose to codify, at § 419.94, the preclusion of administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of (1) the requirements established by proposed Subpart K; (2) the determination of payment amounts under proposed Subpart K; and (3) the determination of whether an REH meets the requirements of proposed Subpart K.

7. Conforming Revisions to 42 CFR 410 and 413

In addition to codifying the requirements of section 1861(kkk) and 1834(x) of the Act at 42 CFR 419 as proposed above, we propose to make conforming changes to 42 CFR 410, which describes the origin and destination requirements for the coverage of ambulance services, and 42 CFR 413, which specifies principles of reasonable cost reimbursement.

a. Rural Emergency Hospitals Ambulance Services Background

Section 1861(s)(7) of the Act establishes an ambulance service as a Medicare Part B service where the use of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations. The House Ways and Means Committee and Senate Finance Committee Reports that accompanied the 1965 Social Security Amendments suggests that the Congress intended:

- The ambulance benefit cover transportation services only if other means of transportation are contraindicated by the beneficiary's medical condition; and
- Only ambulance service to local facilities be covered unless necessary services are not available locally, in which case, transportation to the nearest facility furnishing those services is covered (H.R. Rep. No. 213, 89th Cong., 1st Sess. 37 and Rep. No. 404, 89th Cong., 1st Sess. Pt 1, 43 (1965)).

The reports indicate that transportation may also be provided from one hospital to another, to the beneficiary's home, or to an extended care facility. Since April 1, 2002, payment for ambulance services is made under the ambulance fee schedule (AFS), which the Secretary established under section 1834(l) of the Act.

We have established regulations at § 410.40 that govern Medicare coverage of ambulance services. Under § 410.40(e)(1), Medicare Part B covers ground (land and water) and air ambulance transport services only if they are furnished to a Medicare beneficiary whose medical condition is such that other means of transportation are contraindicated. The beneficiary's condition must require both the ambulance transportation itself and the level of service provided for the billed services to be considered medically necessary. The origin and destination requirements for coverage of ambulance services are addressed in our regulations at § 410.40(f).

b. Proposed Revision to the Origin and Destination Requirements under the AFS
(42 CFR 410.40(f))

Section 125 of the Consolidated Appropriations Act, 2021, added section 1834(x)(3) of

the Act for payment for ambulance services. Specifically, newly added section 1834(x)(3) of the Act states: “For provisions relating to payment for ambulance services furnished by an entity owned and operated by a rural emergency hospital, see section 1834(l) of the Act.” Accordingly, the statute makes clear that the ambulance provisions under section 1834(l) of the Act apply to REHs that owns and operates an ambulance transportation in the same manner that they do for other ambulance providers and suppliers that receive AFS payment for ambulance services. The previous section includes a discussion about this provision, including CMS’s proposal, consistent with section 1834(x)(3) of the Act, to codify, at 42 CFR 419.92(c)(1), that an entity that is owned and operated by an REH that provides ambulance services will receive payment for such services under the ambulance fee schedule as described in section 1834(l) of the Act.

The REH is an appropriate destination for an ambulance transport if furnished to a Medicare beneficiary whose medical condition is such that other means of transportation are contraindicated. the beneficiary’s condition must require both the ambulance transportation itself and the level of service provided for the billed services to be considered medically necessary. We propose to revise our regulations at § 410.40(f) to include REH as a covered origin and destination for ambulance transport.

There are several different types of ambulance providers and suppliers that are enrolled in Medicare and furnished ambulance services payable under the AFS, such as a hospital provider. We propose that an REH that owns and operates an ambulance transportation may enroll in Medicare as an ambulance provider and receive payment under the AFS if all coverage and payment requirements are met.

We invite comments on our proposals to include REHs as a covered origin and destination for ambulance transport under the AFS and that an REH that owns and operates an ambulance transportation may enroll in Medicare as an ambulance provider and receive payment under the AFS if all coverage and payment requirements are met.

c. Conforming Revisions to 42 CFR §§ 413.1; 413.13 and 413.24

We also propose to make conforming changes to the regulation text specifying principles of reasonable cost reimbursement in 42 CFR 413 to incorporate references to REHs. Specifically, we propose to modify § 413.1(a)(1)(ii) by adding subparagraph (L), to state that Section 1834(x) of the Act authorizes payment for services furnished by REHs and establishes the payment methodology. We also propose to modify § 413.1(a)(2)(i) to add REHs to the listing of provider types covered by the regulations in 42 CFR part 413. Additionally, we propose to amend § 413.13(c)(2) by adding subparagraph (vii) to the listing of services not subject to the lesser of costs or charges principle, to specify that services furnished by REHs are subject to the payment methodology set forth in Part 419, subpart K.

Furthermore, we propose to amend § 413.24(f)(4)(i) to specify that an REH is required to file annual cost reports, and to amend § 413.24(f)(4)(ii) to specify that effective for cost reporting periods beginning on or after January 1, 2023, REHs are required to submit their cost reports in a standardized electronic format. Finally, we propose to amend § 413.24(f)(4)(iv)(A), which requires providers to submit a hard copy of a settlement summary, if applicable, and the certification statement described in § 413.24(f)(4)(iv)(B), by adding subparagraph (5) to state that for REHs, these requirements are effective for cost reporting periods beginning on or after January 1, 2023.

B. REH Conditions of Participation

Section 125 of Division CC of the Consolidated Appropriations Act, 2021 (CAA) added a new section 1861(kkk) to establish REHs as a new Medicare provider type to address the growing concern over closures of rural hospitals. The CAA created a pathway for certain critical access hospitals (CAHs) and certain rural hospitals to convert to this new provider type, allowing for continued access to emergency care in rural areas. In accordance with the statute, a facility is eligible to be an REH if it was a CAH or rural hospital with less than 50 beds as of the date of enactment of the CAA (December 27, 2020). REHs must provide emergency services and observation care and they may not provide inpatient services. Additionally, REHs may provide

skilled nursing facility services in a separately certified distinct part skilled nursing facility. The statute also allows the Secretary discretion to establish additional requirements for REHs in the interest of health and safety.

CMS published a Request for Information (RFI) for REHs in the CY 2022 OPPS/ASC proposed rule on August 4, 2021, and used this information to inform our development of the REH health and safety, payment, quality measures, and enrollment policies. The proposed health and safety standards (that is, the Conditions of Participation) for REHs were published in the **Federal Register** on July 6, 2022 titled “Medicare and Medicaid Programs; Conditions of Participation (CoPs) for Rural Emergency Hospitals (REHs) and Critical Access Hospital CoP Updates” (87 FR 40350), while the proposed payment, quality measures, and enrollment policies are included in this proposed rule. All of the final health and safety, payment, quality measures, and enrollment policies will be published in the CY 2023 OPPS/ASC final rule with comment period.

C. REH Provider Enrollment

Section 1866(j)(1)(A) of the Act requires the Secretary to establish a process for the enrollment of providers and suppliers in the Medicare program. The overall purpose of the enrollment process is to help confirm that providers and suppliers seeking to bill Medicare for services and items furnished to Medicare beneficiaries meet all Federal and State requirements to do so. The process is, to an extent, a “gatekeeper” that prevents unqualified and potentially fraudulent individuals and entities from being able to enter and inappropriately bill Medicare. Since 2006, we have taken steps via rulemaking to outline our enrollment procedures. These regulations are generally incorporated in 42 CFR part 424, subpart P (currently §§ 424.500 through 424.570 and hereafter occasionally referenced as subpart P). They address, among other things, requirements that providers and suppliers must meet to obtain and maintain Medicare billing privileges. All enrolling and enrolled Medicare providers and suppliers, irrespective of type and including REHs, must comply with these regulatory provisions.

Section 1861(kkk)(2)(A) states that REHs must be enrolled under section 1866(j) of the Act. We are proposing several provisions that identify the enrollment requirements with which REHs must comply as part of the enrollment process.

1. General Compliance with Part 424, Subpart P

In addition to the previously mentioned requirement for REHs to enroll in Medicare, section 1861(kkk)(4)(B) of the Act states that an REH's enrollment remains in effect until: (1) the REH elects to convert back to its prior designation as a CAH or a hospital (as defined in section 1886(d)(1)(B) of the Act); or (2) the Secretary determines that the facility does not meet the requirements for REHs under this subsection. We are concerned that section

1861(kkk)(4)(B) of the Act could be misconstrued to suggest that our ordinary enrollment authorities do not apply to REHs (such as the authority to revoke the REH's enrollment if, for example, the provider: (1) certifies as "true" misleading or false information on the enrollment application; (2) abuses its billing privileges; or (3) fails to report certain required information).

To clarify and confirm that our enrollment authority under subpart P applies to REHs to the same extent it does to all other Medicare provider and supplier types, we propose to add a new § 424.575 to subpart P. Paragraph (a) of this section would state that an REH (as that term is defined in 42 CFR § 485.502) must comply with all applicable provisions and requirements in this subpart in order to enroll and maintain enrollment in Medicare.³²³ We note that these requirements would include, but not be limited to, the following:

- Per § 424.510(a)(1) and (d)(1), completion and submission of the applicable enrollment application, which, for REHs, would be the Form CMS-855A (Medicare Enrollment Application: Institutional Providers; OMB control number 0938-0685).
- Submission of all required supporting documentation with the enrollment application per § 424.510(d)(1) and (d)(2)(iii).

³²³ This definition of rural emergency hospital is being proposed in the CMS proposed rule titled "Medicare and Medicaid Programs; Conditions of Participation (CoPs) for Rural Emergency Hospitals (REH) and Critical Access Hospital CoP Updates."

- Per § 424.510(d)(5), completion of any applicable State surveys, certifications, and provider agreements.
- Reporting changes to any of the REH's enrollment information per § 424.516.
- Revalidation of enrollment per § 424.515.
- Undergoing risk-based screening per § 424.518 (discussed further in section XVIII.C.2 of this proposed rule).

Another requirement in subpart P pertains to application fees. Section 424.514 states that institutional providers submitting an initial or revalidation application, or adding a new practice location, must submit either or both of the following: (1) the applicable application fee (which, for CY 2022, is \$631); or (2) a request for a hardship exception to the application fee. The term "institutional provider" is defined (for purposes of the application fee) in § 424.502. It means any provider or supplier that submits a paper Medicare enrollment application using the Form CMS-855A, Form CMS-855B (not including physician and non-physician practitioner organizations) (Medicare Enrollment Application: Clinics/Group Practices and Certain Other Suppliers; OMB control number 0938-1377), Form CMS-855S (Medicare Enrollment Application - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Suppliers; OMB control number: 0938-1056), or an associated internet-based PECOS enrollment application.

Although an REH would submit a Form CMS-855A to enroll as such, it would not have to pay an application fee with its application. This is because we are proposing at new § 424.575(b) that the REH would submit a Form CMS-855A change of information under § 424.516 instead of an initial enrollment; that is, the facility would be merely reporting its conversion from a CAH or a hospital (as defined in section 1886(d)(1)(B) of the Act) to an REH - as well as submitting any other required information and documentation - and not newly enrolling in the Medicare program. Since this particular REH enrollment transaction would not

be an initial enrollment, revalidation, or practice location addition, the fee payment requirement in § 424.514 would be inapplicable.

Our general policy has long been that a provider or supplier that is changing its provider or supplier type (for example, a home health agency switching to a home infusion therapy supplier) must terminate its existing enrollment and initially enroll as the new provider or supplier type. We believe the situation involving REHs is unique and warrants a deviation from this policy. Section 1861(kkk)(3) of the Act defines an REH, in part, as a facility that, as of the date of enactment of the Consolidated Appropriations Act, 2021 (December 27, 2020), was a CAH or a hospital (as defined in section 1886(d)(1)(B) of the Act). In addition: (1) section 1861(kkk)(4)(B)(i) of the Act references a “conversion” from an REH back to a CAH or a section 1886(d)(1)(B) hospital (rather than termination as an REH and initial enrollment as a CAH or section 1886(d)(1)(B) hospital); and (2) payments to REHs are to begin effective January 1, 2023, as already explained in this proposed rule. In light of this, and strictly from an enrollment application processing perspective, we believe there is a sufficiently close nexus between REHs and CAHs/section 1886(d)(1)(B) hospitals such that any conversion to an REH can be accomplished via a change of information application. We prefer this mechanism because such applications generally involve the mere disclosure of enrollment data that has changed as opposed to, with initial enrollments, the completion of the entire application. MACs can typically process change of information applications faster than initial applications. This is an important consideration given the need for CMS to also determine the facility’s compliance with the REH conditions of participation before the REH can be enrolled as such. We want to ensure that the foregoing processes can be completed by January 1, 2023 so that REHs can begin billing for services effective upon that date, and we believe permitting a change of information submission can help facilitate this. We note, however, that this deviation based on the unique circumstances of REH enrollment does not change our aforementioned general policy that

requires an initial enrollment application for enrolled individuals and entities aiming to change their provider or supplier type.

2. Screening Risk Levels

Section 424.518 outlines provider enrollment screening categories and requirements based on our assessment of the risk of fraud, waste, and abuse posed by a particular category of provider or supplier. In general, the higher the level of risk that a certain provider or supplier type poses, the greater the degree of scrutiny with which we will screen and review enrollment applications submitted by providers or suppliers within that category. There are three levels of screening addressed in § 424.518: limited; moderate; and high. Irrespective of which level a provider or supplier type falls within, the MAC performs certain minimum screening functions upon receipt of an initial enrollment application, a revalidation application, or an application to add a new practice location. These include:

- Verification that the provider or supplier meets all applicable Federal regulations and State requirements for their provider or supplier type.
- State license verifications.
- Database reviews on a pre- and post-enrollment basis to ensure that providers and suppliers continue to meet the enrollment criteria for their provider or supplier type.

Providers and suppliers at the moderate and high categorical risk levels must also undergo a site visit. Moreover, for those in the high categorical risk level, the MAC performs two additional functions under § 424.518(c)(2). First, the MAC requires the submission of a set of fingerprints for a national background check from all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier. Second, it conducts a fingerprint-based criminal history record check of the Federal Bureau of Investigation's (FBI) Integrated Automated Fingerprint Identification System on all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier. These

additional verification activities are intended to correspond to the heightened risk involved with such provider or supplier types.

Hospitals currently fall within the limited screening category per § 424.518(a)(1)(viii). This also includes, as stated in § 424.518(a)(1)(viii), CAHs, Department of Veterans Affairs, and other federally-owned hospital facilities. We have no evidence to suggest that REHs as a category of provider type would present a risk of fraud, waste, and abuse warranting placement in the moderate or high screening level. Accordingly, we propose to revise § 424.518(a)(1)(viii) to incorporate REHs therein.

3. Effective Date of Billing Privileges

Section 424.520 lists the effective dates of billing privileges for enrolling Medicare providers and suppliers. For surveyed, certified, or accredited providers and suppliers, § 424.520(a) states that the effective date of billing privileges is that specified in 42 CFR 489.13. Paragraph (b) of the latter section states, in part, that the provider agreement or approval is effective on the date the State agency, CMS, or the CMS contractor survey is completed (or on the effective date of the accreditation decision, as applicable) if, on that date, the provider or supplier meets all applicable Federal requirements. Among these Federal requirements are the previously referenced enrollment requirements in Part 424, subpart P; as mentioned in 42 CFR 489.13(b), CMS determines the date on which all enrollment requirements have been met.

Hospitals and CAHs are among the provider types that fall within the scope of § 424.520(a). Since REHs, like other hospitals, would also come within the purview of § 424.520(a), it is unnecessary to revise § 424.520(a) to specifically reference them. We are merely discussing this issue in this proposed rule so that prospective REHs will understand what their effective date of billing privileges would be.

D. Use of the Medicare Outpatient Observation Notice by REHs

REHs are prohibited by section 1866(kkk)(2)(B) of the Act from providing inpatient services, other than those that are provided in a distinct part SNF. Section 2 of the Notice of Observation Treatment and Implication for Care Eligibility Act (NOTICE Act) (Pub. L. 114-42), amended section 1866(a)(1) of the Act by adding a new subparagraph (Y) that requires hospitals and CAHs to provide written notification and an oral explanation of such notification to individuals receiving observation services as outpatients for more than 24 hours. The notification must explain the status of the individual as an outpatient, not an inpatient, and the implications of such status. We implemented section 1866(a)(1)(Y), as added by section 2 of the Notice Act, in the FY 2017 IPPS/LTCH final rule (81 FR 57037 through 57052).

REHs will furnish emergency department and observation care, and other specified outpatient medical and health services, if elected by the REH, that do not exceed an annual per patient average of 24 hours. There may be instances in which REH patients receive observation services at an REH for a period exceeding 24 hours, but REHs are not required to provide required notification under the NOTICE Act, known as the Medicare Outpatient Observation Notice (MOON), because REHs are excluded from the definition of “hospital” in section 1861(e) and the requirements at section 1866(a)(1)(Y) of the Act apply only to hospitals and CAHs. We understand that there may be occasional circumstances in which a facility is not immediately available to provide a higher level of care, resulting in patients receiving services at an REH for more than 24 hours. Notwithstanding the inapplicability of the NOTICE Act requirements at section 1866(a)(1)(Y) to REHs and the expected infrequency of individuals receiving observation services in REHs for more than 24 hours, CMS is soliciting comments on the potential need for REHs to notify beneficiaries of their status as outpatients, the implications of such status, and whether the MOON would be the appropriate notice for communicating this information.

E. Physician Self-Referral Law Update

1. Background

Section 1877 of the Act, also known as the physician self-referral law: (1) prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless the requirements of an applicable exception are satisfied; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third-party payer) for any improperly referred designated health services. A financial relationship may be an ownership or investment interest in the entity or a compensation arrangement with the entity. The statute establishes a number of specific exceptions and grants the Secretary the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse. Section 1903(s) of the Act extends aspects of the physician self-referral prohibitions to Medicaid. (For additional information about section 1903(s) of the Act, see 66 FR 857 through 858.)

The following discussion provides a chronology of our more significant and comprehensive rulemakings; it is not an exhaustive list of all rulemakings related to the physician self-referral law. After the passage of section 1877 of the Act, we proposed rulemakings in 1992 (related only to referrals for clinical laboratory services) (57 FR 8588) (the 1992 proposed rule) and 1998 (addressing referrals for all designated health services) (63 FR 1659) (the 1998 proposed rule). We finalized the proposals from the 1992 proposed rule in 1995 (60 FR 41914) (the 1995 final rule) and issued final rules following the 1998 proposed rule in three stages. The first final rulemaking (Phase I) was a final rule with comment period published in the January 4, 2001 **Federal Register** (66 FR 856). The second final rulemaking (Phase II) was an interim final rule with comment period (69 FR 16054) published in the March 26, 2004 **Federal Register**. Due to a printing error, a portion of the Phase II preamble was omitted from the March 26, 2004 **Federal Register** publication. That portion of the preamble, which addressed reporting requirements and sanctions, was published in the

April 6, 2004 **Federal Register** (69 FR 17933). The third final rulemaking (Phase III) was a final rule published in the September 5, 2007 **Federal Register** (72 FR 51012).

After passage of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111-148) (Affordable Care Act), we issued final regulations on November 29, 2010 in the CY 2011 PFS final rule with comment period that codified a disclosure requirement established by the Affordable Care Act for the in-office ancillary services exception (75 FR 73443). We also issued final regulations on November 24, 2010 in the CY 2011 OPPS final rule with comment period (75 FR 71800), on November 30, 2011 in the CY 2012 OPPS final rule with comment period (76 FR 74122), and on November 10, 2014 in the CY 2015 OPPS final rule with comment period (79 FR 66987) that established or revised certain regulatory provisions concerning physician-owned hospitals to codify and interpret the Affordable Care Act's revisions to section 1877 of the Act.

On November 16, 2015, in the CY 2016 PFS final rule, we issued regulations to reduce burden and facilitate compliance (80 FR 71300 through 71341). In that rulemaking, we established two new exceptions to the physician self-referral law, clarified certain provisions of the physician self-referral regulations, updated regulations to reflect changes in terminology, and revised definitions related to physician-owned hospitals. In the December 2, 2020 **Federal Register**, we published a final rule entitled "Modernizing and Clarifying the Physician Self-Referral Regulations" (the "MCR final rule") (85 FR 77492) that established three new exceptions to the physician self-referral law applicable to compensation arrangements that qualify as "value-based arrangements," established exceptions for limited remuneration to a physician and the donation of cybersecurity technology and services, and revised or clarified several existing exceptions. The MCR final rule also provided guidance and updated or established regulations related to the fundamental terminology used in many provisions of the physician self-referral law. Most notably, we defined the term "commercially reasonable" in regulation, established an objective test for evaluating whether compensation varies with the

volume or value of referrals or other business generated between the parties, and revised the definitions of “fair market value” and “general market value.” The MCR final rule also revised the definition of “indirect compensation arrangement,” which was further revised in the CY 2022 PFS final rule (86 FR 65343 through 65353).

2. Application of the physician self-referral law to rural emergency hospitals

The referral and billing prohibitions of the physician self-referral law are implicated only when all six of the following elements are present: a physician makes a referral for designated health services payable by Medicare to an entity with which the physician (or an immediate family member of the physician) has a financial relationship. Where all six elements exist, the physician self-referral law prohibits the physician from making a referral for designated health services to the entity with which he or she has the financial relationship unless an exception applies and its requirements are satisfied.

Our regulations at § 411.351 define “entity” to mean a person, sole proprietorship, public or private agency or trust, corporation, partnership, limited liability company, foundation, nonprofit corporation, or unincorporated association that furnishes designated health services. Section 1877(h)(6) of the Act defines “designated health services” to mean any of the following items or services: clinical laboratory services; physical therapy services; occupational therapy services; outpatient speech-language pathology services; radiology services, including magnetic resonance imaging, computerized axial tomography, and ultrasound services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services. Under the regulation at § 411.351, only services payable in whole or in part by Medicare are designated health services. Services that are paid by Medicare as part of a composite rate are excluded from the definition of “designated health services.”

The proposals described in the proposed rule titled “Medicare and Medicaid Programs; Conditions of Participation (CoPs) for Rural Emergency Hospitals (REH) and Critical Access Hospital CoP Updates” (87 FR 40350), if finalized, would require an REH to furnish radiology and certain imaging services, clinical laboratory services, and outpatient prescription drugs, all of which are designated health services under section 1877(h) of the Act. An REH could elect to provide other designated health services as well. Therefore, with respect to such services furnished to Medicare beneficiaries, an REH would be an entity that furnishes designated health services payable (in whole or in part) by Medicare for purposes of the physician self-referral law.

For purposes of the physician self-referral law, a physician has the meaning set forth in section 1861(r) of the Act. A physician makes a referral when the physician requests or orders a designated health service, certifies or recertifies the need for a designated health service, or establishes a plan of care that includes the provision of a designated health service. (If the physician personally performs or provides the designated health service, the physician has not made a referral.) Under the regulations at § 411.354, a physician (or an immediate family member of a physician) has a financial relationship with an entity if the physician (or immediate family member) has a direct or indirect ownership or investment interest in the entity or has a direct or indirect compensation arrangement with the entity.

Once an entity is enrolled in Medicare as an REH, the physician self-referral law would prohibit a physician from making a referral for designated health services to the REH if the physician (or an immediate family member of the physician) has a financial relationship with the REH unless an exception to the law’s referral and billing prohibitions applies and all its requirements are satisfied. There are numerous statutory and regulatory exceptions to the physician self-referral law’s prohibitions.

Although there are more than 40 exceptions to the physician self-referral law’s prohibitions, only five permit all specified referrals by a physician to an entity in which the physician (or an immediate family member of the physician) has an ownership or investment

interest when all requirements of the exception are satisfied. These are the exceptions for publicly traded securities, mutual funds, rural providers (commonly referred to as the “rural provider exception”), hospitals in Puerto Rico, and hospitals outside of Puerto Rico (commonly referred to as the “whole hospital exception”). Nine additional “services” exceptions in § 411.355, when applicable, may permit a physician’s referral on a service-by-service basis, but the protection from the law’s prohibitions requires an analysis of each referral by the physician and the resulting designated health service furnished by the entity.

We believe that most physician-owned entities that are not publicly traded or hospitals located in Puerto Rico rely on the rural provider and whole hospital exceptions in section 1877(d)(2) and (3) of the Act and in our regulations at § 411.356(c)(1) and (3), respectively. An entity that is a “hospital” for purposes of the physician self-referral law, including a critical access hospital or small rural hospital, may use either the rural provider exception (if applicable) or the whole hospital exception to avoid the law’s referral and billing prohibitions, provided that all requirements of the selected exception are satisfied, including requirements set forth in the Affordable Care Act and included in our regulations at § 411.362.

The rural provider exception requires that the designated health services are furnished in a rural area and that the entity furnishes not less than 75 percent of the designated health services that it furnishes to residents of a rural area. For purposes of the physician self-referral law, a rural area is an area that is not an urban area, a term further defined elsewhere in CMS regulations to include certain areas defined by the Executive Office of Management and Budget (OMB). (See section XVIII.E.6 of this proposed rule for our proposal to make a technical amendment to the definition of “rural area” in § 411.351 to address changes in terminology used by OMB in its designation of these areas.) OMB regularly publishes updates to the list of areas that CMS considers to be urban areas. The whole hospital exception is available only to entities that are “hospitals” for purposes of the physician self-referral law. Under § 411.351, a hospital is an entity that qualifies as a “hospital” under section 1861(e) of the Act, as a “psychiatric

hospital” under section 1861(f) of the Act, or as a “critical access hospital” under section 1861(mm)(1) of the Act.

Whether an entity furnishes designated health services in a rural area is subject to change as OMB updates the list of areas that CMS considers to be urban areas. Therefore, the continuous applicability of the rural provider exception to a particular entity is not guaranteed. Reliance on the rural provider exception also requires the entity to monitor the residence of the patients to whom it furnishes designated health services in order to ensure that the entity furnishes not less than 75 percent of the designated health services that it furnishes to residents of a rural area. As with the location where designated health services are furnished, whether an individual resides in a rural area is subject to change as OMB updates the list of areas that CMS considers to be urban areas, which may increase the monitoring burden.

Satisfaction of the requirements of the whole hospital exception is not dependent on whether the entity—which must be a hospital for purposes of the exception—furnishes designated health services in a rural area or where its patients reside. However, section 1861(e) of the Act, as amended by section 125 of the CAA, expressly excludes REHs from qualifying as a hospital for most Medicare purposes. Although critical access hospitals and small rural hospitals meet the definition of “hospital” in § 411.351, once a critical access hospital or small rural hospital converts to an REH, it will no longer be a “hospital” for purposes of the physician self-referral law and, therefore, the whole hospital exception will no longer be available to it. Although we considered deeming REHs to be hospitals for purposes of the physician self-referral law, which would have continued access to the whole hospital for such entities, as explained in section XVIII.E.4 of this proposed rule, we are not proposing to do so because we believe it would likely undermine the ability of REHs to ensure access to outpatient care for residents of rural and underserved communities as contemplated in the CAA.

We are concerned that, without a broadly-applicable exception to its referral and billing prohibitions for ownership or investment in REHs, the physician self-referral law could inhibit

access to medically necessary designated health services furnished by REHs that are owned or invested in by physicians (or their immediate family members) and thwart the underlying goal of section 125 of the CAA to safeguard or expand such access. For this reason, using the Secretary's authority under section 1877(b)(4) of the Act to establish exceptions to the physician self-referral law for financial relationships that do not pose a risk or program or patient abuse, we propose a new exception at § 411.356(c)(4) for ownership or investment interests in an REH for purposes of the designated health services furnished by the REH. For purposes of this preamble, we refer to this exception as "the proposed REH exception."

We are not proposing any new exceptions for specific designated health services or for compensation arrangements between REHs and physicians (or immediate family members of physicians). We believe that, for the most part, the existing exceptions in §§ 411.355 and 411.357 are sufficiently comprehensive to allow for nonabusive referrals and compensation arrangements between REHs and physicians (or immediate family members of physicians). However, certain of the exceptions in § 411.357 are applicable only to compensation arrangements between a hospital (or other specific type of entity) and a physician (or an immediate family member of a physician). Because an REH is not considered a hospital for purposes of the physician self-referral law and is not one of the other specific types of entities to which the exceptions currently apply, for the reasons explained in section XVIII.E.5 of this proposed rule, and using the Secretary's authority under section 1877(b)(4) of the Act, we propose to amend our regulations to permit an REH to use these exceptions where doing so would not be a risk of program or patient abuse.

3. Proposed Exception for Rural Emergency Hospitals (proposed § 411.356(c)(4))

a. Scope and structure of the proposed REH exception

The proposed REH exception would be available only to entities that are "rural emergency hospitals." To delineate the scope of the applicability of the proposed REH exception, we propose to amend § 411.351 to add a definition of "rural emergency hospital" for

purposes of the physician self-referral law. Under proposed § 411.351, the term “rural emergency hospital” has the meaning set forth in section 1861(kkk)(2) of the Act and § 419.91. As proposed, § 419.91 cross-references § 485.502, which is proposed in a separate rulemaking to define “rural emergency hospital” to mean an entity that operates for the purpose of providing emergency department services, observation care, and other outpatient medical and health services specified by the Secretary in which the annual per patient average length of stay does not exceed 24 hours. In addition, the entity must not provide inpatient services, except those in connection with a distinct part unit licensed as a skilled nursing facility to furnish post-hospital extended care services.

Section 1877(d) of the Act and § 411.356(c) establish exceptions for ownership of or investment in specific types of providers: rural providers, hospitals located in Puerto Rico, and hospitals located outside of Puerto Rico. These exceptions apply only with respect to referrals for and billing of the specific services identified in the relevant exception. For example, the exception at section 1877(d)(1) of the Act and § 411.356(c)(2) applies to all referrals and billing for designated health services furnished by a hospital located in Puerto Rico. In contrast, the exception at section 1877(d)(2) of the Act and § 411.356(c)(1) applies only to referrals and billing for designated health services that the entity furnishes in a rural area. The proposed REH exception follows the established construct of the existing exceptions for other specific providers and would apply to all referrals and billing for designated health services furnished by an REH. If all the requirements of the exception are satisfied, the referral and billing prohibitions of the physician self-referral law would not apply with respect to designated health services referred by a physician who has (or whose immediate family member has) an ownership or investment interest in the REH.

Because all REHs would have been critical access hospitals or small rural hospitals prior to their enrollment in Medicare as an REH, we believe it is appropriate to include in the proposed REH exception program integrity requirements similar to those that apply to hospitals, including

critical access hospitals and small rural hospitals, under the rural provider and whole hospital exceptions at § 411.356(c)(1) and (3)(iv). These requirements would apply to an REH even if it was not owned or invested in by physicians (or their immediate family members) when it was a critical access hospital or small rural hospital. We are not proposing to include every requirement of existing § 411.362 in the proposed REH exception; rather, our focus is on certain requirements in existing § 411.362(b)(4) that relate to ensuring *bona fide* investment as they would apply to an REH. In our view, requirements that relate to disclosure of conflicts of interest, prohibition on facility expansion, and prohibition on increasing aggregate physician ownership or investment levels are program integrity policies that the Congress applied specifically to physician-owned hospitals under the Affordable Care Act. If the Congress had intended all of these requirements to also apply to REHs, it could have considered an REH to be a hospital for purposes of section 1877 of the Act or expressly applied them to REHs under section 1877 of the Act. Importantly, we are concerned that limitations on facility expansion or the amount of physician investment or ownership in an REH could negatively impact access to needed services in rural and other underserved areas. Also, we are confident that the comprehensive set of program integrity requirements included in the proposed REH exception is sufficient to protect against program and patient abuse; therefore, the inclusion of other requirements in section 1877(i) of the Act and § 411.362, such as reporting and website disclosure requirements, is not necessary. We note that the requirement at existing § 411.362(b)(3)(ii)(B), which states that a hospital must not condition any physician ownership or investment interests either directly or indirectly on the physician owner or investor making or influencing referrals to the hospital or otherwise generating business for the hospital, is included under the statutory and regulatory set of requirements related to disclosure of conflict of interests. However, as explained in the Conference Committee report for the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152), this requirement was seen as a requirement to ensure *bona fide* ownership and investment (Conference Committee report, H.

Rept. No. 443, 111th Cong., 2nd Sess. 354 (2010)). We agree that it is a requirement to ensure *bona fide* ownership and investment and are proposing to include a similar requirement at proposed § 411.356(c)(4)(iii) as described later in this section XVIII.E.3 of this proposed rule.

We seek comment on this approach and whether we should apply more or fewer of the requirements related to physician-owned hospitals to physician ownership of or investment in an REH. We are considering whether to require that an REH must submit an annual report to CMS containing a detailed description of the identity of each owner of or investor in the REH, as well as the nature and extent of all ownership and investment interests in the REH. We would require that the REH submit the report at such time and in such manner as specified by CMS. In addition, we are seeking comment on whether we should require an REH to disclose on any public website for the REH and in public advertising for the REH that it is owned or invested in by physicians (or immediate family members of physicians), and require an REH to require that each physician with an ownership or investment interest in the REH who is a member of the REH's medical staff to agree, as a condition of continued medical staff membership, to provide written disclosure of their ownership or investment interest in the REH to all patients whom the physician refers to the REH. We would require that disclosure must be made by a time that permits the patient to make a meaningful decision regarding the receipt of care. We seek comment regarding the appropriateness of these requirements and whether they are necessary to protect against program and patient abuse.

b. Entity enrolled as an REH

We propose that an entity that uses the proposed REH exception must be enrolled in Medicare as an REH. The requirement at proposed § 411.356(c)(4)(i) would ensure that a hospital (for purposes of the physician self-referral law) that may technically meet the definition of "rural emergency hospital" but is not enrolled in Medicare as such may not avail itself of the proposed REH exception. A hospital must instead use the rural provider or whole hospital exception, and all of the requirements in § 411.362 would apply, including the prohibitions on

facility expansion and exceeding the aggregate percentage of investment interests held by physicians (and their immediate family members) as of March 23, 2010. We seek comment on this proposed requirement.

c. Ownership in the entire REH

We propose to require at proposed § 411.356(c)(4)(ii) that the physician's (or immediate family member's) ownership or investment interest is in the entire REH and not merely in a distinct part or department of the REH. This requirement is similar to the requirement at § 411.356(c)(3)(iii) in the whole hospital exception, and we would interpret it in the same manner for REHs. When the physician self-referral law was first enacted and later amended to apply to referrals of designated health services beyond clinical laboratory services, the Congress included the whole hospital exception to allow physician ownership or investment in hospitals because, at the time, there were a number of rural hospitals in particular where physicians held ownership interests, and avoiding barriers to accessible health care for patients in rural areas was imperative. These hospitals were usually the only hospitals in the area and provided a breadth of services, and therefore, the Congress did not view ownership or investment in the hospital as a significant incentive for self-referral. Even so, the whole hospital exception explicitly prohibited ownership in a subdivision of a hospital because of the concern that if physicians owned only the particular part of a hospital to which they referred—such as a cardiac wing or department—there would be an incentive for self-referral. (*See* Opening Statement of the Honorable Bill Thomas, Physician Ownership and Referral Arrangements and H.R. 345, “The Comprehensive Physician Ownership and Referral Act of 1993,” House of Representatives, Committee on Ways and Means, Subcommittee on Health, April 20, 1993, 145-146; Comments of the Honorable Pete Stark, Hearing before the Committee on Ways and Means of the U.S. House of Representatives 109th Cong., 1st Sess., 4-5 (Mar. 8, 2005) (Ser. No. 109-37); and House Committee on Budget Report on H.R. 3200 and H.R. 4872, H. Rep. No. 443, pt.1, 111th Cong., 2nd Sess., 355-356 (2010).) We similarly believe that ownership or investment in only a distinct part or department

of an REH—such as an imaging center—would be an incentive for self-referral, and, therefore, that proposed § 411.356(c)(4)(ii) is necessary to protect against the harms the physician self-referral law was enacted to address, namely, overutilization and patient steering to less convenient, lower quality, or more expensive services and facilities. We seek comment on this proposed requirement.

d. Conditioning ownership or investment on making or influencing referrals or generating business for the REH

In line with requirements for hospitals under the rural provider and whole hospital exceptions, we propose to require at § 411.356(c)(4)(iii) that the REH does not directly or indirectly condition any ownership or investment interest held or to be held by a physician (or an immediate family member of a physician) on the physician making or influencing referrals to the REH or otherwise generating business for the REH. This proposed requirement is essentially identical to the requirement at existing § 411.362(b)(3)(ii)(B), which applies to hospitals that use the rural provider and whole hospital exceptions, and we would interpret the requirements applicable to REHs and hospitals in the same way.

It is our position that an REH might fail to satisfy this proposed requirement if it requires a specified action or achievement with respect to referrals to or the generation of business for the REH prior to the purchase or receipt of the ownership or investment interest, or requires divestiture of an ownership or investment interest following the occurrence or nonoccurrence of a specified action or achievement with respect to referrals to or the generation of business for the REH. For example, we would consider an REH to condition the ownership or investment interest to be held by a physician on the physician making or influencing referrals to the REH or otherwise generating business for the REH if the physician was permitted to purchase an ownership interest in the REH only if the physician had ordered a specific number of advanced imaging services during each of the 2 years prior to the purchase date of the ownership interest. We would also consider an REH to condition an ownership or investment interest held by a

physician on the physician making or influencing referrals to the REH or otherwise generating business for the REH if the REH required the physician to sell their ownership interest back to the REH in the event that they failed to perform a specific percentage of their outpatient surgeries at the REH during the current year or reduced the hours that they work in their private practice below 75 percent of the prior year. Similarly, the REH may not condition the amount of an ownership or investment interest that a physician (or an immediate family member of a physician) may purchase, receive, or maintain on the occurrence or nonoccurrence of a specified action or achievement under proposed § 411.356(c)(4)(iii). For example, if a physician who performs at least 80 percent of their surgeries at an REH would be permitted to purchase and maintain 20 shares in the REH, while a physician who performs only 25 percent of their surgeries at the REH would be permitted to purchase and maintain only 5 shares in the REH, we would consider the REH to condition an ownership or investment interest held or to be held by a physician on the physician making or influencing referrals to the REH or otherwise generating business for the REH. The examples provided here are for illustrative purposes only and are not intended to indicate, nor do they indicate, that any particular absolute number, percentage, or other standard is acceptable or unacceptable. We seek comment on our interpretation of what it means to “condition” an ownership or investment interest held or to be held by a physician (or an immediate family member of a physician) on the physician making or influencing referrals to the REH or otherwise generating business for the REH under proposed § 411.356(c)(4)(iii). We also seek comment specifically on whether we should consider an REH’s policy or other mandate that a physician (or an immediate family member of a physician) must relinquish their ownership or investment interest in an REH upon the physician’s full retirement from the practice of medicine or the relocation of the physician’s medical practice to a location outside the REH’s service area to fail to satisfy the proposed requirement at § 411.356(c)(4)(iii), as well as other examples of conduct that we should consider to “condition” an ownership or investment interest held or to be held by a physician (or an immediate family member of a physician) on the physician making or

influencing referrals to the REH or otherwise generating business for the REH under proposed § 411.356(c)(4)(iii).

Like existing § 411.362(b)(3)(ii)(B), which applies to hospitals that use the rural provider and whole hospital exceptions, the requirement at proposed § 411.356(c)(4)(iii) prohibits policies and conduct that *directly or indirectly* condition ownership or investment interests held or to be held by a physician (or an immediate family member of a physician) on the physician making or influencing referrals to the REH or otherwise generating business for the REH. For purposes of this requirement, an REH *directly* conditions ownership or investment interests by adopting policies that require a specific number, volume, or value of referrals to or other business for the REH during a particular time period. For example, a requirement that a physician owner of an REH must have ordered at least 50 clinical laboratory tests during three of the prior four quarters to maintain their ownership (or level of ownership) would not satisfy the requirement at proposed § 411.356(c)(4)(iii). Similarly, a policy that permits an immediate family member to purchase an ownership or investment interest in an REH only if their child, who is a physician in private practice, increases the number of patients that they refer to the REH by 25 percent during the calendar year prior to the purchase would not satisfy the proposed requirement. However, if the REH directs the referrals of the physician under a *bona fide* employment relationship, personal service arrangement, or managed care contract between the REH and the physician, and the directed referral requirement meets all the conditions of § 411.354(d)(4), we would not consider the directed referral requirement to constitute directly or indirectly conditioning an ownership or investment interest held or to be held by a physician (or an immediate family member of a physician) on the physician making or influencing referrals to the REH or otherwise generating business for the REH.

For purposes of this requirement, we would consider an REH to *indirectly* condition ownership or investment interests if it adopted policies or standards of another person or organization to establish qualification criteria for purchasing or maintaining ownership or

investment interests in the REH and those policies or standards required the physician to make or influence referrals to or generate business for the REH. For example, if an REH required that a physician have active medical staff privileges at the REH to hold an ownership or investment interest in the REH, and also approved the medical staff bylaws that required a minimum of 50 outpatient therapeutic services per year performed or supervised by the physician, the REH would likely not satisfy the requirement at proposed § 411.356(c)(4)(iii). This is because the REH would indirectly adopt the policy mandating a minimum of 50 outpatient therapeutic services per year as the REH's own criteria for qualification to hold an ownership or investment interest in the REH. We recognize that the medical staff of an entity, although accountable to the entity's governing body for the quality of patient care provided by medical staff members to the entity's patients, is independently organized under its own bylaws and establishes the criteria for appointment to the medical staff, credentialing, privileging, and oversight. We also recognize that an entity's medical staff is responsible for peer review, which, to be effective, requires the review of a minimum body of a medical staff member's work in order to determine whether to grant or continue active (or some other category of) medical staff privileges. We are not proposing, nor would we be able, to establish a bright-line rule applicable in all instances defining an acceptable number of referrals to or amount of business generated for an entity that a medical staff could require in order to complete effective peer review activities. Rather, such medical staff requirements must directly relate to its peer review obligations—including the evaluation of a physician's (or other practitioner's) individual character, competence, training, experience, and judgment—and not be a proxy for referrals to or the generation of business for the entity. To be clear, if an REH adopted a requirement that a physician owner of or investor in the REH must have active privileges at the REH, we would consider it to have effectively (albeit indirectly) adopted a condition that the physician owner must make the same number of referrals to or generate the same amount of business for the REH for purposes of the requirement at proposed § 411.356(c)(4)(iii) as the number of referrals to or amount of business for the REH

that is required by the medical staff to hold active privileges at the REH. To illustrate, if the REH requires all physician owners or investors to maintain active medical staff privileges, and the REH's medical staff requires a physician to admit and treat a minimum of five patients per year to maintain active privileges, we would consider the REH to require a minimum of five admissions per year for physician owners to hold their ownership interests in the REH. Whether the requirement constitutes prohibited indirect conditioning of ownership or investment in the REH under proposed § 411.356(c)(4)(iii) requires a case-by-case determination, including a review of the underlying purpose of, need for, and available alternatives to the minimum requirement.

It is our position that there are many ways that an REH could indirectly condition an ownership or investment interest held or to be held by a physician (or an immediate family member of a physician) on the physician making or influencing referrals to the REH or otherwise generating business for the REH. For example, an REH could require a physician to earn a minimum number of "points" in a year to maintain the physician's (or an immediate family member's) ownership interest or level of ownership. Although this would not *per se* be prohibited under proposed § 411.356(c)(4)(iii), if the required points are merely a proxy for referrals to or the generation of business for the REH (for example, if the physician is awarded one point for each designated health service that they order), we would consider the REH to indirectly condition an ownership or investment interest held or to be held by a physician (or an immediate family member of a physician) on the physician making or influencing referrals to the REH or otherwise generating business for the REH. An REH could also indirectly condition ownership or investment interests under a points system if it awards points only for a physician's personally performed services but the personally performed services also result in the furnishing of designated health services by the REH. Whether a point system or other condition for ownership or investment in an REH runs afoul of proposed § 411.356(c)(4)(iii) requires a case-by-case determination. A point system that allows the awarding of only one point per

patient closely ties the referral of the patient or the generation of the business to the physician who ordered the designated health service or other REH service and, therefore, would likely not be permissible. In contrast, a point system that awards points for a variety of physician activities, including activities that are not tied to the physician's own referral of the patient or business generated for the REH (such as points for chairing a committee of the REH, serving as an assistant at surgery, or providing a professional consultation for another physician's patient), may be permissible under proposed § 411.356(c)(4)(iii).

As we explained in the MCR final rule, our policies with respect to determining whether compensation is determined in any manner that takes into account the volume or value of a physician's referrals (the "volume or value standard") or the other business generated by a physician (the "other business generated standard") have never applied and do not to apply for purposes of analyzing ownership or investment interests for compliance with the physician self-referral law, as none of our exceptions in § 411.356 include a requirement identical or analogous to the volume or value standard or other business generated standard (85 FR 77541). Any guidance regarding our interpretation of the volume or value standard or other business generated standard is not relevant for purposes of applying the exceptions at § 411.356(c)(1) and (3), both of which incorporate the requirements of § 411.362, including the requirement at § 411.362(b)(3)(ii)(B) that a hospital must not condition any physician ownership or investment interests either directly or indirectly on the physician owner or investor making or influencing referrals to the hospital or otherwise generating business for the hospital (85 FR 77541). The same is true with respect to the proposed REH exception—our interpretation of the volume or value standard and the other business generated standard is not relevant. Likewise, the interpretations with respect to the proposed REH exception explained in this proposed rule are not relevant for purposes of applying the special rules at § 411.354(d)(6) when analyzing compensation arrangements for compliance with the physician self-referral law.

Proposed § 411.356(c)(4)(iii) prohibits an REH conditioning any ownership or investment interests held or to be held by a physician (or an immediate family member of a physician) on the physician *making or influencing* referrals to the REH (or otherwise generating business for the REH). For purposes of the physician self-referral law generally, a physician makes a referral (as defined in § 411.351) by ordering the designated health service, writing a prescription for a designated health service, including the provision of a designated health service in a plan of care, certifying or recertifying the need for a designated health service, or otherwise requesting the designated health service. A physician also makes a referral when the physician requests a consultation with another physician and the consulting physician orders a designated health service to be performed by (or under the supervision of) the consulting physician. (A physician who transfers the care of a patient, in whole or in part, to another physician for specialty or other care to be provided by the other physician—as opposed to a request for a consultation with the other physician—does not make a referral for designated health services ordered or otherwise referred by the other physician.) A physician may make a referral orally, in writing, electronically, or in any other form. For purposes of proposed § 411.356(c)(4)(iii), we would interpret the making of referrals to an REH in the same way.

With respect to the influencing of referrals to an REH under proposed § 411.356(c)(4)(iii), impactful pressure or persuasion to refer, or an enforceable requirement for or control over the referrals of another, would demonstrate a physician’s influence over the referrals of another physician to an REH. Under § 411.351, “referral” is defined in the context of a physician’s action or conduct. We would interpret the term “referral” consistent with its meaning throughout the physician self-referral regulations, and interpret the requirement at proposed § 411.356(c)(4)(iii) to relate only to the influencing of referrals by a physician to the REH. For example, an REH would not satisfy the requirement at proposed § 411.356(c)(4)(iii) if it withheld the opportunity to purchase an ownership or investment interest in the REH from the physician owners of a physician practice unless the practice required all of its employed and

contracted physicians to refer all of their patients to the REH for diagnostic testing and clinical laboratory services, or required them to perform all outpatient surgeries at the REH. (We note that, with respect to the employed and contracted physicians' referrals for designated health services furnished by the physician practice, the requirement for referrals to the REH may be permissible, provided that all requirements of § 411.354(d)(4) are satisfied.)

Proposed § 411.356(c)(4)(iii) also prohibits an REH conditioning any ownership or investment interests held or to be held by a physician (or an immediate family member of a physician) on the physician *otherwise generating business* for the REH. We would interpret the phrase "otherwise generating business" in proposed § 411.356(c)(4)(iii) consistent with our interpretation of the same and similar phrases in our other regulations. We addressed our interpretation of the phrase "other business generated" and its variations, such as "otherwise generating business," in several of our prior rulemakings. We indicated that other business generated does not include a physician's personally performed services, but does include a referred technical component that corresponds to a physician's personally performed service (69 FR 16067 through 16068). We also indicated that other business generated by a physician includes Federal and private pay business (other than Medicare) (66 FR 877), as well as non-Federal health care business (69 FR 16068). It is important to highlight that these statements are examples of what is and is not "other business generated" for purposes of the physician self-referral law. Our longstanding interpretation of the phrase "other business generated" is that it means *any* other business or revenues generated by a physician (66 FR 877) (emphasis added). Although such business or revenues may be generated through the furnishing of health care services by the entity, our interpretation is not limited to business or revenue generated through the furnishing of health care services.

It is our position that a physician may generate business for an REH in a variety of ways, including, but not limited to, ordering services to be furnished or billed by the REH, writing a prescription for a service to be furnished or billed by the REH, establishing a plan of care for

services to be furnished or billed by the REH, certifying or recertifying the need for services to be furnished or billed by the REH, or otherwise requesting services to be furnished or billed by the REH. A physician may also generate business for an REH that is unrelated to the REH's furnishing of health care services. We interpret the generation of business by a physician to include the physician's direct actions and the actions of others whom the physician directs or otherwise influences to generate business for the REH.

We seek comment on our interpretation of this proposed requirement and request specific examples of directly and indirectly conditioning any ownership or investment interests held or to be held by a physician (or an immediate family member of a physician) on the physician making or influencing referrals to the REH or otherwise generating business for the REH. We are particularly interested in examples of conduct by an REH that would constitute "conditioning" of ownership or investment interests, as well as examples of conduct that we should not consider to condition ownership or investment interests. We are also interested in examples of conduct by a physician (or an immediate family member of a physician) that could "influence" referrals to an REH, as well as examples of conduct that we should not consider to influence referrals to an REH.

e. Offer of ownership or investment on more favorable terms

We propose to require at § 411.356(c)(4)(iv) that the REH does not offer any ownership or investment interests to a physician (or an immediate family member of a physician) on terms more favorable than the terms offered to a person that is not a physician (or an immediate family member of a physician). This proposed requirement is essentially identical to the requirement at existing § 411.362(b)(4)(ii), which applies to hospitals that use the rural provider and whole hospital exceptions, and we would interpret the requirements applicable to REHs and hospitals in the same way. For example, an REH that permits a physician owner or investor to pay for purchased shares in the REH over 5 years while requiring non-physicians to pay the full purchase price in advance of the purchase would not satisfy the proposed requirement.

Similarly, an REH could not permit a physician to purchase additional shares in the REH every year while allowing non-physicians to purchase shares only once every 3 years.

We note that, in the requirement at existing § 411.362(b)(4)(ii) from which this proposed requirement is drawn, the word “who” follows “person.” We believe that the statutory requirement on which that regulation is based is intended to prohibit the offering of ownership or investment interests to physicians (or immediate family members of physicians) on terms more favorable than any other owner of or investor in a hospital. For this reason, we propose to use the word “that” following “person” to indicate that the person to which less favorable terms are offered could be a natural person (that is, an individual) or a non-natural person (that is, a corporation, partnership, or similar organization).

We seek comment regarding this proposed requirement and specific examples of conduct that would satisfy (or fail to satisfy) the proposed requirement.

f. Providing loans or financing for ownership or investment

We propose at § 411.356(c)(4)(v) to prohibit an REH and the owners of or investors in the REH from directly or indirectly providing loans or financing for any investment in the REH by a physician (or an immediate family member of a physician). This proposed requirement is essentially identical to the requirement at existing § 411.362(b)(4)(iii), which applies to hospitals that use the rural provider and whole hospital exceptions, and we would interpret the requirements applicable to REHs and hospitals in the same way. For purposes of this proposed requirement, an REH directly provides loans or financing by lending the funds or other assets of the REH for use in purchasing the physician’s (or immediate family member’s) ownership or investment interest in the REH. In such a case, the REH is the lender. Similarly, an individual or corporate owner of or investor in an REH directly provides loans or financing by lending their own funds or other assets for use in purchasing the physician’s (or immediate family member’s) ownership or investment interest in the REH.

An REH indirectly provides loans or financing for investment in the REH by controlling or meaningfully influencing another person's decision to lend funds or assets for use in purchasing the physician's (or immediate family member's) ownership or investment interest in the REH. In such a case, the REH is not the lender. For example, if an REH is the sole owner of the corporation that loans money to a physician to purchase an ownership or investment interest in the REH, we would consider the REH to indirectly provide the loan because the REH exercises control over its wholly-owned subsidiary corporation. In contrast, merely introducing a physician (or an immediate family member of a physician) to an individual or corporation that might lend funds or assets for use in purchasing an ownership or investment interest in an REH, in the absence of actual control or meaningful influence over the lender's decision whether a loan will be provided, would not constitute the indirect provision of a loan or financing for investment in the REH.

We seek comment on our interpretation of this proposed requirement and request specific examples of directly and indirectly providing loans or financing for investment in an REH.

g. Guarantee, make a payment on, or otherwise subsidize a loan

At proposed § 411.356(c)(4)(vi), we propose to prohibit an REH and the owners of or investors in the REH from directly or indirectly guaranteeing a loan, making a payment toward a loan, or otherwise subsidizing a loan for a physician (or an immediate family member of a physician) that is related to acquiring any ownership or investment interest in the REH. This proposed requirement is essentially identical to the requirement at existing § 411.362(b)(4)(iv), which applies to hospitals that use the rural provider and whole hospital exceptions, and we would interpret the requirements applicable to REHs and hospitals in the same way. We note that existing § 411.362(b)(4)(iv) extends the prohibition on guaranteeing, making a payment toward, or otherwise subsidizing a loan to such activities when they are for a group of physician owners or investors, whereas proposed § 411.356(c)(4)(vi) prohibits these activities as they relate to individual physicians (and immediate family members). A group of physician owners or

investors is made up of individual physicians and, therefore, the proposed requirement would also prohibit guaranteeing, making a payment toward, or otherwise subsidizing a loan for a group of physician owners or investors.

For purposes of proposed § 411.356(c)(4)(vi), an REH, individual owner of or investor in an REH, or corporate owner of or investor in an REH guarantees a loan when the REH, owner, or investor formally or informally promises the lender that, should a physician (or an immediate family member of a physician) fail to make a required payment on a loan related to the physician's (or immediate family member's) acquisition of any ownership or investment interest in the REH, the REH, owner, or investor, respectively, will make or otherwise ensure that the payment will be made to the lender. A direct guarantee would include pledging the guarantor's own funds or assets as collateral for the guaranteed loan, whereas an indirect guarantee would include pledging or arranging for the pledge of the funds or assets of another individual or corporate entity as collateral for the guaranteed loan. We would also consider the pledge of funds or assets of an REH, individual owner of or investor in an REH, or corporate owner of or investor in an REH to guarantee a loan for property that serves as collateral for the loan related to acquiring the physician's (or immediate family member's) ownership or investment interest in the REH to be an indirect guarantee of such loan.

We would interpret the direct or indirect making of a payment toward a loan similarly. That is, a person directly makes a payment toward a loan by using the person's own funds or assets to make the payment, and indirectly makes a payment toward a loan by using or arranging for the use of the funds or assets of another individual or corporate entity to make the payment. An REH would not be prohibited from garnishing the wages or other compensation due to a physician (or an immediate family member of a physician) to make loan payments on behalf of the physician (or immediate family member).

Finally, for purposes of proposed § 411.356(c)(4)(vi), an REH, individual owner of or investor in an REH, or corporate owner of or investor in an REH otherwise subsidizes a loan

when the REH, owner, or investor pays part of the cost of a loan for a physician (or an immediate family member of a physician). Subsidies would include, for example, payments to reduce the principal amount of the loan, reduce the interest rate applied to the loan, or cover the cost of fees, such as origination fees, late fees, or early payoff penalties. As with guaranteeing or making payments toward a loan, we would interpret directly and indirectly subsidizing a loan to mean that a person directly subsidizes a loan by using the person's own funds or assets to pay part of the cost of the loan, and indirectly subsidizes a loan by using or arranging for the use of funds or assets of another individual or corporate entity to pay part of the cost of the loan.

We seek comment on our interpretation of this proposed requirement and request specific examples of direct and indirect guarantees of, payments toward, and otherwise subsidizing a loan for a physician (or an immediate family member of a physician) that is related to acquiring any ownership or investment interest in an REH.

h. Proportional distributions

We propose to require at § 411.356(c)(4)(vii) that ownership or investment returns are distributed to each owner or investor in an REH in an amount that is directly proportional to the ownership or investment interest in the REH of such owner or investor. This proposed requirement is essentially identical to the requirement at existing § 411.362(b)(4)(v), which applies to hospitals that use the rural provider and whole hospital exceptions, and we would interpret the requirements applicable to REHs and hospitals in the same way. Simply put, distributions of profits, dividend payments, and other payouts on equity may only be tied to the number of shares owned by an investor, and not to their referrals or the other business the investor generates for the REH. We would interpret "proportional" as it is defined in the dictionary: corresponding in size or amount.

To ensure that the ownership or investment return to each owner or investor in the REH is directly proportional to the particular owner's or investor's interest in the REH, all owners and investors must be treated the same. That is, if any owner or investor is eligible to

receive or actually receives an ownership or investment return, all other owners or investors must be eligible to receive or actually receive an ownership or investment return, respectively. For example, an REH wholly-owned by physicians would not satisfy this proposed requirement if the REH made distributions only to physicians who generate a minimum amount of business for the REH during the ownership or investment period. In addition, an REH could not exclude owners or investors that are not physicians (or their immediate family members) from eligibility for ownership or investment returns for the purpose of making distributions only to owners or investors who are physicians in a position to generate business for the REH or their immediate family members. This would be the case even if the distributions were in amounts that are directly proportional to the physician's (or immediate family member's) ownership or investment interest in the REH.

We seek comment on our interpretation of this proposed requirement and request specific examples of potentially nonabusive classifications of owners or investors that could justify the distribution of ownership or investment returns only to a subset of owners or investors in an REH or in an amount that is not directly proportional to the ownership or investment interest in the REH of each owner or investor.

i. Guaranteed receipt of or right to purchase other business interests

We are also proposing to require that any physician (or immediate family member of a physician) who has an ownership or investment interest in an REH does not directly or indirectly receive any guaranteed receipt of or right to purchase other business interests related to the REH, including the purchase or lease of any property under the control of any other owner or investor in the REH or located near the premises of the REH. This requirement is at proposed § 411.356(c)(4)(viii) and is essentially identical to the requirement at existing § 411.362(b)(4)(vi), which applies to hospitals that use the rural provider and whole hospital exceptions. We would interpret the requirements applicable to REHs and hospitals in the same way.

For purposes of this requirement, other business interests related to the REH would include a wide array of investment opportunities, ventures, and interests, as well as the examples of the purchase and lease of property under the control of any other owner of or investor in the REH that are listed in the statutory and regulatory requirements applicable to hospitals that use the rural provider and whole hospital exceptions. We would consider the business interests of any owner of or investor in the REH to be business interests related to the REH. For example, under the proposed requirement at § 411.356(c)(4)(viii), a physician owner of or investor in an REH may not directly or indirectly receive an interest in another component of the health care system that includes an REH upon the physician's purchase of their ownership or investment interest in the REH, nor may the physician owner directly or indirectly be guaranteed the right to invest in a venture in which another owner of the REH is also an investor. In these examples, the physician owner would directly receive an interest or be guaranteed the right to invest in a business interest related to an REH if the interest is held or would be held, if purchased, in the physician's name. In contrast, the physician owner would indirectly receive an interest or be guaranteed the right to invest in a business interest related to an REH if the interest is received by, held in the name of, or, if purchased, would be held in the name of a person or corporate entity over which the physician exercises meaningful control or influence, such as a partnership or limited liability company in which the physician holds a substantial interest. We seek comment on our interpretation of this proposed requirement and request specific examples of direct and indirect guaranteed receipt of other business interests, direct and indirect guaranteed rights to purchase business interests, and the types of business interests we should consider related to an REH.

j. Offer to purchase or lease other property on more favorable terms

Finally, at proposed § 411.356(c)(4)(ix), we propose to require that an REH does not offer a physician (or an immediate family member of a physician) the opportunity to purchase or lease any property under the control of the REH or any other owner of or investor in the REH on

more favorable terms than the terms offered to a person that is not a physician (or an immediate family member of a physician). This proposed requirement is essentially identical to the requirement at existing § 411.362(b)(4)(vii), which applies to hospitals that use the rural provider and whole hospital exceptions, and we would interpret the requirements applicable to REHs and hospitals in the same way.

We highlight that there are two main differences between the requirements at proposed §§ 411.356(c)(4)(viii) and (ix). The former applies to any business interests related to the REH and prohibits the guaranteed receipt of or right to purchase such other business interests. The latter applies only to property under the control of the REH, an owner of the REH, or an investor in the REH, and prohibits the offering of the opportunity to purchase or lease such property on terms more favorable than the terms offered to a person that is not a physician (or an immediate family member of a physician).

With respect to the prohibition on offering an opportunity to purchase or lease property on terms more favorable than the terms offered to a person that is not a physician (or an immediate family member of a physician), we would interpret this requirement in the same way as proposed § 411.356(c)(4)(iv), which, as described earlier in this section XVIII.E.3 of this proposed rule, would prohibit an REH from offering any ownership or investment interests to a physician (or an immediate family member of a physician) on terms more favorable than those offered to a person that is not a physician (or an immediate family member of a physician). We note that the requirement at existing § 411.362(b)(4)(vii), from which this proposed requirement is drawn, states that the physician owner may not be offered the opportunity to purchase or lease certain property on more favorable terms than those offered to an “individual” who is not a physician owner or investor, in contrast to the requirement at existing § 411.362(b)(4)(ii), which references “persons” in a similar manner, as described earlier in this section XVIII.E.3 of this proposed rule. We believe that the statutory requirement on which existing § 411.362(b)(4)(vii) is based is intended to prohibit the offering of the opportunity to purchase or lease the specified

property on terms more favorable than any other owner of or investor in a hospital. For this reason, proposed § 411.356(c)(4)(ix) includes the words “person that” in the same way as proposed § 411.356(c)(4)(iv) to indicate that the person to which less favorable terms are offered could be a natural person (that is, an individual) or a non-natural person (that is, a corporation, partnership, or similar organization).

4. Alternative to proposed REH exception considered but not proposed

Section 1861(e) of the Act excludes critical access hospitals (formerly referred to as rural primary care hospitals) for most purposes of Title XVIII of the Act unless the context otherwise requires. However, as we explained in the 1998 proposed rule, we believe that the reference to context in this statutory provision indicates that critical access hospitals may be deemed to be hospitals where, in specific contexts, it is consistent with the purpose of the legislation to do so (63 FR 1681). For that reason, we included such entities in our definition of “hospital” at § 411.351 (66 FR 954). We based this policy on our belief that a physician who has a financial relationship with a critical access hospital is in as much of a position to profit from overutilizing referrals to the critical access hospital as they would be if the financial relationship was with an ordinary hospital. In addition, a critical access hospital provides services that are very similar to inpatient hospital services (63 FR 1681).

Section 125 of the CAA amended section 1861(e) of the Act to also exclude REHs from the definition of “hospital” for most Medicare purposes, unless the context otherwise requires. We considered whether to include REHs in the definition of “hospital” in § 411.351 for purposes of the physician self-referral law similar to our treatment of critical access hospitals. We are not proposing to do so for two primary reasons. First, REHs are not the same as critical access hospitals (or other hospitals that furnish inpatient care). By definition, an REH may not furnish inpatient care, a fundamental attribute of and requirement for a hospital for purposes of Medicare. (See section 1861(e) of the Act.) Second, if we were to consider an REH to be a hospital for purposes of the physician self-referral law, in order for an REH to avoid the law’s

referral and billing prohibitions, the ownership or investment interests of physicians (and their immediate family members) would have to satisfy the requirements of one of the existing exceptions applicable to such ownership or investment interests, which could prove challenging, thus limiting the ability of such potential investors to bring needed resources to underserved and rural communities. If we proposed to include REHs as “hospitals” for purposes of the physician self-referral law, we would not propose to establish the exception for ownership or investment in an REH with the requirements described in this section XVIII.E of this proposed rule because we do not believe that the Secretary’s authority under section 1877(b)(4) of the Act would permit us to establish an exception that applies to only one type of hospital (for purposes of the physician self-referral law) without including the same (or equally stringent) program integrity requirements established by the Congress in statute.

To avoid the physician self-referral law’s referral and billing prohibitions under the rural provider or whole hospital exception, an ownership or investment interest must satisfy the requirements of the applicable exception at the time of the physician’s referral and the hospital must meet the requirements of section 1877(i) of the Act and § 411.362 no later than September 23, 2011. Section 1877(i)(1)(A) of the Act and § 411.362(b)(1) require that the hospital had physician ownership or investment on December 31, 2010, and a provider agreement under section 1866 of the Act on that date (emphasis added). Put another way, for a hospital to bill Medicare (or another individual, entity, or third-party payer) for a designated health service furnished as a result of a physician owner’s referral today, the hospital must have had both physician ownership or investment and a Medicare provider agreement on December 31, 2010. Thus, the hospital submitting the claim today must be the same hospital that had both physician ownership or investment and a Medicare provider agreement on December 31, 2010.

If we were to include REHs as hospitals for purposes of the physician self-referral law, certain REHs would be presumptively excluded from using the rural provider or whole hospital

exceptions: REHs that had no physician owners or investors, as defined at § 411.362(a), on March 23, 2010 or December 31, 2010, and REHs that did not have a Medicare provider agreement in effect on December 31, 2010. Although we are uncertain how many REHs this would affect, we believe that prohibiting critical access hospitals and small rural hospitals that could not avail themselves of the rural provider or whole hospital exceptions prior to conversion to an REH from accepting investment in the REH by a physician (or an immediate family member of a physician) after conversion could undermine the purpose of section 125 of the CAA to safeguard access to necessary care for underserved patients and those in rural areas, and we are hesitant to do so.

Critical access hospitals and small rural hospitals that had physician ownership on March 23, 2010 and December 31, 2010 and a Medicare provider agreement in effect on December 31, 2010 may avail themselves of the rural provider and whole hospital exceptions, provided that all other requirements of the applicable exception are satisfied. This would continue after conversion to an REH if we deemed REHs to be hospitals for purposes of the physician self-referral law. However, as noted above, the REH/hospital would have to be the same hospital that had physician ownership on March 23, 2010 and December 31, 2010 and a Medicare provider agreement in effect on December 31, 2010 (the “original hospital”). We would consider many factors when determining whether an REH would qualify as the same hospital that had physician ownership on March 23, 2010 and December 31, 2010 and a Medicare provider agreement in effect on December 31, 2010 including, but not limited to: status of, type of, and party to the State license for both the REH and the original hospital, including any lapses in State licensure or operation of either the REH or the original hospital; status of and party to the Medicare provider agreement, including any lapses in Medicare participation of either the REH or the original hospital; whether the REH has the same Medicare provider number as the original hospital; the location and structure of the REH building(s) and those of the original hospital; whether the REH is under the same State’s licensure regime as the original

hospital; whether the REH serves the same community as the original hospital; whether the REH provides the same scope of services as the original hospital; REH ownership and that of the original hospital; and the number of operating rooms, procedure rooms, and beds operated by the REH and that of the original hospital. No one factor would be dispositive.

Finally, were we to deem REHs to be hospitals for purposes of the physician self-referral law, even those REHs that qualify to use the rural provider or whole hospital exception could not increase the amount of physician ownership or investment in the REH beyond the level of the original hospital on March 23, 2010. In addition, the REH could not expand its aggregate number of operating rooms and procedure rooms (it will likely not have licensed beds by definition) beyond the aggregate number of operating rooms, procedure rooms, and beds for which the original hospital was licensed on March 23, 2010 (or, in the case of an original hospital that did not have a Medicare provider agreement in effect as of March 23, 2010, but did have a Medicare provider agreement in effect on December 31, 2010, the effective date of its Medicare provider agreement) (its “baseline number of operating rooms, procedure rooms, and beds”). Given that an REH may not furnish inpatient services under section 125 of the CAA and the regulations proposed in this proposed rule, the latter limitation may not have a significant impact on access to care in rural and other underserved areas, as an REH could continue to increase the number of its operating rooms and procedure rooms until it reached its baseline number of operating rooms, procedure rooms, and beds. However, as noted, we believe that physicians and their immediate family members may be an important source of needed capital for REHs. We are concerned that limiting the amount of physician ownership or investment in an REH to the level of such ownership or investment in the original hospital on March 23, 2010 could limit the services available to its patients and the community in which it is located and run counter to the purpose of section 125 of the CAA.

5. Applicability of certain exceptions in § 411.357 for compensation arrangements involving REHs

Section 1877(e) of the Act and § 411.357 set forth exceptions to the physician self-referral law for compensation arrangements between entities and physicians (or immediate family members of physicians) when all requirements of the exception are satisfied. Some of these exceptions apply only to specified types of compensation, specified types of entities, or both. The exceptions in § 411.357 that are applicable only to compensation arrangements to which one party is a hospital, federally qualified health center, or rural health clinic would not be available to an REH because it is not a hospital under section 1861(e) of the Act or our regulations at § 411.351. We believe that many of these party-limited exceptions could be important to ensuring access to necessary designated health services and other care furnished by an REH. Therefore, using the Secretary's authority under section 1877(b)(4) of the Act, we propose to revise the exceptions at § 411.357(e), (r), (t), (v), (x), and (y) to make them applicable to compensation arrangements to which an REH is a party.

The current exceptions for physician recruitment (§ 411.357(e)), obstetrical malpractice insurance subsidies (§ 411.357(r)), retention payments in underserved areas (§ 411.357(t)), and assistance to compensate a nonphysician practitioner (§ 411.357(x)) are available to hospitals, federally qualified health centers, and rural health clinics. We propose to revise these exceptions to also permit an REH to provide remuneration to a physician if all requirements of the applicable exception are satisfied because we believe that REHs will face the same challenges as hospitals, federally qualified health centers, and rural health clinics in recruiting and retaining qualified physicians and other practitioners in their service areas. Consistent with our rationale when expanding the statutory exception for physician recruitment to federally qualified health centers (69 FR 16095), we propose the extension of these exceptions to REHs to help ensure that the physician self-referral law does not impede efforts by REHs, which will provide substantial services to underserved populations, to recruit, assist with the recruitment of, and retain adequate staffs. We do not believe that a compensation arrangement between an REH and a physician (or an immediate family member of a physician) that is properly structured to satisfy all the

requirements of these exceptions would pose a risk of program or patient abuse. We are also proposing a technical amendment at proposed § 411.357(t)(5) to cross-reference the definition of the geographic area served by a federally qualified health center or rural health clinic that was previously omitted from this paragraph. The cross-referenced definition would also apply to REHs under this proposal.

The current exception for electronic prescribing items and services at § 411.357(v) is available only to hospitals, group practices that meet the requirements in § 411.352, PDP sponsors, and MA organizations and applies to hardware, software, or information technology and training services necessary and used solely to receive and transmit electronic prescription information that is provided to physicians specified in the regulation. For the reasons set forth in this and many of our prior rulemakings regarding the benefits of electronic prescribing, we believe that allowing REHs to use the exception at § 411.357(v) would advance our goals to expand the use of electronic prescribing. We do not believe that a compensation arrangement between an REH and a physician (or an immediate family member of a physician) that is properly structured to satisfy all the requirements of the exception would pose a risk of program or patient abuse.

The current exception for timeshare arrangements at § 411.357(y) is available only to hospitals and certain physician organizations (as defined in § 411.351) and applies to arrangements for the use of premises, equipment, personnel, items, supplies, and services. One of the underlying policy considerations for establishing this exception was to facilitate access to care in rural and other underserved areas (80 FR 71326). We believe that timeshare arrangements between REHs and physicians (or physician organizations in whose shoes such physicians stand under § 411.354(c)) may similarly increase access to necessary care for patients in underserved areas, and that it would be appropriate to extend the availability of the exception for timeshare arrangements to REHs. We do not believe that a compensation arrangement between an REH and a physician (or an immediate family member of a physician) that is

properly structured to satisfy all the requirements of the exception would pose a risk of program or patient abuse.

We seek comment on our proposals to permit an REH to use the exceptions for physician recruitment (§ 411.357(e)), obstetrical malpractice insurance subsidies (§ 411.357(r)), retention payments in underserved areas (§ 411.357(t)), electronic prescribing items and services (§ 411.357(v)), assistance to compensate a nonphysician practitioner (§ 411.357(x)), and timeshare arrangements (§ 411.357(y)). Because the REH will not provide inpatient services and may elect not to provide outpatient services beyond emergency room and observation services, we are particularly interested in comments regarding the need for an REH to recruit physicians to establish or join medical practices in the geographic area served by the REH and how to define the geographic service area served by an REH for physician recruitment purposes. For the same reason, we are interested in comments regarding the need to extend the availability of the exception for assistance to compensate a nonphysician practitioners. We are also particularly interested in comments regarding the need for an REH to subsidize obstetrical malpractice insurance premium costs in light of the fact that an REH may elect not to serve obstetrical and newborn patients outside its emergency department.

We note that the current exception for medical staff incidental benefits at § 411.357(m) applies to items or services (not including cash or cash equivalents) provided to a member of the entity's medical staff. The exception applies to hospitals, as well as other facilities and health care clinics (including, but not limited to, federally qualified health centers) that have *bona fide* medical staffs. Prior to conversion to an REH, as a hospital for purposes of the physician self-referral law, a critical access hospital or small rural hospital would have been able to use the exception for medical staff incidental benefits. An REH that has a *bona fide* organized medical staff could use the exception for medical staff incidental benefits under current § 411.357(m)(8). However, we seek comment regarding whether we should revise § 411.357(m) to expressly include REHs as entities to which the exception applies.

6. Revised cross-reference in definition of “rural area” for purposes of the physician self-referral law

As discussed earlier in section XVIII.E of this proposed rule, the rural provider exception applies to designated health services furnished in a rural area. Section 1877(d)(2) of the Act defines “rural area” by reference to section 1886(d)(2)(D) of the Act. In the 1992 proposed rule, we proposed to define “rural area” as an area that is not an “urban area,” as the term is the term is defined at § 412.62(f)(1)(ii) (57 FR 8598). Section 411.62 established the Federal rates for inpatient operating costs for fiscal year 1984. We finalized the definition of “rural area,” including the reference § 412.62(f)(1)(ii), in the 1995 final rule (60 FR 41980). In the FY 2005 IPPS final rule, CMS revised the definitions of urban and rural areas based on OMB’s revised standards for defining Metropolitan Statistical Areas (MSAs) (69 FR 49077). The revised definitions of urban and rural areas were codified at § 412.64(b). Section 412.64 establishes Federal rates for inpatient operating costs for Federal fiscal year 2005 and subsequent fiscal years. Despite the revised definition of rural and urban areas in the FY 2005 IPPS final rule, the definition of “rural area” as codified in § 411.351 for purposes of the physician self-referral law was never updated to reflect OMB’s revised standards for defining MSAs. As a consequence, the current definition of “rural area” in § 411.351 includes, by reference to § 412.62(f)(1)(ii), terminology that is no longer employed by OMB, such as “New England County Metropolitan Area (NECMA)” (see, for example, 65 FR 51065). To ensure that the definition of “rural area” for purposes of the physician self-referral law is aligned with CMS’ updated definitions of rural and urban areas at § 412.64 and takes into account OMB’s revised standards for defining MSAs, we propose to modify the definition of “rural area” in § 411.351 to reference § 412.64(b) instead of § 412.62(f). Specifically, we propose to define “rural area” as an area that is not an urban area as defined at § 412.64(b) of this chapter. We believe that this technical change will have no effect on the entities that qualify as “rural providers” under § 411.356(c)(1). We seek comment on this proposal.

XIX. Request for Information on Use of CMS Data to Drive Competition in Healthcare

Marketplaces

A. Background

On July 9, 2021, the President issued an Executive Order on Promoting Competition in the American Economy (EO 14036). According to EO 14036, “robust competition is critical to preserving America’s role as the world’s leading economy,” and “the American promise of a broad and sustained prosperity depends on an open and competitive economy.”

A fact sheet released in conjunction with EO 14036³²⁴ goes on to identify hospital consolidation as a major concern, stating “[h]ospital consolidation has left many areas, especially rural communities, without good options for convenient and affordable healthcare service.”

Research suggests that mergers in rural areas could result in reduced service lines and responsiveness to community needs.³²⁵ Furthermore, in urban and rural areas, hospitals in consolidated markets charge far higher prices than hospitals in markets with several competitors.

The Fact Sheet that accompanies EO 14036:

- Underscores that hospital mergers can be harmful to patients and encourages the Justice Department and the Federal Trade Commission to review and revise their merger guidelines to ensure patients are not harmed by such mergers.
- Directs HHS to support existing hospital price transparency rules and to finish implementing bipartisan Federal legislation to address surprise hospital billing.

Additionally, in 2018, MedPAC reviewed the literature and data on health care provider consolidation in response to a congressional request.³²⁶ They found that by 2017, in most markets, a single hospital system had more than a 50 percent market share of discharges, and that

³²⁴ <https://www.whitehouse.gov/briefing-room/statements-releases/2021/07/09/fact-sheet-executive-order-on-promoting-competition-in-the-american-economy/>

³²⁵ Hencke, RM, et al “Access To Obstetric, Behavioral Health, And Surgical Inpatient Services After Hospital Mergers In Rural Areas,” <https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2021.00160>, October 2021.

³²⁶ March 2018 Report to the Congress: Medicare Payment Policy. Accessed online 4/20/2022. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/mar18_medpac_entirereport_sec_rev_0518.pdf

hospital consolidation leads to higher prices for commercially insured patients. Furthermore, the literature synthesized by MedPAC suggested these high prices primarily reflected hospitals negotiating higher prices with insurers, rather than cost shifting as a result of lower Medicare or Medicaid rates. Even when Medicare or Medicaid revenues increase, hospitals still aimed to negotiate larger, rather than smaller, rate increases from commercial insurers. The MedPAC report concludes that “taken together, these findings imply that hospitals seek higher prices from insurers and will get them when they have greater bargaining power.”

Research has similarly demonstrated that higher prices are also observed when physician practices merge, for example, one national study found that physicians in the most concentrated markets charged fees that were 14-30 percent higher than fees in the least concentrated markets.³²⁷

Overall, while provider mergers increased prices, their effects on quality were mixed. The MedPAC report noted “Because the literature is mixed, we cannot make a definitive conclusion about the effect of mergers on the quality of care other than to say the effect is not large enough to result in consistent findings across studies.”

Over the years, CMS has undertaken several value-based purchasing activities that drive value care and support competition. For example, beginning in 2001, HHS and CMS began launching Quality Initiatives³²⁸ to assure quality health care for all Americans through accountability and public disclosure. The various Quality Initiatives touch every aspect of the healthcare system. Some initiatives focus on publicly reporting quality measures for nursing homes, home health agencies, hospitals, and kidney dialysis facilities. Consumers can use the quality measures information that is available at www.medicare.gov for these healthcare settings to assist them in making healthcare choices or decisions. CMS also releases vast amounts of healthcare cost information that is available to the public, such as select measures provided by

³²⁷ Abe Dunn and Adam Shapiro. “Do Physicians Possess Market Power?” *Journal of Law and Economics* 57, no. 1 (January 1, 2014).

³²⁸ <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo>

Medicare providers through their annual cost report,³²⁹ and detailed use and payment information for procedures, services, and prescription drugs by specific inpatient and outpatient healthcare providers and suppliers.³³⁰ CMS also finalized regulations designed to enhance healthcare price transparency to drive competition through its Hospital Price Transparency³³¹ and Transparency in Coverage³³² initiatives.

More recently, CMS has released data files to the public outlining hospital and nursing facilities' mergers, acquisitions, consolidations, and changes in ownership that were reported to the Medicare Provider Enrollment, Chain, and Ownership System (PECOS) from 2016 to 2022, in order to promote transparency of these mergers, acquisitions, consolidations, and changes in ownership.³³³

PECOS is the System of Record for Medicare Provider Enrollment and was created to collect and maintain information regarding provider or supplier enrollment into Medicare. In addition to collecting information about individual practitioners or organizational entities, the CMS 855 forms collect information about ownership, authorized officials, delegated officials, managing employees, practice location, provider or supplier type, provider and supplier specific information, and affiliated provider information.

For additional information about the data that is collected in the PECOS system, please refer to the CMS 855 forms at this link: <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/Enrollment-Applications>.

In conjunction with this release of PECOS information showing hospital and skilled nursing facility mergers, acquisitions, consolidations, and changes in ownership, HHS's Office of the Assistant Secretary for Planning and Evaluation (ASPE) also released a related report

³²⁹ <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Cost-Report>

³³⁰ <https://data.cms.gov/provider-summary-by-type-of-service>

³³¹ <https://www.cms.gov/hospital-price-transparency>

³³² <https://www.cms.gov/healthplan-price-transparency>

³³³ <https://www.cms.gov/newsroom/press-releases/hhs-releases-new-data-and-report-hospital-and-nursing-home-ownership>

analyzing the CMS data to examine trends in changes of ownership over the 6 years.³³⁴ The ASPE report identified several findings from the new data release including:

- Changes in ownership have been much more common in nursing homes than hospitals over the 6-year period.
- There is wide variation in ownership changes by State. For instance, 19 percent of hospitals (14 out of 73) in South Carolina were sold during the 6-year period, while most states had fewer than 4 percent of hospitals change ownership.
- A majority (62.3 percent) of skilled nursing facilities (SNFs) that were purchased have a single organizational owner, 6.9 percent have multiple organization owners, while 18.2 percent have only individual owners and 12.7 percent have both types of owners.

These merger, acquisition, consolidation, and changes in ownership data are available on [data.CMS.gov](https://data.cms.gov) and are expected to be updated on a quarterly basis going forward.

B. Request for Public Comment

In response to the EO 14036's call for a "whole-of-government approach" to address excessive concentration, abuses of market power, unfair competition, and the effects of monopoly and monopsony, CMS is seeking information from the public on how data that CMS collects could be used to promote competition across the health care system or protect the public from the harmful effects of consolidation within healthcare. Specifically, CMS seeks comment from the public on the following:

- What additional data that is already collected by form 855A (PECOS) would be helpful to release to the public and researchers, to help identify the impact of provider mergers, acquisitions, consolidations, and changes in ownership on the affordability and availability of medical care, and why?

³³⁴ <https://aspe.hhs.gov/sites/default/files/documents/4d960147d5fd8e2ea9af508f115ca7b7/aspe-datapoint-change-ownership-pecos.pdf>

- Do commenters suggest that CMS release data on any mergers, acquisitions, consolidations, and changes in ownership that have taken place for any additional types of providers beyond nursing facilities and hospitals? If so, for which types of providers?
- What additional information collected by CMS would be useful for the public or researchers who are studying the impacts of mergers, acquisitions, consolidations, or changes in ownership?
- Section 6401 (a) of the Affordable Care Act established a requirement for all enrolled providers/suppliers to revalidate their Medicare enrollment information in PECOS under new enrollment screening criteria. In 2016, the Centers for Medicare & Medicaid Services (CMS) completed its initial round of revalidations and resumed regular revalidation cycles in accordance with 42 CFR 424.515.³³⁵ Would data for transactions occurring before the 2016 CMS revalidation effort be useful for the public or researchers, even if such data may be less complete?

XX. Addition of a New Service Category for Hospital Outpatient Department (OPD) Prior Authorization Process

A. Background

In the CY 2020 OPPS/ASC final rule with comment period, we established a prior authorization process for certain hospital OPD services (84 FR 61142, 61446 through 61456) using our authority under section 1833(t)(2)(F) of the Act, which allows the Secretary to develop “a method for controlling unnecessary increases in the volume of covered OPD services.”³³⁶ As part of the CY 2021 OPPS/ASC final rule with comment period, we added two additional service categories to the prior authorization process for certain hospital OPD services (85 FR 85866, 86236 through 86248). The regulations governing the prior authorization process for certain

³³⁵ <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1605.pdf>

³³⁶ See also Correction Notice issued January 3, 2020 (85 FR 224).

hospital OPD services are located in subpart I of 42 CFR part 419, specifically at §§ 419.80 through 419.89, with the specific service categories listed in § 419.83.

Paragraph (a)(1) of § 419.83 lists the specific service categories for which prior authorization must be obtained for service dates on or after July 1, 2020, which are: (i) Blepharoplasty; (ii) Botulinum toxin injections; (iii) Panniculectomy; (iv) Rhinoplasty; and (v) Vein ablation. Paragraph (a)(2) of § 419.83 lists two additional service categories for which prior authorization must be obtained for service dates on or after July 1, 2021, which are: (i) Cervical Fusion with Disc Removal; and (ii) Implanted Spinal Neurostimulators. Paragraph (b) states that CMS will adopt the list of hospital outpatient department-service categories requiring prior authorization-and any updates or geographic restrictions through formal notice-and-comment rulemaking. Additionally, paragraph (c) describes the circumstances under which CMS may elect to exempt a provider from the prior authorization process, and paragraph (d) states that CMS may suspend the prior authorization process generally or for a particular service at any time by issuing a notification on the CMS website.

B. Controlling Unnecessary Increases in the Volume of Covered OPD Services

1. Proposed Addition of a New Service Category

In accordance with § 419.83(b), we propose to require prior authorization for a new service category: Facet Joint Interventions. We propose adding the new service category at § 419.83(a)(3). We also propose that the prior authorization process for this additional service category would be effective for dates of services on or after March 1, 2023. As explained more fully below, the proposed addition of this service category is consistent with our authority under section 1833(t)(2)(F) of the Act and is based upon our determination that there has been an unnecessary increase in the volume of these services. Because we propose that prior authorization would be required for this service category at a later date than for the first seven service categories, we propose to revise paragraph (a)(3) to include this new service category and reflect the March 1, 2023 implementation date for the prior authorization requirement for this

additional service category. Specifically, we propose that paragraph (a)(3) would read, “[t]he Facet Joint Interventions service category requires prior authorization beginning for service dates on or after March 1, 2023.” We also propose that existing paragraph (a)(3) be moved to paragraph (b) and that paragraph (b) be revised by modifying the title to read, “Adoption of the list of services and technical updates.” We also propose to re-designate the current paragraph (b) as subparagraph (b)(1). Subparagraph (b)(1) would read, “CMS will adopt the list of hospital outpatient department service categories requiring prior authorization and any updates or geographic restrictions through formal notice-and-comment rulemaking.” As previously mentioned, current paragraph (a)(3) would be moved to new paragraph (b)(2) and read, “Technical updates to the list of services, such as changes to the name of the service or CPT code, will be published on the CMS website.”

The proposed Facet Joint Interventions service category would consist of facet joint injections, medial branch blocks, and facet joint nerve destruction. Facet joint injections are procedures in which a practitioner injects a medication into the facet joints (the connections between the bones of the spine) to help diagnose the cause and location of pain and also to provide pain relief. Medial branch block is a procedure in which a medication is injected near the medial branch nerve connected to a specific facet joint to achieve pain relief. Facet joint nerve destruction (also known as nerve denervation) is a procedure that uses heat to destroy the small area of the facet joint nerve for pain management.

We propose that the list of proposed additional OPD services in the Facet Joint Interventions service category that would require prior authorization beginning on March 1, 2023 are those identified by the CPT codes in Table 79. For ease of review and brevity, we only include in the regulation text in proposed new § 419.83(a)(3) the name of the service category, but not the CPT codes that fall into that service category, which are listed in Table 79. Note that this is the same approach we took in establishing the initial five service categories in § 419.83(a)(1) and two additional service categories in § 419.83(a)(2). For ease of reference, we

have included the 2020 Final List of Outpatient Services that Require Prior Authorization for the five initial service categories and the 2021 Final List of Outpatient Services that Require Prior Authorization for two additional service categories in Table 80. Again, we propose that the prior authorization process for the proposed additional service category would be effective for dates of service on or after March 1, 2023. We propose an effective date slightly earlier in the calendar year (compared to the July 1, 2020 and July 1, 2021 effective dates for the services categories previously added to the prior authorization regulation) because Medicare Contractors, CMS, and the OPD providers already have knowledge of and experience with the prior authorization process. Also, this new service category can be performed by some of the same provider types who furnish other services currently subject to the OPD prior authorization process, such as implanted spinal neurostimulators and cervical fusion with disc removal.

2. Basis for Proposing to Add a New Service Category

As part of our responsibility to protect the Medicare Trust Funds, we continue our routine analysis of data associated with all aspects of the Medicare program. This responsibility includes monitoring the total amount or types of claims submitted by providers and suppliers; analyzing the claims data to assess the growth in the number of claims submitted over time (for example, monthly and annually, among other intervals); and conducting comparisons of the data with other relevant data, such as the total number of Medicare beneficiaries served by providers, to help ensure the continued appropriateness of payment for services furnished in the hospital OPD setting.

In proposing the addition of this new service category, we reviewed approximately 1 billion claims related to OPD services during the 10-year period from 2012 through 2021. We determined that the overall rate of OPD claims submitted for payment to the Medicare program increased each year by an average rate of 0.6 percent. This equated to an increase from approximately 105 million OPD claims submitted for payment in 2012 to approximately 111 million claims submitted for payment in 2021. The 0.6 percent rate reflects a decrease when

compared to the 2.8 percent rate identified in the CY 2021 OPPS/ASC proposed rule, when we looked at the period from 2007 through 2018. Our analysis also showed an average annual rate-of-increase in the Medicare allowed amount (the amount that Medicare would pay for services regardless of external variables, such as beneficiary plan differences, deductibles, and appeals) of 4.2 percent. Again, this is a decrease when compared to the 7.8 percent rate identified in the CY 2021 OPPS/ASC proposed rule for a slightly earlier timeframe. The decrease in the average annual increase in the claim volume and allowed amount from the increases noted in the CY 2021 OPPS/ASC proposed rule is likely due in part to the PHE as discussed in more detail below. We found that the total Medicare allowed amount for the OPD services claims processed in 2012 was approximately \$48 billion and increased to \$73 billion in 2021, while during this same 10-year period, the average annual increase in the number of Medicare beneficiaries per year was only 0.4 percent.

Our analysis of Integrated Data Repository (IDR³³⁷) data showed that, with regard to the facet joint interventions, CPT codes 64490-64495 and 64633-64636, claims volume increased by 47 percent between 2012 and 2021, reflecting a 4 percent average annual increase, which is higher than the 0.6 percent annual increase for all OPD services. For the facet joint injection and medial branch block services, CPT codes 64490-64495, we observed an increase of 27 percent between 2012 and 2021, reflecting a 2.5 percent average annual increase. This reflects an increase from approximately 136,000 claims submitted for payment in 2012 to approximately 173,775 claims submitted for payment in 2021. For the nerve destruction services, CPT codes 64633 through 64636, we observed an increase in volume of 102 percent between 2012 and 2021, which was an average annual increase of 7 percent. This accounts for an increase from approximately 48,000 claims submitted for payment in 2012 to approximately 97,000 claims

³³⁷ The IDR is a high-volume data warehouse integrating Medicare Parts A, B, C, and D, and DME claims, beneficiary and provider data sources, along with ancillary data such as contract information and risk scores. Additional information is available at: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/IDR/index.html>.

submitted for payment in 2021. Both the facet joint injections/medial branch block CPT codes and nerve destruction CPT codes, with 2.5 and 7 percent annual increases, respectively, demonstrated higher average annual increases in claim submissions between 2012 and 2021 than the 0.6 percent annual increase for all OPD services over the same time period.

When analyzing the data, we took the COVID-19 Public Health Emergency (PHE) into consideration. As a result of the PHE, healthcare use and spending dropped sharply due to cancellations of elective and non-emergency care to increase hospital capacity and social distancing measures to reduce the community spread of the coronavirus. Consequently, the claims data for CY 2020 showed a significant decrease in volume compared to the previous year, which is likely due to the PHE. However, over the 9-year period of our analysis, services for facet joint interventions demonstrated increases. These volume increases led us to further research the reasons behind them, to determine if they were unnecessary.

The Department of Health and Human Services' Office of the Inspector General (OIG) has published multiple reports indicating questionable billing practices, improper Medicare payments, and questionable utilization of facet joint interventions. An OIG report published in 2020 identified \$748,555 in improper payments out of \$3.3 million in paid Medicare claims for facet joint injections with an audit period from January 1, 2017 through May 31, 2019. The OIG recommended that CMS and its contractors provide additional oversight on claims for facet joint injections to prevent additional improper payments³³⁸. In 2021, the OIG published a report on facet denervation procedures. During the audit period from January 2019 through 2020, the OIG reported that Medicare improperly paid physicians \$9.5 million for selected facet joint denervation procedures. According to the OIG, these improper payments occurred because CMS's oversight was not adequate to prevent or detect improper payments for selected facet-joint denervation procedures³³⁹. Further, in March 2022, the Department of Justice reported on

³³⁸ <https://oig.hhs.gov/oas/reports/region9/92003003.asp>

³³⁹ <https://oig.hhs.gov/oas/reports/region9/92103002.asp>

a \$250 million health care fraud scheme that took place from 2007 to 2018 involving physicians from multiple states who allegedly subjected their patients to medically unnecessary facet joint injections in order to obtain illegal prescriptions for opioids. The physicians required patients to receive the facet joint injections due to their high reimbursement rates³⁴⁰. Both our data analysis and research show that the increases in volume for these procedures are unnecessary, and further program integrity action is warranted.

Our conclusion that increases in volume for facet joint services are unnecessary was based not only on the data specific to this service category, but also on a comparison of the rate of increase for the service category to the overall trends for all OPD services. We believe that comparing the utilization rate for the particular service category to the overall rate of growth for Medicare OPD services generally is an appropriate method for identifying unnecessary increases in volume, particularly where there are no legitimate clinical or coding reasons for the changes. We researched possible causes for the increases in volume that would indicate the services are increasingly necessary, but we did not find any explanations that would cause us to believe that was the case. We continue to believe prior authorization is an effective mechanism to ensure Medicare beneficiaries receive medically necessary care while protecting the Medicare Trust Funds from unnecessary increases in volume by virtue of improper payments without adding onerous new documentation requirements. A broad program integrity strategy must use a variety of tools to best account for potential fraud, waste, and abuse, including unnecessary increases in volume. We believe prior authorization for these services will be an effective method for controlling unnecessary increases in the volume of these services and expect that it will reduce the instances in which Medicare pays for services that are determined not to be medically necessary. We request comments on the addition of this service category, and specifically

³⁴⁰ <https://www.justice.gov/opa/pr/16-defendants-including-12-physicians-sentenced-prison-distributing-66-million-opioid-pills>

request comments on the potential for any unintended clinical consequences from the addition of this service category.

TABLE 79: 2023 PROPOSED LIST OF ADDITIONAL OUTPATIENT DEPARTMENT SERVICES THAT REQUIRE PRIOR AUTHORIZATION

Beginning for service dates on or after March 1, 2023	
Code	Facet Joint Interventions
64490	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; single level
64491	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; second level
64492	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; third and any additional level(s)
64493	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; single level
64494	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; second level
64495	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; third and any additional level(s)
64633	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint
64634	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, each additional facet joint
64635	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, single facet joint
64636	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional facet joint

TABLE 80: FINAL LIST OF OUTPATIENT DEPARTMENT SERVICES THAT REQUIRE PRIOR AUTHORIZATION

Beginning for service dates on or after July 1, 2020	
Code	(i) Blepharoplasty, Blepharoptosis Repair, and Brow Ptosis Repair ³⁴¹
15820	Blepharoplasty, lower eyelid
15821	Blepharoplasty, lower eyelid; with extensive herniated fat pad
15822	Blepharoplasty, upper eyelid
15823	Blepharoplasty, upper eyelid; with excessive skin weighting down lid
67900	Repair of brow ptosis (supraciliary, mid-forehead or coronal approach)

³⁴¹ CPT 67911 (Correction of lid retraction) was removed on January 7, 2022.

67901	Repair of blepharoptosis; frontalis muscle technique with suture or other material (eg, banked fascia)
67902	Repair of blepharoptosis; frontalis muscle technique with autologous fascial sling (includes obtaining fascia)
67903	Repair of blepharoptosis; (tarso) levator resection or advancement, internal approach
67904	Repair of blepharoptosis; (tarso) levator resection or advancement, external approach
67906	Repair of blepharoptosis; superior rectus technique with fascial sling (includes obtaining fascia)
67908	Repair of blepharoptosis; conjunctivo-tarso-Muller's muscle-levator resection (eg, Fasanella-Servat type)
Code	(ii) Botulinum Toxin Injection
64612	Chemodeneration of muscle(s); muscle(s) innervated by facial nerve, unilateral (eg, for blepharospasm, hemifacial spasm)
64615	Chemodeneration of muscle(s); muscle(s) innervated by facial, trigeminal, cervical spinal and accessory nerves, bilateral (eg, for chronic migraine)
J0585	Injection, onabotulinumtoxina, 1 unit
J0586	Injection, abobotulinumtoxina, 5 units
J0587	Injection, rimabotulinumtoxinb, 100 units
J0588	Injection, incobotulinumtoxin a, 1 unit
Code	(iii) Panniculectomy, Excision of Excess Skin and Subcutaneous Tissue (Including Lipectomy), and related services
15830	Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen, infraumbilical panniculectomy
15847	Excision, excessive skin and subcutaneous tissue (includes lipectomy), abdomen (eg, abdominoplasty) (includes umbilical transposition and fascial plication)
15877	Suction assisted lipectomy; trunk
Code	(iv) Rhinoplasty, and related services ³⁴²
20912	Cartilage graft; nasal septum
21210	Graft, bone; nasal, maxillary or malar areas (includes obtaining graft)
30400	Rhinoplasty, primary; lateral and alar cartilages and/or elevation of nasal tip
30410	Rhinoplasty, primary; complete, external parts including bony pyramid, lateral and alar cartilages, and/or elevation of nasal tip
30420	Rhinoplasty, primary; including major septal repair
30430	Rhinoplasty, secondary; minor revision (small amount of nasal tip work)
30435	Rhinoplasty, secondary; intermediate revision (bony work with osteotomies)
30450	Rhinoplasty, secondary; major revision (nasal tip work and osteotomies)
30460	Rhinoplasty for nasal deformity secondary to congenital cleft lip and/or palate, including columellar lengthening; tip only
30462	Rhinoplasty for nasal deformity secondary to congenital cleft lip and/or palate, including columellar lengthening; tip, septum, osteotomies
30465	Repair of nasal vestibular stenosis (eg, spreader grafting, lateral nasal wall reconstruction)

³⁴² CPT 21235 (Obtaining ear cartilage for grafting) was removed on June 10, 2020

30520	Septoplasty or submucous resection, with or without cartilage scoring, contouring or replacement with graft
Code	(v) Vein Ablation, and related services
36473	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated
36474	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; subsequent vein(s) treated in a single extremity, each through separate access sites
36475	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated
36476	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; subsequent vein(s) treated in a single extremity, each through separate access sites
36478	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated
36479	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; subsequent vein(s) treated in a single extremity, each through separate access sites
36482	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; first vein treated
36483	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; subsequent vein(s) treated in a single extremity, each through separate access sites
Beginning for service dates on or after July 1, 2021	
Code	(i) Cervical Fusion with Disc Removal
22551	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2
22552	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace
Code	(ii) Implanted Spinal Neurostimulators ³⁴³
63650	Percutaneous implantation of neurostimulator electrode array, epidural

XXII. Overall Hospital Quality Star Rating

A. Background

³⁴³ CPT codes 63685 (Insertion or replacement of spinal neurostimulator pulse generator or receiver) and 63688 (Revision or removal of implanted spinal neurostimulator pulse generator or receiver) were temporarily removed from the list of OPD services that require prior authorization, as finalized in the CY 2021 OPSS/ASC final rule with comment period.

The Overall Hospital Quality Star Rating provides a summary of certain existing hospital quality information based on publicly available quality measure results reported through CMS programs in a way that is simple and easy for patients to understand, by assigning hospitals between one and five stars (85 FR 86193). The Overall Hospital Quality Star Rating was first introduced and reported on our Hospital Compare website in July 2016³⁴⁴ (now reported on its successor website at <https://www.medicare.gov/care-compare>) and has been refreshed multiple times, with the most current refresh planned for 2022.^{345, 346, 347, 348, 349, 350, 351} In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86182), we finalized a methodology to calculate the Overall Hospital Quality Star Rating. We refer readers to section XVI (“Overall Hospital Quality Star Rating Methodology for Public Release in CY 2021 and Subsequent Years”) of the CY 2021 OPPS/ASC final rule with comment period and 42 CFR 412.190 for details.

In this proposed rule, we are: (1) providing information on the previously finalized policy for inclusion of quality measure data from Veteran’s Health Administration (VHA) hospitals;

³⁴⁴ Centers for Medicare & Medicaid Services. (2016, July 27). First Release of the Overall Hospital Quality Star Rating on Hospital Compare. Retrieved from CMS.gov newsroom at: <https://www.cms.gov/newsroom/fact-sheets/first-release-overall-hospital-quality-star-rating-hospital-compare>.

³⁴⁵ Centers for Medicare & Medicaid Services. (2016, May). Overall Hospital Quality Star Rating on Hospital Compare: July 2016 Updates and Specifications Report.

³⁴⁶ Centers for Medicare & Medicaid Services. (2016, October). Overall Hospital Quality Star Rating on Hospital Compare: December 2016 Updates and Specifications Report.

³⁴⁷ Centers for Medicare & Medicaid Services. (2017, October). Overall Hospital Quality Star Rating on Hospital Compare: July 2017 Updates and Specifications Report.

³⁴⁸ Centers for Medicare & Medicaid Services. (2019, November 4). Overall Hospital Quality Star Rating on Hospital Compare: January 2020 Updates and Specifications Report. Retrieved from qualitynet.org: <https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab2>.

³⁴⁹ Centers for Medicare & Medicaid Services. (2018, November 30). Overall Hospital Quality Star Rating on Hospital Compare: February 2019 Updates and Specifications Report. Retrieved from qualitynet.org: <https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab2>.

³⁵⁰ Centers for Medicare & Medicaid Services. (2017, November). Star Methodology Enhancement for December 2017 Public Release. Retrieved from www.qualitynet.org: <https://qualitynet.org/outpatient/public-reporting/overall-ratings/resources>.

³⁵¹ Centers for Medicare & Medicaid Services. (2022, May 17). Overall Hospital Quality Star Rating on Hospital Compare: July 2022 Updates and Specifications Report. Retrieved from qualitynet.org: <https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab2>.

(2) proposing to amend the language of § 412.190(c) to state that we would use publicly available measure results on Hospital Compare or its successor websites from a quarter within the prior twelve months; and (3) conveying that although CMS intends to publish Overall Hospital Quality Star Ratings in 2023, we may apply the suppression policy if applicable.

B. Veterans Health Administration Hospitals

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86197 and 86198), we finalized a policy to include Veterans Health Administration hospitals' (VHA hospitals) quality measure data for the purpose of calculating the Overall Hospital Quality Star Ratings beginning with the 2023 refresh. In that final rule, we also stated that we intended to provide more information about the statistical impact of adding VHA hospitals to the Overall Star Rating and discuss procedural aspects in a future rule (85 FR 48999). Since the publication of the CY 2021 OPPS/ASC final rule, we conducted an internal analysis from February 28, 2022, through March 30, 2022, with measure data from all VHA hospitals in the calculation of the Overall Hospital Quality Star Ratings methodology. The internal analysis included a period of confidential reporting and feedback during which VHA hospitals reviewed their Overall Hospital Quality Star Ratings internal analysis results, and in addition, further familiarized themselves with the Overall Hospital Quality Star Ratings methodology and had the opportunity to ask questions. All VHA hospitals were made aware of the internal analysis and were provided the opportunity to participate. For the internal analysis, the Overall Hospital Quality Star Ratings were calculated using VHA hospital measure data along with subsection (d) hospitals and CAHs. The internal analysis included the same measures used for the April 2021 refresh of Overall Hospital Quality Star Ratings on our public reporting website, Care Compare. At the time of the 2022 VHA internal analysis, VHA hospitals in each peer group reported a similar number of measures when compared to non-VHA hospitals for most measure groups. VHA hospitals in the 5 measure group peer group reported a lower median number of Safety and Readmission measures. VHA hospitals in all three peer groups reported fewer measures in the Timely and

Effective Care measure group. The measurement periods for VHA and non-VHA hospitals were the same, except for the HAI-1, HAI-2, PSI 04, PSI 90, and OP-22 measures. The specific performance periods for these measures were provided to VHA hospitals during the internal analysis. The reasons for the differing measure reporting periods are:

- The HAI-1 and HAI-2 measures were first publicly reported for VHA hospitals in July 2021, but only included one quarter of measure data. Therefore, we chose to use the next public reporting, April 2022, which included four quarters of these measures' data.
- For the PSI 04 and PSI 90 measures, we used measure data that was publicly reported in July 2021. VHA hospitals first publicly reported these measures in October 2020; however, a different software was used for the measure calculations than the software used to calculate subsection (d) hospitals and CAHs measure data. We chose to use measure data publicly reported in 2021 for better comparison.
- For the OP-22 measure, VHA hospitals began submitting their measure data in January 2021 for public reporting.
- For the HIP/KNEE measures (total hip arthroplasty (THA) and total knee arthroplasty (TKA)), we used measure data that was publicly reported in October 2020. This data did not initially include VHA hospitals, so we recalculated to include them. The recalculated results including VHA hospitals was not publicly reported until July 2021.

Using these data from the internal analysis, we compared 2021 Overall Hospital Quality Star Ratings scores for non-VHA hospitals before and after adding VHA hospitals to Overall Hospital Quality Star Ratings. 119 out of 171 VHA hospitals met the requirements to receive a Star Rating. This increased the number of hospitals receiving a star rating from 3,355 to 3,474. The distribution of Star Ratings was nearly identical for VHA and non-VHA hospitals. As part of the Overall Hospital Quality Star Ratings methodology, hospitals are assigned to peer groups based on the number of measure groups with at least three measures. Peer group assignments were similar across VHA and non-VHA hospitals. In Peer Group 3, assignments were 12

percent VHA vs. 10 percent non-VHA; in Peer Group 4, assignments were 25 percent VHA vs. 16 percent non-VHA; and in Peer Group 5, assignments were 63 percent VHA vs. 74 percent non-VHA). 3,119 (93 percent) non-VHA hospitals maintained the same number of stars after adding VHA hospitals to 2021 Overall Hospital Quality Star Ratings. For the 236 non-VHA hospitals with a different star rating, 23 gained a star and 213 lost a star. No hospital gained or lost more than one star. As with any update to either the underlying measures or the Overall Hospital Quality Star Ratings methodology, we expect that some hospitals would shift star rating categories. However, for this internal analysis, over 90 percent of non-VHA hospitals did not experience a change in their Overall Hospital Quality Star Ratings score, which is consistent with prior changes to the measures or methodology in our experience. As previously finalized, we intend to include VHA hospitals in future Overall Hospital Quality Star Ratings.

C. Frequency of Publication and Data Used

We are also proposing to amend our policy regarding the data periods used to refresh Overall Hospital Quality Star Ratings. In the CY 2021 OPPS final rule with comment period, we stated that "we would use publicly available measure results on Hospital Compare or its successor websites from a quarter within the prior year" to refresh Overall Hospital Quality Star Ratings (85 FR 86202). Since adopting that policy, it has come to our attention that this wording could be confusing. We intended for the phrase "within the prior year" to refer to any time within the prior 12 months, and not to a Care Compare refresh from the prior calendar year. Therefore, we are proposing to change § 412.190 (c) to state "The Overall Star Rating are published once annually using data publicly reported on Hospital Compare or its successor website from a quarter within the previous 12 months." For example, for the Overall Hospital Quality Star Ratings in July 2023, we would use any Care Compare refreshes from the previous 12 months: July 2023, April 2023, January 2022, October 2022, or July 2022.

We invite public comments on this proposal.

D. Overall Hospital Quality Star Ratings Suppression

During development of the Overall Hospital Quality Star Ratings, we established guiding principles to use methods that are scientifically valid, inclusive of hospitals and measure information, account for the heterogeneity of available measures and hospital reporting, and accommodate changes in the underlying measures (85 FR 86193).³⁵² Overall Hospital Quality Star Ratings aggregates performance on underlying measures adopted under certain CMS quality programs, so any changes or updates to the measures from those programs are already included (85 FR 86194).³⁵³ We continue to believe that the robustness of Overall Hospital Quality Star Ratings to changes in the underlying measures enables the methodology to maintain validity even when there are changes in the health system or underlying measure data (85 FR 86203 through 86205).

We recognize that there may be some concerns with publishing Overall Hospital Quality Star Ratings if the underlying measures reflect some aspect of extenuating circumstances, for example, skewed data or performance related to treating patients with COVID-19. However, we want to balance that with providing important quality information to Medicare beneficiaries and the public during times when hospital care is critical. The goal of the Overall Hospital Quality Star Ratings is to summarize hospital quality information in a way that is simple and easy for patients to understand to increase transparency and empower patients to make more informed decisions about their healthcare.

Although Overall Hospital Quality Star Ratings will have been refreshed twice (i.e., in 2021 and 2022) since the emergence of COVID-19, almost all measures included in both Overall

³⁵² Centers for Medicare & Medicaid Services. (2017, December). Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0). Retrieved from www.qualitynet.org: <https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab1>.

³⁵³ Centers for Medicare & Medicaid Services. (2017, November). Star Methodology Enhancement for December 2017 Public Release. Retrieved from www.qualitynet.org: <https://qualitynet.org/outpatient/public-reporting/overall-ratings/resources>.

Hospital Quality Star Ratings refreshes used pre-COVID-19 data to calculate both the 2021 and 2022 Overall Star Ratings. This is because we issued a nationwide Extraordinary Circumstance Exception (ECE) for hospitals and other facilities participating in our quality reporting and value-based purchasing programs in response to the COVID–19 Public Health Emergency (PHE). The ECE can be found at this website: <https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf>. Among other requirements, this ECE exempted data reporting requirements for Q1 and Q2 2020 data, including excluding the use of claims data and data collected through the Centers for Disease Control’s (CDC) National Healthcare Safety Network (NHSN) for this data period.³⁵⁴ Because the ECE only applied through Q2 2020, beginning July 1, 2020, any subsequent measure data collected from these programs would be incorporated into the Overall Hospital Quality Star Ratings. This would include measurement periods that are either partially or fully concurrent with the COVID-19 PHE.

If a measure is considered valid and reliable enough to be reported on Care Compare then it meets the criteria to be included in Overall Hospital Quality Star Ratings calculations (85 FR 86193 through 86236). This remains true even for measures that were suppressed in certain programs due to the impact of COVID-19 (86 FR 45301 through 45304). Consistent with this policy, we will continue to include measures in the Overall Hospital Quality Star Ratings that might have been suppressed in the Hospital Value-Based Purchasing, Hospital-Acquired Condition Reduction, and Hospital Readmissions Reduction Programs but are still publicly reported (86 FR 44778 through 44779).

³⁵⁴ CMS, Exceptions and Extensions for Quality Reporting Requirements for Acute Care Hospitals, PPS-Exempt Cancer Hospitals, Inpatient Psychiatric Facilities, Skilled Nursing Facilities, Home Health Agencies, Hospices, Inpatient Rehabilitation Facilities, Long-Term Care Hospitals, Ambulatory Surgical Centers, Renal Dialysis Facilities, and MIPS Eligible Clinicians Affected by COVID–19 (Mar. 27, 2020), <https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf>

In the CY 2021 OPPTS/ASC rule with comment period (85 FR 48996 through 49027), we finalized that we will allow for suppression, but only in limited circumstances. Specifically, for the Overall Hospital Quality Star Rating beginning with the CY 2021 and for subsequent years, we adopted a policy that we would consider suppressing the Overall Star Rating only under extenuating circumstances that affect numerous hospitals (as in, not an individualized or localized issue) as determined by CMS or when CMS is at fault, including but not limited to when--

- There is an Overall Star Rating calculation error by CMS;
- There is a systemic error at the CMS quality program level that substantively affects the Overall Hospital Star Rating calculation. For example, there is a CMS quality program level error for one or more measures included within the Overall Star Rating due to incorrect data processing or measure calculations that affects a substantial number of hospitals reporting those measures. We note that we would strive to first correct systemic errors at the program level per program policies and then recalculate the Overall Star Rating, if possible; or
- A Public Health Emergency substantially affects the underlying measure data.

This is codified at §412.190(f)(1). Although CMS intends to publish the Overall Hospital Quality Star Rating in 2023, CMS may exercise the authority described above should the COVID-19 PHE substantially affect the underlying measure data.

XXII. Files Available to the Public via the Internet

The Addenda to the OPPTS/ASC proposed rules and the final rules with comment period are published and available via the Internet on the CMS website. In the CY 2019 OPPTS/ASC final rule with comment period (83 FR 59154), for CY 2019, we changed the format of the OPPTS Addenda A, B, and C, by adding a column titled “Copayment Capped at the Inpatient Deductible of \$1,364.00” where we flag, through use of an asterisk, those items and services with a copayment that is equal to or greater than the inpatient hospital deductible amount for any given year (the copayment amount for a procedure performed in a year cannot exceed the amount of

the inpatient hospital deductible established under section 1813(b) of the Act for that year). For CY 2023, we propose to retain these columns, updated to reflect the amount of the 2023 inpatient deductible. In the CY 2022 OPPS/ASC final rule with comment period (85 FR 86266), we updated the format of the OPPS Addenda A, B, and C by adding a column titled “Drug Pass-Through Expiration during Calendar Year” where we flagged through the use of an asterisk, each drug for which pass-through payment was expiring during the calendar year on a date other than December 31. For CY 2023, we propose to retain these columns that are updated to reflect the drug codes for which pass-through payment is expiring in CY 2023.

In addition, for CY 2023, we propose to update a column titled “Drug Pass-Through Expiration during Calendar Year” to include devices, so that the column reads “Drug and Device Pass-Through Expiration during Calendar Year” where we propose to flag through the use of an asterisk, each drug and device for which pass-through payment would be expiring during the calendar year on a date other than December 31.

To view the Addenda to this proposed rule pertaining to proposed CY 2023 payments under the OPPS, we refer readers to the CMS website at:

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html>; select

“CMS-1772-P” from the list of regulations. All OPPS Addenda to this proposed rule are contained in the zipped folder titled “2023 NPRM OPPS Addenda” in the related links section at the bottom of the page. To view the Addenda to this proposed rule pertaining to CY 2023 payments under the ASC payment system, we refer readers to the CMS website at:

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices.html>; select “CMS-1772-P” from the list of regulations. The ASC

Addenda to this proposed rule are contained in a zipped folder titled “Addendum AA, BB, DD1, DD2, EE, and FF” in the related links section at the bottom of the page.

XXIII. Collection of Information Requirements

A. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of title 44 of the U.S. Code, as added by section 2 of the Paperwork Reduction Act of 1995, requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

B. ICRs for the Hospital OQR Program

1. Background

The Hospital Outpatient Quality Reporting (OQR) Program is generally aligned with the CMS quality reporting program for hospital inpatient services known as the Hospital Inpatient Quality Reporting (IQR) Program. We refer readers to the CY 2011 through CY 2022 OPSS/ASC final rules (75 FR 72111 through 72114; 76 FR 74549 through 74554; 77 FR 68527 through 68532; 78 FR 75170 through 75172; 79 FR 67012 through 67015; 80 FR 70580 through 70582; 81 FR 79862 through 79863; 82 FR 59476 through 59479; 83 FR 59155 through 59156; 84 FR 61468 through 61469; 85 FR 86266 through 86267; and 86 FR 63961 through 63968, respectively) for detailed discussions of the previously finalized Hospital OQR Program ICRs.

The ICRs associated with the Hospital OQR Program are currently approved under OMB control number 0938-1109, which expires on February 28, 2025.

In the CY 2022 OPPTS/ASC final rule with comment period, our burden estimates were based on an assumption of 3,300 hospitals (86 FR 63961). For this proposed rule, we propose to update our assumption to 3,350 hospitals based on recent data from the CY 2022 payment determination which reflects a closer approximation of the total number of hospitals reporting data for the Hospital OQR Program.

In the CY 2018 OPPTS/ASC final rule with comment period (82 FR 52617), we finalized a proposal to utilize the median hourly wage rate for Medical Records and Health Information Technicians, in accordance with the Bureau of Labor Statistics (BLS), to calculate our burden estimates for the Hospital OQR Program. In BLS' most recent set of National Occupational Employment and Wage Estimates published on March 31, 2022, this occupation title has been removed. As a result, we now utilize the "Medical Records Specialists" occupation title. The BLS describes Medical Records Specialists as those responsible for compiling, processing, and maintaining medical records of hospital and clinic patients in a manner consistent with medical, administrative, ethical, legal, and regulatory requirements of the healthcare system and classifying medical and healthcare concepts, including diagnosis, procedures, medical services, and equipment, into the healthcare industry's numerical coding system³⁵⁵; therefore, we believe it is reasonable to assume that these individuals will be tasked with abstracting clinical data for submission to the Hospital OQR Program. The latest data from the BLS' May 2021 Occupational Employment and Wages data reflects a median hourly wage of \$23.23 per hour for a Medical Records Specialists. We have finalized a policy to calculate the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage (82 FR 52617). This is

³⁵⁵ <https://www.bls.gov/oes/current/oes292072.htm> (Accessed June 23, 2022). The hourly rate of \$46.46 includes an adjustment of 100 percent of the median hourly wage to account for the cost of overhead, including fringe benefits.

necessarily a rough adjustment, both because fringe benefits and overhead costs can vary significantly from employer-to-employer and because methods of estimating these costs vary widely from study-to-study. Nonetheless, we believe that doubling the hourly wage rate ($\$23.23 \times 2 = \46.46) to estimate the total cost is a reasonably accurate estimation method and allows for a conservative estimate of hourly costs.

2. Summary

In section XV.B.4 of this proposed rule, we propose to: (1) change the Cataracts: Improvement in Patient's Visual Function within 90 days Following Cataract Surgery measure (OP-31) to voluntary beginning with the CY 2025 reporting period/CY 2027 payment determination; (2) add an additional targeting criterion to the validation selection policy beginning with the CY 2023 reporting period; and (3) align the patient encounter quarters with the calendar year and update the data submission deadlines for each of these quarters beginning with the Q2 2023 reporting period.

3. Estimated Burden of Hospital OQR Program Requirements for the CY 2025 Payment Determination and Subsequent Years

a. Information Collection Burden Estimate for OP-31: Cataracts – Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery Measure

In the CY 2022 OPSS/ASC final rule with comment period (86 FR 63845 through 63846), we finalized to require this measure with mandatory reporting beginning with the CY 2025 reporting period/CY 2027 payment determination. We previously finalized voluntary reporting of this measure in the CY 2015 OPSS/ASC final rule with comment period (79 FR 66947 through 66948) and estimated that 20 percent of hospitals would elect to report it annually (79 FR 67014). As discussed in section XV.B.5.b of this proposed rule, we propose to change this measure to voluntary beginning with the CY 2025 reporting period/CY 2027 payment determination. We continue to estimate it will require hospitals 10 minutes once annually to report this measure using a CMS web-based tool. As a result of this proposal, we

estimate only 20 percent of hospitals would voluntarily submit data, which results in a total annual burden estimate of 112 hours (3,350 hospitals x 20 percent x 0.1667 hours) at a cost of \$5,188 (112 hours × \$46.46/hour). In addition to reporting the measure, for hospitals that chose to voluntarily submit, we also require hospitals to perform chart abstraction and estimate that each hospital would spend 2.92 minutes (0.049 hours) per case per measure to perform this activity. In the CY 2022 OPPS/ASC final rule with comment period, we used an estimate of 25 minutes per case per measure (86 FR 63963). Upon review, this estimate was erroneous, therefore we are correcting our assumption to 2.92 minutes (0.049 hours) per case per measure as finalized in the CY 2016 OPPS/ASC final rule (80 FR 70582). The currently approved burden estimate assumes 242 cases per measure. For chart abstraction, we estimate an annual burden of 12 hours (0.049 hours × 242 cases) at a cost of \$549 (12 hours × \$46.46/hour) per hospital and a total annual burden of 7,891 hours (3,350 hospitals x 20 percent x 12 hours) at a cost of \$368,028 (7,891 hours × \$46.46/hour) for all participating hospitals. In aggregate, we estimate a total annual burden of 8,003 hours (112 hours + 7,891 hours) at a cost of \$373,216 (\$5,188 + \$368,028) for all hospitals. This is a decrease of 325,847 hours and \$15,138,852 per year from the currently approved estimate due to the 80 percent of hospitals we assume will no longer report this measure, the updated assumption of the number of hospitals participating in the Hospital OQR Program, the updated burden estimate for chart abstraction, and the updated wage rate.

The information collection requirement and the associated burden will be submitted as part of a revision of the information collection request currently approved under OMB control number 0938–1109, which expires on February 28, 2025.

b. Information Collection Burden Estimate for the Addition of an Additional Targeting Criterion to the Validation Selection Policy

In section XV.B.4 of this proposed rule, we propose to adopt an additional targeting criterion to the validation selection policy beginning with the CY 2023 reporting period/CY 2025

payment determination. We also propose to codify this targeting criterion at § 419.46(f)(3). We do not believe this proposal would increase reporting burden, because it changes neither the total number of hospitals required to submit data nor the amount of data hospitals selected for validation would be required to submit.

c. Information Collection Burden Estimate for the Alignment of Patient Encounter Quarters with the Calendar Year

In section XV.B.4.b of this proposed rule, we propose to align patient encounter quarters with the calendar year (January through December), beginning with the CY 2026 payment determination and subsequent years. We do not anticipate that this proposal, if finalized, would result in any increase in information collection burden because it would not change the amount of data hospitals would be required to submit.

d. Summary of Information Collection Burden Estimates for the Hospital OQR Program

In summary, under OMB control number 0938–1109 which expires on February 28, 2025 we estimate that the updated assumptions and proposals in this proposed rule will result in a decrease of 325,847 hours annually for 3,350 OPSS hospitals for the CY 2025 reporting period/CY 2027 payment determination and subsequent years. The total cost decrease related to this information collection is approximately -\$15,138,852 (325,847 hours × \$46.46/hour) (which also reflects use of an updated hourly wage rate as previously discussed). Table 81 summarizes the estimated total burden change compared to our currently approved information collection burden estimates. We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–1109. We are not proposing any changes for the CY

2024 reporting period/CY 2026 payment determination, therefore the previously finalized burden estimates for the CY 2024 reporting period/CY 2026 payment determination remain unchanged.

TABLE 81: SUMMARY OF PROPOSED ESTIMATED HOSPITAL OQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2025 REPORTING PERIOD/CY 2027 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2027 Payment Determination and Subsequent Years								
Activity	Estimated time per record (minutes)	Number reporting quarters per year	Number of OPPS hospitals reporting	Average number records per hospital per quarter	Annual burden (hours) per hospital	Proposed annual burden (hours) across OPPS hospitals	Previously finalized annual burden (hours) across OPPS hospitals	Net difference in annual burden hours
Voluntary Reporting of OP-31 Measure	10	1	670	1	0.167	112	550	-438
Chart Abstraction for OP-31 Measure	2.9	1	670	242	12	7,891	333,300	-325,409
Total Change in Information Collection Burden Hours: -325,847								
Total Cost Estimate: Updated Hourly Wage (\$46.46) x Change in Burden Hours (-325,847) = -\$15,138,852								

C. ICRs for the ASCQR Program

1. Background

We refer readers to the CY 2012 OPPS/ASC final rule (76 FR 74554), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53672), and the CY 2013, CY 2014, CY 2015, CY 2016, CY 2017, CY 2018, CY 2019, CY 2020, CY 2021, and CY 2022 OPPS/ASC final rules (77 FR 68532 through 68533; 78 FR 75172 through 75174; 79 FR 67015 through 67016; 80 FR 70582 through 70584; 81 FR 79863 through 79865; 82 FR 59479 through 59481; 83 FR 59156 through 59157; 84 FR 61469; 85 FR 86267; and 86 FR 63968 through 63971, respectively) for detailed discussions of the Ambulatory Surgical Center Quality Reporting (ASCQR) Program ICRs we have previously finalized. The ICRs associated with the ASCQR Program for the CY 2014 through CY 2023 payment determinations are currently approved under OMB control number 0938-1270, which expires on July 31, 2024.

In the CY 2018 OPPTS/ASC final rule with comment period (82 FR 52619 through 52620), we finalized a proposal to utilize the median hourly wage rate for Medical Records and Health Information Technicians, in accordance with the BLS, to calculate our burden estimates for the ASCQR Program. In BLS' most recent set of National Occupational Employment and Wage Estimates published on March 31, 2022, this occupation title has been removed. As a result, we now utilize the "Medical Records Specialists" occupation title. The BLS describes Medical Records Specialists as those responsible for compiling, processing, and maintaining medical records of hospital and clinic patients in a manner consistent with medical, administrative, ethical, legal, and regulatory requirements of the healthcare system and classifying medical and healthcare concepts, including diagnosis, procedures, medical services, and equipment, into the healthcare industry's numerical coding system³⁵⁶; therefore, we believe it is reasonable to assume that these individuals will be tasked with abstracting clinical data for submission to the ASCQR Program. The latest data from the BLS' May 2021 Occupational Employment and Wages data reflects a median hourly wage of \$23.23 per hour for a Medical Records Specialists. We have finalized a policy to calculate the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage (82 FR 52619 through 52620). This by necessity is a rough adjustment, both because fringe benefits and overhead costs can vary significantly from employer-to-employer and because methods of estimating these costs vary widely from study-to-study. Nonetheless, we believe that doubling the hourly wage rate ($\$23.23 \times 2 = \46.46) to estimate the total cost is a reasonably accurate estimation method and allows for a conservative estimate of hourly costs.

Based on an analysis of the CY 2020 payment determination data, we found that of the 6,651 ASCs that met eligibility requirements for the ASCQR Program, 3,494 were required to

³⁵⁶ <https://www.bls.gov/oes/current/oes292072.htm> (Accessed June 23, 2022). The hourly rate of \$42.40 includes an adjustment of 100 percent of the median hourly wage to account for the cost of overhead, including fringe benefits.

participate in the Program and did so. In addition, 689 ASCs that were not required to participate due to having low Medicare claims volume (less than 240), did so, for a total of 4,183 participating facilities. As noted in section XXV.C.5.a of the “Regulatory Impact Analysis” of this proposed rule, for the CY 2021 payment determination, all 6,811 ASCs that met eligibility requirements for the ASCQR Program received the annual payment update due to data submission requirements being excepted under the ASCQR Program’s ECE policy in consideration of the COVID-19 PHE; 3,957 of these ASCs would have been required to participate without the PHE exception. Therefore, we estimate that 3,957 plus 689, or 4,646, ASCs will submit data for the ASCQR Program for the CY 2023 payment determination unless otherwise noted.

2. Summary

In section XV.B.4 of this proposed rule, we propose to change the Cataracts: Improvement in Patient’s Visual Function within 90 days Following Cataract Surgery measure (ASC-11) to voluntary beginning with the CY 2025 reporting period/CY 2027 payment determination.

3. Estimated Burden of ASCQR Program Requirements for the CY 2025 Payment Determination and Subsequent Years

a. Information Collection Burden Estimate for Proposal to Change ASC-11: Cataracts – Improvement in Patient’s Visual Function Within 90 Days Following Cataract Surgery Measure from Mandatory to Voluntary

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63886 through 63887), we finalized to require this measure with mandatory reporting beginning with the CY 2025 reporting period/CY 2027 payment determination. We previously finalized voluntary reporting of this measure in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66985) and estimated that 20 percent of ASCs would elect to report it annually (79 FR 67016). As discussed in section XV.B.5.b of this proposed rule, we propose to change

the ASC-11 measure to voluntary beginning with the CY 2025 reporting period/CY 2027 payment determination. We continue to estimate it will require ASCs 10 minutes once annually to report this measure using a CMS web-based tool. As a result of this proposal, we estimate only 20 percent of ASCs would voluntarily submit data, which results in a total annual burden estimate for all participating ASCs of 155 hours (4,646 ASCs x 20 percent x 0.1667 hours) at a cost of \$7,194 (115 hours × \$46.46/hour). In addition to reporting the measure, for ASCs that chose to voluntarily submit, we also require ASCs to perform chart abstraction for a minimum required sample size of 63 cases. In the CY 2022 OPPS/ASC final rule, we estimated that each ASC would spend 15 minutes (0.25 hours) per case to perform this activity (86 FR 63969). However, upon review, we believe the effort involved with this activity is similar to what is required for the OP-31 measure in the Hospital OQR Program, therefore, we are updating our assumption to 2.92 minutes (0.049 hours) per case per measure. Therefore, we estimate an annual burden of 3.1 hours (0.049 hours × 63 cases) at a cost of \$142 (3.1 hours × \$46.46/ hour) per ASC and a total annual burden of 2,848 hours (4,646 ASCs x 20 percent x 3.1 hours) at a cost of \$132,333 (2,848 hours × \$46.46/hour) for all participating ASCs. In aggregate, we estimate a total annual burden of 3,003 hours (155 hours + 2,848 hours) at a cost of \$139,527 (\$7,194 + \$132,333) for all ASCs. This is a decrease of 72,107 hours and \$3,350,091 per year from the currently approved estimate due to the 80 percent of ASCs we assume would no longer report this measure, the updated burden estimate per case per measure, and the updated wage rate.

b. Summary of Information Collection Burden Estimates for the ASCQR Program

In summary, under OMB control number 0938-1270 which expires on July 31, 2024, we estimate that the policies promulgated in this proposed rule would result in a decrease of 72,107 hours annually for 4,646 ASCs for the CY 2025 reporting period/CY 2027 payment determination and subsequent years. The total cost decrease related to this information collection is approximately \$3,350,091 (72,107 hours × \$46.46/hour). Table 82 summarizes the

total burden change compared to our currently approved information collection burden estimates.

We will submit the revised information collection estimates to OMB for approval under OMB control number 0938-1270.

TABLE 82: SUMMARY OF PROPOSED ESTIMATED ASCQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2025 REPORTING PERIOD/CY 2027 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1270 for the CY 2025 Payment Determination and Subsequent Years								
Activity	Estimated time per record (minutes)	Number reporting quarters per year	Number of ASCs reporting	Average number records per ASC per quarter	Annual burden (hours) per ASC	Proposed annual burden (hours) across ASCs	Previously finalized annual burden (hours) across ASCs	Net difference in annual burden hours
Voluntary Reporting of ASC-11 Measure	10	1	929	1	0.167	155	774	-619
Chart Abstraction for ASC-11 Measure	2.9	1	929	63	3.1	2,848	74,336	-71,488
Total Change in Information Collection Burden Hours: -72,107								
Total Cost Estimate: Updated Hourly Wage (\$46.46) x Change in Burden Hours (-72,107) = -\$3,350,091								

D. ICRs for Rural Emergency Hospitals (REH) Physician Self-Referral Law Update

As discussed in section XVIII.E of this proposed rule, we propose to revise certain existing exceptions applicable to compensation arrangements involving specific types of providers to make them applicable to compensation arrangements to which an REH is a party. Specifically, we propose to revise the exceptions for physician recruitment at § 411.357(e), obstetrical malpractice insurance subsidies at § 411.357(r), retention payments in underserved areas at § 411.357(t), electronic prescribing items and services at § 411.357(v), assistance to compensate a nonphysician practitioner at § 411.357(x), and timeshare arrangements at § 411.357(y) to also permit an REH to provide remuneration to a physician (or an immediate family member of a physician) if all requirements of the applicable exception are satisfied. All

of the proposed revisions would ensure that exceptions that may already be utilized by existing hospitals eligible to undergo conversion to an REH remain available to REHs.

The existing exceptions at § 411.357(e), (r), (t), (v), (x), and (y) each require that the compensation arrangements to which the exceptions apply be documented in a writing signed by the parties. The existing exception at § 411.357(t)(2) also requires a written certification that the physician has a *bona fide* opportunity for future employment by a hospital, academic medical center, or physician organization that requires the physician to move the location of his or her medical practice at least 25 miles and outside the geographic area served by the hospital. The existing exception at § 411.357(x) also requires that records of the actual amount of remuneration provided by the hospital to the physician, and by the physician to the nonphysician practitioner, must be maintained for a period of at least 6 years. We are not proposing any changes to the existing writing, signature, or record retention requirements. The burden associated with writing and signature requirements would be the time and effort necessary to prepare written documents and obtain signatures of the parties. The burden associated with record retention requirements would be the time and effort necessary to compile and store the records.

While the writing, signature, and record retention requirements are subject to the PRA, we believe the associated burden is exempt under 5 CFR 1320.3(b)(2). We believe that the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons without Federal regulation during the normal course of their activities. Specifically, we believe that, for normal business operations purposes, health care providers and suppliers document their financial arrangements with physicians and others and retain these documents in order to identify and be able to enforce the legal obligations of the parties. Therefore, we believe that the writing, signature, and record retention requirements should be considered usual and customary business practices.

E. ICRs for Addition of a New Service Category for Hospital Outpatient Department (OPD)

Prior Authorization Process

In the CY 2020 OPPS/ASC final rule with comment period, we established a prior authorization process for certain hospital OPD services using our authority under section 1833(t)(2)(F) of the Act, which allows the Secretary to develop a method for controlling unnecessary increases in the volume of covered OPD services. (84 FR 61142, 61446 through 61456).³⁵⁷ As part of the CY 2021 OPPS/ASC final rule with comment period we added additional service categories to the prior authorization process (85 FR 85866, 86236 through 86248). The regulations governing the prior authorization process are located in subpart I of 42 CFR part 419, specifically at §§ 419.80 through 419.89.

In accordance with § 419.83(b), we propose to require prior authorization for a new service category: Facet Joint Interventions. We propose adding the service category to § 419.83(a)(3). We also propose that the prior authorization process for the additional service category would be effective for dates of services on or after March 1, 2023. The ICR associated with prior authorization requests for these covered outpatient department services is the required documentation submitted by providers. The prior authorization request must include all relevant documentation necessary to show that the service meets applicable Medicare coverage, coding, and payment rules and the request must be submitted before the service is provided to the beneficiary and before the claim is submitted for processing.

The burden associated with the prior authorization process for the new category, Facet Joint Interventions, will be the time and effort necessary for the submitter to locate and obtain the relevant supporting documentation to show that the service meets applicable coverage, coding, and payment rules, and to forward the information to CMS or its contractor (MAC) for review and determination of a provisional affirmation. We expect that this information will

³⁵⁷ See also Correction Notice issued January 3, 2020 (85 FR 224).

generally be maintained by providers within the normal course of business and that this information will be readily available. We estimate that the average time for office clerical activities associated with this task will be 30 minutes, which is equivalent to that for normal prepayment or post payment medical review. We anticipate that most prior authorization requests will be sent by means other than mail. However, we estimate a cost of \$5 per request for mailing medical records. Due to the proposed March 1, 2023 start date, the first year of the prior authorization for the new service category would only include 10 months. Based on CY 2019 data, we estimate that for those first 10 months there would be 69,501 initial requests mailed during the year. In addition, we estimate there would be 22,805 resubmissions of a request mailed following a non-affirmed decision. Therefore, the total mailing cost is estimated to be \$461,532 (92,306 mailed requests x \$5). Based on CY 2019 data for the new service category, we estimate that annually there would be 83,401 initial requests mailed during a year. In addition, we estimate there would be 27,366 resubmissions of a request mailed following a non-affirmed decision. Therefore, the total annual mailing cost is estimated to be \$553,838 (110,786 mailed requests x \$5). We also estimate that an additional 3 hours per provider would be required for attending educational meetings, training staff on what services require prior authorization, and reviewing training documents.

The average labor costs (including 100 percent fringe benefits) used to estimate the costs were calculated using data available from the Bureau of Labor Statistics (BLS). Based on the BLS information, we estimate an average clerical hourly rate of \$17.13 with a loaded rate of \$34.26. The prior authorization program for the new service category would not create any new documentation or administrative requirements. Instead, it would just require the same documents needed to support claim payments to be submitted earlier in the claim process. The estimate uses the clerical rate since we do not believe that clinical staff would need to spend more time on completing the documentation than would be needed in the absence of the prior authorization policy. The hourly rate reflects the time needed for the additional clerical work of

submitting the prior authorization request itself. CMS believes providers would have provided education to their staff on what services are included in the prior authorization process.

Following this education, the staff would know which services need prior authorization and would not need additional time or resources to determine if a service requires prior authorization. We estimate that the total number of submissions for the first year (10 months) will be 307,688 (215,382 submissions through fax or electronic means + 92,306 mailed submissions). Therefore, we estimate that the total burden for the first year (10 months) for the new service category, allotted across all providers, would be 161,305 hours (.5 hours x 307,688 submissions plus 3 hours x 2,487 providers for education). The burden cost for the first year (10 months) is \$5,987,841 (161,305 hours x \$34.26 plus \$461,532 for mailing costs). In addition, we estimate that the total annual number of submissions would be 369,225 (258,458 submissions through fax or electronic means + 110,768 mailed submissions). The annual burden hours for the new service category, allotted across all providers, would be 192,074 hours (.5 hours x 369,225 submissions plus 3 hours x 2,487 providers for education). The annual burden cost would be \$7,134,276 (192,074 hours x \$34.26 plus \$553,838 for mailing costs). For the total burden and associated costs for the new service category, we estimate the annualized burden to be 181,818 hours and \$6,752,131 million. The annualized burden is based on an average of 3 years, that is, 1 year at the 10-month burden and 2 years at the 12-month burden. The ICR approved under OMB control number 0938-1368 would be revised and submitted to OMB for approval.

Table 83 below is a chart reflecting the total burden and associated costs for the provisions included in this proposed rule.

TABLE 83: TOTAL BURDEN FOR NEW SERVICE CATEGORY

Information Collection Requests	Burden Hours Increase/Decrease (+/-)*	Cost (+/-)*
Addition of a New Service Category for Hospital Outpatient Department (OPD) Prior Authorization Process	+181,818	+\$6.8 million

* Numbers rounded.

F. ICRs for Proposed Payment Adjustments for Domestic NIOSH-Approved Surgical N95

Respirators

In section X.H of this proposed rule, we propose IPPS and OPSS payment adjustments for the additional resource costs of domestic NIOSH-approved surgical N95 respirators for cost reporting periods beginning on or after January 1, 2023. The proposed payment adjustments would be based on the IPPS and OPSS shares of the estimated difference in the reasonable costs of a hospital to purchase domestic NIOSH-approved surgical N95 respirators compared to non-domestic ones. As discussed in section X.H of this proposed rule, in order to calculate the N95 payment adjustment for each eligible cost reporting period, we propose to create a new cost report form to collect additional information from hospitals.

Specifically, we propose to collect the following: (1) total quantity of domestic NIOSH-approved surgical N95 respirators purchased by hospital; (2) total aggregate cost of domestic NIOSH-approved surgical N95 respirators purchased by hospital; (3) total quantity of non-domestic NIOSH-approved surgical N95 respirators purchased by hospital; and (4) total aggregate cost of non-domestic NIOSH-approved surgical N95 respirators purchased by hospital. This information would be used along with other information already collected on the cost report to calculate an IPPS payment adjustment amount and an OPSS payment adjustment amount. This new cost report worksheet may be submitted by a provider of service as part of the annual filing of the cost report and make available to its contractor and CMS, documentation to substantiate the data included on this Medicare cost report worksheet. These proposed documentation requirements are based on the recordkeeping requirements at current § 413.20, which require providers of services to maintain sufficient financial records and statistical data for proper determination of costs payable under Medicare.

The burden associated with this proposal would be the time and effort necessary for the provider to locate and obtain the relevant supporting documentation to report the quantity and

aggregate costs of domestic NIOSH-approved surgical N95 respirators and non-domestic NIOSH-approved surgical N95 respirators purchased by hospital for the period.

G. ICRs for Proposed REH Provider Enrollment Requirements

As stated earlier in section XIX.C.1 of this proposed rule, proposed § 424.575, as well as existing § 424.510(a)(1) and (d)(1), would require REHs to complete and submit the applicable enrollment application, which, for REHs, would be the Form CMS-855A (OMB control number 0938-0685). The only impacts associated with our proposed REH enrollment policies are those concerning the submission of a Form CMS-855A change of information application to convert from a CAH or hospital (as defined in section 1886(d)(1)(B) of the Act) to an REH. Per a North Carolina Rural Health Research Program³⁵⁸ study (and as stated in the CMS proposed rule titled “Medicare and Medicaid Programs; Conditions of Participation (CoPs) for Rural Emergency Hospitals (REHs) and Critical Access Hospital CoP Updates,” published in the **Federal Register** on July 6, 2022 (87 FR 40350), we estimate that 68 REHs would convert from either a CAH or section 1886(d)(1)(B) hospital. (However, as we did in the aforementioned July 6, 2022 proposed rule, we acknowledge that the number of conversions could be less than or significantly greater than this estimate.) For purposes of these calculations, we assume that all of these facilities would do so within the first year of our proposed requirements.

Form CMS-855A applications are typically completed by the provider’s office or administrative staff. According to the most recent BLS wage data for May 2021, the mean hourly wage for the general category of “Office and Administrative Support Workers, All Other” (the most appropriate BLS category for owners) is \$20.47 (*see* http://www.bls.gov/oes/current/oes_nat.htm#43-0000). With fringe benefits and overhead, the figure is \$40.94. This would result in an estimated Year 1 burden involving proposed § 424.575 of 68 hours (68 applications x 1 hour) at a cost of \$2,784. Over a 3-year period, this results in an annual burden of 23 hours at a cost of \$928.

³⁵⁸ <https://www.shepscenter.unc.edu/product/how-many-hospitals-might-convert-to-a-rural-emergency-hospital-reh/>.

The burden associated with this proposed requirement will be included as part of a resubmission of the information collection previously approved under 0938-0685. In addition to the announcement in this rule, we will also be publishing the required 60-day and 30-day notices to formally announce the aforementioned resubmission request and to both inform the public on where to find the revised PRA package for review and where to submit comments.

XXIV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We consider all comments we receive by the date and time specified in the “DATES” section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

XXV. Economic Analyses

A. Statement of Need

This proposed rule is necessary to make updates to the Medicare hospital OPPS rates. It is necessary to make changes to the payment policies and rates for outpatient services furnished by hospitals and CMHCs in CY 2023. We are required under section 1833(t)(3)(C)(ii) of the Act to update annually the OPPS conversion factor used to determine the payment rates for APCs. We also are required under section 1833(t)(9)(A) of the Act to review, not less often than annually, and revise the groups, the relative payment weights, and the wage and other adjustments described in section 1833(t)(2) of the Act. We must review the clinical integrity of payment groups and relative payment weights at least annually. We propose to revise the APC relative payment weights using claims data for services furnished on and after January 1, 2021, through and including December 31, 2021, and processed through December 31, 2021, and June

2020 HCRIS information with cost reporting periods prior to the PHE, as discussed in section X.B of this proposed rule with comment period.

This proposed rule also is necessary to make updates to the ASC payment rates for CY 2023, enabling CMS to make changes to payment policies and payment rates for covered surgical procedures and covered ancillary services that are performed in ASCs in CY 2023. Because ASC payment rates are based on the OPPS relative payment weights for most of the procedures performed in ASCs, the ASC payment rates are updated annually to reflect annual changes to the OPPS relative payment weights. In addition, we are required under section 1833(i)(1) of the Act to review and update the list of surgical procedures that can be performed in an ASC, not less frequently than every 2 years.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59075 through 59079), we finalized a policy to update the ASC payment system rates using the hospital market basket update instead of the CPI-U for CY 2019 through 2023. We believed that this policy would help stabilize the differential between OPPS payments and ASC payments, given that the CPI-U has been generally lower than the hospital market basket, and encourage the migration of services to lower cost settings as clinically appropriate.

In this proposed rule we are also requesting information on possible alternative methodologies for counting organs for transplant hospitals and organ procurement organizations to calculate Medicare's share of organ acquisition costs, but we are not making any proposals at this time. We propose to exclude research organs from total usable organs used in the calculation of Medicare's share of organ acquisition costs and require a cost offset, but we are unable to estimate the extent to which the research organ proposal may impact the cost of research organs and the costs to Medicare. We also propose to clarify that certain costs associated with cardiac death are covered as organ acquisition costs but we do not anticipate an impact from this proposal. Therefore, there is no impact from the organ acquisition proposals in this proposed rule.

B. Overall Impact of Provisions of this Proposed Rule

We have examined the impacts of this proposed rule, as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)). This section of this proposed rule contains the impact and other economic analyses for the provisions we propose for CY 2023.

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) having an annual effect on the economy of \$100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This proposed rule has been designated as an economically significant rule under section 3(f)(1) of Executive Order 12866 and hence also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act).”

Accordingly, this proposed rule has been reviewed by the Office of Management and Budget. We have prepared a regulatory impact analysis that, to the best of our ability, presents the costs and benefits of the provisions of this proposed rule. We are soliciting public comments on the regulatory impact analysis in this proposed rule, and we will address any public comments we receive in the final rule with comment period, as appropriate.

We estimate that the total increase in Federal Government expenditures under the OPSS for CY 2023, compared to CY 2022, due only to the proposed changes to the OPSS in this proposed rule, would be approximately \$1.79 billion. Taking into account our estimated changes in enrollment, utilization, and case-mix for CY 2023, we estimate that the OPSS expenditures, including beneficiary cost-sharing, for CY 2023 would be approximately \$86.2 billion, which is approximately \$6.2 billion higher than estimated OPSS expenditures in CY 2022. Because the provisions of the OPSS are part of a proposed rule that is economically significant, as measured by the threshold of an additional \$100 million in expenditures in 1 year, we have prepared this regulatory impact analysis that, to the best of our ability, presents its costs and benefits. Table 84 of this proposed rule displays the distributional impact of the CY 2023 changes in OPSS payment to various groups of hospitals and for CMHCs.

We note that we formally propose for CY 2023 that drugs and biologicals that are acquired under the 340B Program would be paid at ASP minus 22.5 percent, WAC minus 22.5 percent, or 69.46 percent of AWP, as applicable. The impacts on hospital rates as a result of this formal proposal are reflected in the discussion of the estimated effects of this proposed rule. However, we fully expect to revert to our previous policy of paying ASP plus 6 percent for drugs acquired under the 340B program and anticipate budget neutralizing the increase in payments for these drugs consistent with our longstanding policy of offsetting increases or decreases in particular payments through an adjustment to the OPSS conversion factor.

We estimate that the proposed update to the conversion factor and other budget neutrality adjustments would increase total OPSS payments by 2.7 percent in CY 2023. The proposed

changes to the APC relative payment weights, the proposed changes to the wage indexes, the proposed continuation of a payment adjustment for rural SCHs, including EACHs, the formal proposed continuation of payment policy for separately payable drugs acquired under the 340B program, and the proposed payment adjustment for cancer hospitals would not increase total OPPS payments because these changes to the OPPS are budget neutral. However, these updates would change the distribution of payments within the budget neutral system. We estimate that the total change in payments between CY 2022 and CY 2023, considering all budget-neutral payment adjustments, changes in estimated total outlier payments, pass-through payments, the application of the frontier State wage adjustment, in addition to the application of the OPD fee schedule increase factor after all adjustments required by sections 1833(t)(3)(F), 1833(t)(3)(G), and 1833(t)(17) of the Act, the proposed exception for rural sole community hospitals from the clinic visit policy when provided at off-campus provider based departments, and the proposed payment adjustment for the additional resource costs for domestic NIOSH-approved surgical N95 respirators would increase total estimated OPPS payments by 2.9 percent.

We estimate the total increase (from changes to the ASC provisions in this proposed rule as well as from enrollment, utilization, and case-mix changes) in Medicare expenditures (not including beneficiary cost-sharing) under the ASC payment system for CY 2023 compared to CY 2022, to be approximately \$130 million. Tables 85 and 86 of this proposed rule display the redistributive impact of the CY 2023 changes regarding ASC payments, grouped by specialty area and then grouped by procedures with the greatest ASC expenditures, respectively.

C. Detailed Economic Analyses

1. Estimated Effects of OPPS Changes in This Proposed Rule

a. Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the proposed CY 2023 policy changes on various hospital groups. We post on the CMS website our hospital-specific estimated payments for CY 2023 with the other supporting documentation for

this proposed rule. To view the hospital-specific estimates, we refer readers to the CMS website at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>. At the website, select “regulations and notices” from the left side of the page and then select “CMS-1772-P” from the list of regulations and notices. The hospital-specific file layout and the hospital-specific file are listed with the other supporting documentation for this proposed rule. We show hospital-specific data only for hospitals whose claims were used for modeling the impacts shown in Table 84 of this proposed rule. We do not show hospital-specific impacts for hospitals whose claims we were unable to use. We refer readers to section II.A of this proposed rule for a discussion of the hospitals whose claims we do not use for ratesetting or impact purposes.

We estimate the effects of the individual policy changes by estimating payments per service, while holding all other payment policies constant. We use the best data available, but do not attempt to predict behavioral responses to our policy changes in order to isolate the effects associated with specific policies or updates, but any policy that changes payment could have a behavioral response. In addition, we have not made any adjustments for future changes in variables, such as service volume, service-mix, or number of encounters.

b. Estimated Effects of the Payment Policy for Drugs and Biologicals Obtained under the 340B Program

In section V.B of this proposed rule, we discuss our formal proposal to adjust the payment amount for nonpass-through, separately payable drugs acquired by certain 340B participating hospitals through the 340B Program. Rural SCHs, children’s hospitals, and PPS-exempt cancer hospitals which we propose continue to be excepted from this payment policy in CY 2023. Specifically, in this proposed rule for CY 2023, for hospitals paid under the OPPS (other than those that are proposed to be excepted for CY 2023), we formally propose to pay for separately payable drugs and biologicals that are obtained with a 340B discount, excluding those on pass-through payment status and vaccines, at ASP minus 22.5 percent.

Because we formally propose to continue current Medicare payment policy for CY 2022, the budget neutrality adjustment does not reflect a change as a result of the 340B drug payment policy.

However, in light of the Supreme Court's recent decision in *American Hospital Association*, we fully anticipate reverting to our prior policy of paying for drugs at ASP+6 percent, regardless of whether they were acquired through the 340B program³⁵⁹. We also fully expect that when we revert to paying for drugs acquired through the 340B program at ASP+6 percent, we will budget neutralize that increase consistent with the OPPS statute and our longstanding policy by making a corresponding decrease to the OPPS conversion factor to account for the increase in payment rates for these drugs. As set forth earlier in this proposed rule, to ensure budget neutrality under the OPPS, after applying this alternative payment methodology for drugs and biologicals purchased under the 340B Program, we currently estimate that we would apply an offset of approximately \$1.96 billion to decrease the OPPS conversion factor, which would result in a budget neutrality adjustment of 0.9596 to the OPPS conversion factor, for a revised conversion factor of \$83.279. Accordingly, we have included information with this proposed rule that presents the potential impact on OPPS providers and payment rates if we finalize our anticipated alternative policy to pay for drugs acquired through the 340B program at ASP plus 6 for CY 2023. We are providing a file comparing the budget neutrality and certain other ratesetting adjustments calculated associated with this potential change. Finally, we are making available other proposed rule supporting data files based on this potential change that we ordinarily would have provided if we had had sufficient time to formally propose paying for 340B drugs at ASP plus 6 percent, including: the OPPS impact file, the impact table, addenda, and budget neutrality factors. We refer the reader to the CMS website for this proposed rule for more information on where these supplemental files can be found.

³⁵⁹ Given the timing of the Supreme Court's decision in *American Hospital Ass'n v. Becerra*, we lacked the necessary time to account for that decision before issuing this proposed rule and, for that reason alone, we formally propose here to continue our former policy.

Public comments on the budget neutrality adjustment are welcome and will be carefully considered.

c. Effects of the Proposed IPPS and OPSS Payment Adjustment for Domestic NIOSH-Approved Surgical N95 Respirators

As discussed in section X.H of the preamble of this proposed rule, we propose IPPS and OPSS payment adjustments for the additional resource costs that hospitals incur in procuring domestic NIOSH-approved surgical N95 respirators. We propose that the payment adjustments would commence for cost reporting periods beginning on or after January 1, 2023.

For the IPPS, we propose to make this payment adjustment for the additional resource costs of domestic NIOSH-approved surgical N95 respirators under section 1886(d)(5)(I) of the Act. To further support the strategic policy goal of sustaining a level of supply resilience for domestic NIOSH-approved surgical N95 respirators that is critical to protect the health and safety of personnel and patients in a public health emergency, we are not proposing to make the IPPS payment adjustment budget neutral under the IPPS. The data currently available to calculate a spending estimate for CY 2023 under the IPPS is limited. However, we believe the methodology described next to calculate this spending estimate under the IPPS for CY 2023 is reasonable based on the information available.

To calculate the estimated total spending associated with this policy under the IPPS we multiplied together estimates of the following:

1) Estimate of the total number of NIOSH-approved surgical N95 respirators used in the treatment of IPPS patients in CY 2023.

2) Estimate of the difference in the average unit cost of domestic and non-domestic NIOSH-approved surgical N95 respirators

3) Estimate of the percentage of NIOSH-approved surgical N95 respirators used in the treatment of IPPS patients in CY 2023 that are domestic.

For purposes of this estimate, we believe it is reasonable to assume that on average approximately one NIOSH-approved surgical N95 respirator is used for every day a beneficiary is in the hospital. The FY 2021 MedPAR claims data used for ratesetting in the FY 2023 IPPS/LTCH proposed rule accounted for approximately 7.2 million IPPS discharges and 38.3 million Medicare covered days. Therefore, for CY 2023, we are estimating that the total number of NIOSH-approved surgical N95 respirators (both domestic and non-domestic) used in the treatment of IPPS patients will be 38.3 million. Based on available data, our best estimate of the difference in the average unit costs of domestic and non-domestic NIOSH-approved surgical N95 respirators is \$0.20.

It is particularly challenging to estimate the percentage of NIOSH-approved surgical N95 respirators that will be used in the treatment of IPPS patients in CY 2023 that will be domestic. The OMB's Made in America Office recently conducted a data call on capacity in which several entities attested to being able to supply 3.6 billion NIOSH-approved and Berry-compliant surgical N95 respirators annually in the future if there were sufficient demand. We recognize that it may take time for this capacity to be fully reflected in hospital purchases. Therefore, although this would be sufficient capacity to supply the entire hospital industry if it were to be available and focused on this segment of the marketplace in 2023, we believe it is reasonable to assume that this will not happen instantaneously and hospitals in aggregate may in fact be able to purchase less than half of their NIOSH-approved surgical N95 respirators as domestic in 2023. Therefore, for purposes of this IPPS spending estimate, we set the percentage of NIOSH-approved surgical N95 respirators used in the treatment of IPPS patients in CY 2023 that are domestic to 40 percent, or slightly less than half. We estimate that total CY 2023 IPPS payments associated with this policy will be \$3.1 million (or 38.3 million covered days * \$0.20 * 40 percent).

For the OPSS, we propose to make this payment adjustment for the additional resource costs of domestic NIOSH-approved surgical N95 respirators under section 1833(t)(2)(E) of the

Act, which authorizes the Secretary to establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments. Consistent with this authority, the proposed OPPS payment adjustment would be budget neutral. In section X.H of the preamble of this proposed rule, we estimate that total CY 2023 OPPS payments associated with this policy will be \$8.3 million. This represents approximately 0.01 percent of the OPPS, which we propose to budget neutralize through an adjustment to the OPPS conversion factor.

d. Estimated Effects of OPPS Changes on Hospitals

Table 84 shows the estimated impact of this proposed rule on hospitals. Historically, the first line of the impact table, which estimates the change in payments to all facilities, has always included cancer and children's hospitals, which are held harmless to their pre-Balanced Budget Act (BBA) amount. We also include CMHCs in the first line that includes all providers. We include a second line for all hospitals, excluding permanently held harmless hospitals and CMHCs.

We present separate impacts for CMHCs in Table 84, and we discuss them separately below, because CMHCs are paid only for partial hospitalization services under the OPPS and are a different provider type from hospitals. In CY 2023, we propose to continue to pay CMHCs for partial hospitalization services under APC 5853 (Partial Hospitalization for CMHCs) and to pay hospitals for partial hospitalization services under APC 5863 (Partial Hospitalization for Hospital-Based PHPs).

The estimated increase in the total payments made under the OPPS is determined largely by the increase to the conversion factor under the statutory methodology. The distributional impacts presented do not include assumptions about changes in volume and service-mix. The conversion factor is updated annually by the OPD fee schedule increase factor, as discussed in detail in section II.B of this proposed rule.

Section 1833(t)(3)(C)(iv) of the Act provides that the OPD fee schedule increase factor is equal to the market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the

Act, which we refer to as the IPPS market basket percentage increase. The proposed IPPS market basket percentage increase applicable to the OPD fee schedule for CY 2023 is 3.1 percent. Section 1833(t)(3)(F)(i) of the Act reduces that 3.1 percent by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which is 0.4 percentage point for CY 2023 (which is also the productivity adjustment for FY 2023 in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28403)), resulting in the CY 2023 OPD fee schedule increase factor of 2.7 percent. We propose to use the OPD fee schedule increase factor of 2.7 percent in the calculation of the CY 2023 OPPS conversion factor. Section 10324 of the Affordable Care Act, as amended by HCERA, further authorized additional expenditures outside budget neutrality for hospitals in certain frontier States that have a wage index less than 1.0000. The amounts attributable to this frontier State wage index adjustment are incorporated in the estimates in Table 84 of this proposed rule.

To illustrate the impact of the CY 2023 changes, our analysis begins with a baseline simulation model that uses the CY 2022 relative payment weights, the FY 2022 final IPPS wage indexes that include reclassifications, and the final CY 2022 conversion factor. Table 84 shows the estimated redistribution of the increase or decrease in payments for CY 2023 over CY 2022 payments to hospitals and CMHCs as a result of the following factors: the impact of the APC reconfiguration and recalibration changes between CY 2022 and CY 2023 (Column 2); the wage indexes and the provider adjustments (Column 3); the combined impact of all of the changes described in the preceding columns plus the 2.7 percent OPD fee schedule increase factor update to the conversion factor (Column 4); the estimated differential impact of the proposed rural SCH exception to the Off Campus Provider Based Department Visits Policy (Column 5); the estimated impact taking into account all payments for CY 2023 relative to all payments for CY 2022, including the impact of changes in estimated outlier payments, changes to the pass-through payment estimate, the proposed change to except rural sole community hospitals from the clinic visit policy when provided at campus provider based departments, and the

proposed payment adjustment for the additional resource costs to hospitals of acquiring domestic NIOSH-approved surgical N95 respirators (Column 6).

We did not model an explicit budget neutrality adjustment for the rural adjustment for SCHs because we propose to maintain the current adjustment percentage for CY 2023. Because the updates to the conversion factor (including the update of the OPD fee schedule increase factor), the estimated cost of the rural adjustment, and the estimated cost of projected pass-through payment for CY 2023 are applied uniformly across services, observed redistributions of payments in the impact table for hospitals largely depend on the mix of services furnished by a hospital (for example, how the APCs for the hospital's most frequently furnished services will change), and the impact of the wage index changes on the hospital. However, total payments made under this system and the extent to which this proposed rule will redistribute money during implementation also will depend on changes in volume, practice patterns, and the mix of services billed between CY 2022 and CY 2023 by various groups of hospitals, which CMS cannot forecast.

Overall, we estimate that the rates for CY 2023 would increase Medicare OPPS payments by an estimated 2.9 percent. Removing payments to cancer and children's hospitals because their payments are held harmless to the pre-OPPS ratio between payment and cost and removing payments to CMHCs results in an estimated 3.0 percent increase in Medicare payments to all other hospitals. These estimated payments would not significantly impact other providers.

Column 1: Total Number of Hospitals

The first line in Column 1 in Table 84 shows the total number of facilities (3,502), including designated cancer and children's hospitals and CMHCs, for which we were able to use CY 2021 hospital outpatient and CMHC claims data to model CY 2022 and CY 2023 payments, by classes of hospitals, for CMHCs and for dedicated cancer hospitals. We excluded all hospitals and CMHCs for which we could not plausibly estimate CY 2022 or CY 2023 payment and entities that are not paid under the OPPS. The latter entities include CAHs, all-inclusive

hospitals, and hospitals located in Guam, the U.S. Virgin Islands, Northern Mariana Islands, American Samoa, and the State of Maryland. This process is discussed in greater detail in section II.A. of this proposed rule. At this time, we are unable to calculate a DSH variable for hospitals that are not also paid under the IPPS because DSH payments are only made to hospitals paid under the IPPS. Hospitals for which we do not have a DSH variable are grouped separately and generally include freestanding psychiatric hospitals, rehabilitation hospitals, and long-term care hospitals. We show the total number of OPSS hospitals (3,411), excluding the hold-harmless cancer and children's hospitals and CMHCs, on the second line of the table. We excluded cancer and children's hospitals because section 1833(t)(7)(D) of the Act permanently holds harmless cancer hospitals and children's hospitals to their "pre-BBA amount" as specified under the terms of the statute, and therefore, we removed them from our impact analyses. We show the isolated impact on the 25 CMHCs at the bottom of the impact table (Table 84) and discuss that impact separately below.

Column 2: APC Recalibration – All Changes

Column 2 shows the estimated effect of APC recalibration. Column 2 also reflects any changes in multiple procedure discount patterns or conditional packaging that occur as a result of the changes in the relative magnitude of payment weights. As a result of APC recalibration, we estimate that urban hospitals will experience a 0.1 increase, with the impact ranging from a decrease of 0.3 percent to an increase of 0.6, depending on the number of beds. Rural hospitals will experience an estimated decrease of 0.1 overall. Major teaching hospitals will experience an estimated increase of 0.4 percent.

Column 3: Wage Indexes and the Effect of the Provider Adjustments

Column 3 demonstrates the combined budget neutral impact of the APC recalibration; the updates for the wage indexes with the FY 2023 IPPS post-reclassification wage indexes; the rural adjustment; the frontier adjustment, and the cancer hospital payment adjustment. We modeled the independent effect of the budget neutrality adjustments and the OPD fee schedule increase

factor by using the relative payment weights and wage indexes for each year, and using a CY 2022 conversion factor that included the OPD fee schedule increase and a budget neutrality adjustment for differences in wage indexes.

Column 3 reflects the independent effects of the updated wage indexes, including the application of budget neutrality for the rural floor policy on a nationwide basis, as well as the proposed CY 2023 changes in wage index policy discussed in section II.C this proposed rule. We did not model a budget neutrality adjustment for the proposed rural adjustment for SCHs because we propose to continue the rural payment adjustment of 7.1 percent to rural SCHs for CY 2023, as described in section II.E of this proposed rule. We also did not model a budget neutrality adjustment for the proposed cancer hospital payment adjustment because the proposed payment-to-cost ratio target for the cancer hospital payment adjustment in CY 2023 is 0.89, the same as the ratio that was reported for the CY 2022 OPPS/ASC final rule with comment period (85 FR 85914). We note that, in accordance with section 16002 of the 21st Century Cures Act, we are applying a budget neutrality factor calculated as if the cancer hospital adjustment target payment-to-cost ratio was 0.90, not the 0.89 target payment-to-cost ratio we are applying in section II.F of this proposed rule.

We modeled the independent effect of updating the wage indexes by varying only the wage indexes, holding APC relative payment weights, service-mix, and the rural adjustment constant and using the CY 2023 scaled weights and a CY 2022 conversion factor that included a budget neutrality adjustment for the effect of the changes to the wage indexes between CY 2022 and CY 2023.

Column 4: All Budget Neutrality Changes Combined with the Market Basket Update

Column 4 demonstrates the combined impact of all of the changes previously described and the update to the conversion factor of 2.7 percent. Overall, these changes will increase payments to urban hospitals by 3.0 percent and to rural hospitals by 2.6 percent. Sole community hospitals receive an estimated increase of 2.5 percent while other rural hospitals

receive an estimated increase of 2.6 percent.

Column 5: Off-Campus PBD Clinic Visit Payment Policy

Column 5 displays the estimated effect of including the volume control method to pay for clinic visit HCPCS code G0463 ((Hospital outpatient clinic visit for assessment and management of a patient) when billed with modifier “PO” by an excepted off-campus PBD at a rate that would continue be 40 percent of the OPPS rate for a clinic visit service for CY 2023. Based on our proposal to apply an exception to this policy for rural sole community hospitals in the CY 2023 OPPS, the column includes estimated increases in payment, which are non-budget neutral.

Column 6: All Changes for CY 2023

Column 6 depicts the full impact of the proposed CY 2023 policies on each hospital group by including the effect of all changes for CY 2023 and comparing them to all estimated payments in CY 2021. Column 6 shows the combined budget neutral effects of Columns 2 and 3; the OPD fee schedule increase; the impact of estimated OPPS outlier payments, as discussed in section II.G of this proposed rule; the change in the Hospital OQR Program payment reduction for the small number of hospitals in our impact model that failed to meet the reporting requirements (discussed in section XIV of this proposed rule); the proposed change to except rural sole community hospitals from the clinic visit policy when provided at excepted off-campus provider-based departments, and the proposed adjustment for the additional resource costs of acquiring domestic NIOSH-approved surgical N95 respirators.

Of those hospitals that failed to meet the Hospital OQR Program reporting requirements for the full CY 2022 update (and assumed, for modeling purposes, to be the same number for CY 2023), we included 33 hospitals in our model because they had both CY 2021 claims data and recent cost report data. We estimate that the cumulative effect of all changes for CY 2023 will increase payments to all facilities by 2.9 percent for CY 2022. We modeled the independent effect of all changes in Column 6 using the final relative payment weights for CY 2022 and the proposed relative payment weights for CY 2023. We used the proposed conversion factor for

CY 2023 of \$86.785 and the final CY 2022 conversion factor of \$84.177 discussed in section II.B of this proposed rule.

Column 6 contains simulated outlier payments for each year. We used the 1-year charge inflation factor used in the FY 2021 IPPS/LTCH PPS final rule (87 FR 28667) of 6.4 percent (1.06404) to increase charges on the CY 2021 claims, and we used the overall CCR in the April 2022 Outpatient Provider-Specific File (OPSF) to estimate outlier payments for CY 2022. Using the CY 2021 claims and a 6.4 percent charge inflation factor, we currently estimate that outlier payments for CY 2022, using a multiple threshold of 1.75 and a fixed-dollar threshold of \$6,175, will be approximately 1.29 percent of total payments. The estimated current outlier payments of 1.29 percent are incorporated in the comparison in Column 5. We used the same set of claims and a charge inflation factor of 13.2 percent (1.13218) and the CCRs in the April 2022 OPSF, with an adjustment of 0.974495 (86 FR 25718), to reflect relative changes in cost and charge inflation between CY 2021 and CY 2023, to model the proposed CY 2023 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a fixed-dollar threshold of \$8,350. The charge inflation and CCR inflation factors are discussed in detail in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28666 through 28667).

Overall, we estimate that facilities would experience an increase of 2.9 percent under this proposed rule in CY 2023 relative to total spending in CY 2022. This projected increase (shown in Column 6) of Table 84 of this proposed rule reflects the 2.7 percent OPD fee schedule increase factor, plus 0.34 percent for the change in the pass-through payment estimate between CY 2022 and CY 2023, the proposed change to except rural sole community hospitals from the clinic visit policy when provided at excepted off-campus provider-based departments, and the proposed adjustment for the additional resource costs of acquiring domestic NIOSH-approved surgical N95 respirators, minus the difference in estimated outlier payments between CY 2022 (1.29 percent) and CY 2023 (1.0 percent). We estimate that the combined effect of all proposed changes for CY 2023 would increase payments to urban hospitals by 2.9 percent. Overall, we

estimate that rural hospitals would experience a 3.2 percent increase as a result of the combined effects of all the proposed changes for CY 2023.

Among hospitals, by teaching status, we estimate that the impacts resulting from the combined effects of all changes would include an increase of 2.6 percent for major teaching hospitals and an increase of 3.3 percent for nonteaching hospitals. Minor teaching hospitals would experience an estimated increase of 3.0 percent.

In our analysis, we also have categorized hospitals by type of ownership. Based on this analysis, we estimate that voluntary hospitals would experience an increase of 2.9 percent, proprietary hospitals would experience an increase of 3.5 percent, and governmental hospitals would experience an increase of 2.8 percent.

We note that under our anticipated alternative policy in which 340B-acquired drugs would be paid at ASP+6 percent that providers would experience different estimated changes based on the alternative policy.

Under the anticipated alternative OPPS, the combined effect of all proposed changes for CY 2023 would increase payments to urban hospitals by 4.0 percent. Overall, we estimate that, under the anticipated alternative, rural hospitals would experience a 2.1 percent increase as a result of the combined effects of all the proposed changes for CY 2023.

Among hospitals, by teaching status, under the anticipated alternative, we estimate that the impacts resulting from the combined effects of all changes would include an increase of 5.9 percent for major teaching hospitals and an increase of 2.3 percent for nonteaching hospitals. Under the anticipated alternative, minor teaching hospitals would experience an estimated increase of 3.5 percent.

In our analysis, we also have categorized hospitals by type of ownership. Based on this analysis, under the anticipated alternative, we estimate that voluntary hospitals would experience an increase of 4.0 percent, proprietary hospitals would experience an increase of 0.5 percent, and governmental hospitals would experience an increase of 4.9 percent.

For more information on the changes associated with the anticipated alternative OPPS policy, please see the supporting data files associated with the alternative policy on the CMS website.

TABLE 84: ESTIMATED IMPACT OF THE CY 2023 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

		(1)	(2)	(3)	(4)	(5)	(6)
		Number of Hospitals	APC Recalibration (all changes)	New Wage Index and Provider Adjustments	All Budget Neutral Changes (combined cols 2 and 3) with Market Basket Update	Proposed Rural SCH Exception to Off Campus Provider Based Department Visits Policy	All Changes
ALL PROVIDERS *		3,502	0.0	0.1	2.9	0.1	2.9
ALL HOSPITALS		3,411	0.1	0.2	2.9	0.1	3.0
	(excludes hospitals held harmless and CMHCs)						
URBAN HOSPITALS		2,686	0.1	0.2	3.0	0.0	2.9
	LARGE URBAN	1,376	0.1	0.1	2.9	0.0	2.9
	(GT 1 MILL.)						
	OTHER URBAN	1,310	0.0	0.3	3.0	0.1	3.0
	(LE 1 MILL.)						
RURAL HOSPITALS		725	-0.1	0.0	2.6	0.7	3.2
	SOLE COMMUNITY	374	-0.2	0.1	2.5	1.1	3.4
	OTHER RURAL	351	0.0	-0.1	2.6	0.0	2.7
BEDS (URBAN)							
	0 - 99 BEDS	887	0.6	0.2	3.5	0.0	3.4
	100-199 BEDS	766	0.4	0.2	3.3	0.1	3.3
	200-299 BEDS	415	0.2	0.1	3.0	0.1	3.0
	300-499 BEDS	388	0.1	0.2	3.0	0.0	2.9
	500 + BEDS	230	-0.3	0.2	2.6	0.0	2.6

DSH PATIENT PERCENT							
	0	4	1.1	0.6	4.4	0.0	4.5
	GT 0 - 0.10	242	0.8	0.3	3.8	0.0	3.6
	0.10 - 0.16	211	0.4	0.1	3.3	0.0	3.2
	0.16 - 0.23	565	0.2	0.1	3.1	0.1	3.2
	0.23 - 0.35	1,105	0.0	0.2	2.9	0.2	3.0
	GE 0.35	873	-0.1	0.1	2.7	0.1	2.7
	DSH NOT AVAILABLE **	411	-1.6	0.1	1.2	0.0	0.9
URBAN TEACHING/ DSH							
	TEACHING & DSH	1,074	-0.1	0.2	2.8	0.0	2.8
	NO TEACHING/DSH	1,215	0.5	0.1	3.3	0.0	3.3
	NO TEACHING/NO DSH	4	1.1	0.6	4.4	0.0	4.5
	DSH NOT AVAILABLE2	393	-1.6	0.1	1.1	0.0	0.9
TYPE OF OWNERSHIP							
	VOLUNTARY	1,940	0.0	0.1	2.8	0.1	2.9
	PROPRIETARY	1,033	0.7	0.0	3.5	0.0	3.5
	GOVERNMENT	438	-0.2	0.3	2.8	0.1	2.8
CMHCs		25	-11.3	0.2	-8.7	0	-8.4

Column (1) shows total hospitals and/or CMHCs.

Column (2) includes all proposed CY 2023 OPPS policies and compares those to the CY 2022 OPPS.

Column (3) shows the budget neutral impact of updating the wage index by applying the proposed FY 2023 hospital inpatient wage index. The proposed rural SCH adjustment would continue our current policy of 7.1 percent so the budget neutrality factor is 1. The proposed budget neutrality adjustment for the cancer hospital adjustment is 1.0000 because the proposed CY 2023 target payment-to-cost ratio is the same as the CY 2022 PCR target (0.89)

Column (4) shows the impact of all budget neutrality adjustments and the addition of the 2.7 percent OPD fee schedule update factor (3.1 percent reduced by 0.4 percentage points for the productivity adjustment).

Column (5) shows the differential impact of the proposed exception for rural sole community hospitals from clinic visits policy when furnished at off campus provider based departments.

Column (6) shows the additional adjustments to the conversion factor resulting from a change in the pass-through estimate, and adding estimated outlier payments. Note that previous years included the frontier adjustment in this column, but we have the frontier adjustment to Column 3 in this table.

These 3,502 providers include children and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.

** Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.

e. Estimated Effects of OPPS Changes on CMHCs

The last line of Table 84 demonstrates the isolated impact on CMHCs, which furnish only partial hospitalization services under the OPPS. In CY 2022, CMHCs are paid under APC 5853 (Partial Hospitalization (3 or more services) for CMHCs). We modeled the impact of this APC policy assuming CMHCs will continue to provide the same number of days of PHP care as seen in the CY 2021 claims used for ratesetting in the proposed rule. We excluded days with 1 or 2 services because our policy only pays a per diem rate for partial hospitalization when 3 or more qualifying services are provided to the beneficiary. We estimate that CMHCs would experience an overall 8.4 percent decrease in payments from CY 2022 (shown in Column 6). We note that this includes the trimming methodology as well as the proposed CY 2023 geometric mean costs used for developing the PHP payment rates described in section VIII. of this proposed rule.

Column 3 shows the estimated impact of adopting the proposed FY 2023 wage index values would result in an increase of 0.2 percent to CMHCs. Column 4 shows that combining the OPD fee schedule increase factor, along with proposed changes in APC policy for CY 2023 and the proposed FY 2023 wage index updates, will result in an estimated decrease of 8.7 percent. Column 6 shows that adding the changes in outlier and pass-through payments would result in a total -8.4 percent decrease in payment for CMHCs. This reflects all proposed changes for CMHCs for CY 2023.

f. Estimated Effect of OPPS Changes on Beneficiaries

For services for which the beneficiary pays a copayment of 20 percent of the payment rate, the beneficiary's payment would increase for services for which the OPPS payments will rise and will decrease for services for which the OPPS payments will fall. For further discussion of the calculation of the national unadjusted copayments and minimum unadjusted copayments, we refer readers to section II.H of this proposed rule. In all cases, section 1833(t)(8)(C)(i) of the Act limits beneficiary liability for copayment for a procedure performed in a year to the hospital inpatient deductible for the applicable year.

We estimate that the aggregate beneficiary coinsurance percentage would be 17.8 percent for all services paid under the OPPS in CY 2023. The estimated aggregate beneficiary coinsurance reflects general system adjustments, including the proposed CY 2023 comprehensive APC payment policy discussed in section II.A.2.b of this proposed rule. We note that the individual payments, and therefore copayments, associated with services may differ based on the setting in which they are furnished. However, at the aggregate system level, we do not currently observe significant impact on beneficiary coinsurance as a result of those policies.

g. Estimated Effects of OPPS Changes on Other Providers

The relative payment weights and payment amounts established under the OPPS affect the payments made to ASCs, as discussed in section XIII of this proposed rule. No types of providers or suppliers other than hospitals, CMHCs, and ASCs would be affected by the changes in this proposed rule.

h. Estimated Effects of OPPS Changes on the Medicare and Medicaid Programs

The effect on the Medicare program is expected to be an increase of \$1.8 billion in program payments for OPPS services furnished in CY 2023. The effect on the Medicaid program is expected to be limited to copayments that Medicaid may make on behalf of Medicaid recipients who are also Medicare beneficiaries. We estimate that the changes in this proposed rule would increase these Medicaid beneficiary payments by approximately \$115 million in CY 2023. Currently, there are approximately 10 million dual-eligible beneficiaries, which represent approximately thirty percent of Medicare Part B fee-for-service beneficiaries. The impact on Medicaid was determined by taking 30 percent of the beneficiary cost-sharing impact. The national average split of Medicaid payments is 57 percent Federal payments and 43 percent State payments. Therefore, for the estimated \$115 million Medicaid increase, approximately \$65 million would be from the Federal Government and \$50 million would be from State governments.

i. Alternative OPPS Policies Considered

Alternatives to the OPSS changes we propose and the reasons for our selected alternatives are discussed throughout this proposed rule.

- Alternatives Considered for the Claims Data used in OPSS and ASC Ratesetting due to the PHE.

We refer readers to section X.B of this proposed rule for a discussion of our proposed policy of using cost report data prior to the PHE. We note that in that section we discuss the alternative proposal we are considering regarding applying the standard ratesetting process, in particular the selection of cost report data used, which would include claims and cost report data including the timeframe of the PHE. We note that there are potential issues related to that data, including the effect of the PHE on the provider departmental CCRs that would be used to estimate cost. In this proposed rule, as discussed in section X.D, we propose a policy of using updated CY 2021 claims data in CY 2023 OPSS ratesetting, while using cost report CCRs with reporting periods prior to the PHE.

We note that these policy considerations also have ASC implications since the relative weights for certain surgical procedures performed in the ASC setting are developed based on the OPSS relative weights and claims data.

- Alternative Considered for the Proposed Adjustment for Acquisition of Domestic NIOSH-approved Surgical N95 Respirators

We refer readers to section X.H of this proposed rule for a discussion of our proposed IPSS and OPSS payment adjustments for the additional resource costs that hospitals incur in procuring domestic NIOSH-approved surgical N95 respirators. We note that in that section we discuss an alternative proposal of basing the payment adjustments on the national average cost differential between a domestic NIOSH-approved surgical N95 respirator and a non-domestic one as collected on the hospital cost reports, rather than using hospital specific differentials. We state that we may consider this alternative proposal once we've gained more experience with this payment policy, if finalized, its impact on the N95 marketplace, and the data collected. As

discussed later in this section, our best estimate of the difference in the average unit costs of domestic and non-domestic NIOSH-approved surgical N95 respirators is \$0.20. Using this figure, we estimate the impact of this alternative policy would be the same as the policy we propose in section X.H of this proposed rule. Our estimates of the CY 2023 IPPS and OPPTS payment associated with our proposed policy are \$3.1 million and \$8.3 million, respectively, and are discussed in more detail in this section.

2. Estimated Effects of CY 2023 ASC Payment System Changes

Most ASC payment rates are calculated by multiplying the ASC conversion factor by the ASC relative payment weight. As discussed fully in section XIII of this proposed rule, we are setting the CY 2023 ASC relative payment weights by scaling the proposed CY 2023 OPPTS relative payment weights by the proposed ASC scalar of 0.8474. The estimated effects of the proposed updated relative payment weights on payment rates are varied and are reflected in the estimated payments displayed in Tables 85 and 86.

Beginning in CY 2011, section 3401 of the Affordable Care Act requires that the annual update to the ASC payment system (which, in CY 2019, we adopted a policy to be the hospital market basket update for CY 2019 through CY 2023) after application of any quality reporting reduction be reduced by a productivity adjustment. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (as projected by the Secretary for the 10-year period, ending with the applicable fiscal year, year, cost reporting period, or other annual period). For ASCs that fail to meet their quality reporting requirements, the CY 2023 payment determinations would be based on the application of a 2.0 percentage point reduction to the annual update factor, which would be the hospital market basket update for CY 2023. We calculated the CY 2023 ASC conversion factor by adjusting the CY 2022 ASC conversion factor by 1.0010 to account for changes in the pre-floor and pre-reclassified hospital wage indexes between CY 2022 and CY 2023 and by applying the CY 2023 productivity-

adjusted hospital market basket update factor of 2.7 percent (which is equal to the projected hospital market basket update of 3.1 percent reduced by a productivity adjustment of 0.4 percentage point). The CY 2023 ASC conversion factor is \$51.315 for ASCs that successfully meet the quality reporting requirements.

a. Limitations of Our Analysis

Presented here are the projected effects of the proposed changes for CY 2023 on Medicare payment to ASCs. A key limitation of our analysis is our inability to predict changes in ASC service-mix between CY 2021 and CY 2023 with precision. We believe the net effect on Medicare expenditures resulting from the proposed CY 2023 changes would be small in the aggregate for all ASCs. However, such changes may have differential effects across surgical specialty groups, as ASCs continue to adjust to the payment rates based on the policies of the revised ASC payment system. We are unable to accurately project such changes at a disaggregated level. Clearly, individual ASCs would experience changes in payment that differ from the aggregated estimated impacts presented below.

b. Estimated Effects of ASC Payment System Policies on ASCs

Some ASCs are multispecialty facilities that perform a wide range of surgical procedures from excision of lesions to hernia repair to cataract extraction; others focus on a single specialty and perform only a limited range of surgical procedures, such as eye, digestive system, or orthopedic procedures. The combined effect on an individual ASC of the proposed update to the CY 2023 payments would depend on a number of factors, including, but not limited to, the mix of services the ASC provides, the volume of specific services provided by the ASC, the percentage of its patients who are Medicare beneficiaries, and the extent to which an ASC provides different services in the coming year. The following discussion includes tables that display estimates of the impact of the proposed CY 2023 updates to the ASC payment system on Medicare payments to ASCs, assuming the same mix of services, as reflected in our CY 2021 claims data. Table 85 depicts the estimated aggregate percent change in payment by surgical

specialty or ancillary items and services group by comparing estimated CY 2022 payments to estimated CY 2023 payments, and Table 86 shows a comparison of estimated CY 2022 payments to estimated CY 2023 payments for procedures that we estimate would receive the most Medicare payment in CY 2022.

In Table 85, we have aggregated the surgical HCPCS codes by specialty group, grouped all HCPCS codes for covered ancillary items and services into a single group, and then estimated the effect on aggregated payment for surgical specialty and ancillary items and services groups. The groups are sorted for display in descending order by estimated Medicare program payment to ASCs. The following is an explanation of the information presented in Table 85.

- Column 1—Surgical Specialty or Ancillary Items and Services Group indicates the surgical specialty into which ASC procedures are grouped and the ancillary items and services group which includes all HCPCS codes for covered ancillary items and services. To group surgical procedures by surgical specialty, we used the CPT code range definitions and Level II HCPCS codes and Category III CPT codes, as appropriate, to account for all surgical procedures to which the Medicare program payments are attributed.

- Column 2—Estimated CY 2022 ASC Payments were calculated using CY 2021 ASC utilization data (the most recent full year of ASC utilization) and CY 2022 ASC payment rates. The surgical specialty and ancillary items and services groups are displayed in descending order based on estimated CY 2022 ASC payments.

- Column 3—Estimated CY 2023 Percent Change is the aggregate percentage increase or decrease in Medicare program payment to ASCs for each surgical specialty or ancillary items and services group that is attributable to proposed updates to ASC payment rates for CY 2023 compared to CY 2022.

As shown in Table 85, for the six specialty groups that account for the most ASC utilization and spending, we estimate that the proposed update to ASC payment rates for CY 2023 would result in a 1 percent increase in aggregate payment amounts for eye and ocular

adnexa procedures, a 4 percent increase in aggregate payment amounts for nervous system procedures, 6 percent increase in aggregate payment amounts for musculoskeletal system procedures, a 2 percent increase in aggregate payment amounts for digestive system procedures, a 1 percent increase in aggregate payment amounts for cardiovascular system procedures, and a 3 percent increase in aggregate payment amounts for genitourinary system procedures. We note that these changes can be a result of different factors, including updated data, payment weight changes, and proposed changes in policy. In general, spending in each of these categories of services is increasing due to the 2.7 percent proposed payment rate update. After the payment rate update is accounted for, aggregate payment increases or decreases for a category of services can be higher or lower than a 2.0 percent increase, depending on if payment weights in the OPSS APCs that correspond to the applicable services increased or decreased or if the most recent data show an increase or a decrease in the volume of services performed in an ASC for a category. For example, we estimate a 6 percent increase in proposed aggregate musculoskeletal procedure payments. The increase in payment rates for musculoskeletal procedures as a result of increased device portions is further increased by the proposed 2.7 percent ASC rate update for these procedures. Conversely, we estimate only a 1 percent increase in proposed aggregate eye and ocular adnexa procedures related to a decrease in OPSS relative weights partially offsetting the 2.7 percent ASC rate update. For estimated changes for selected procedures, we refer readers to Table 85 provided later in this section.

TABLE 85: ESTIMATED IMPACT OF THE CY 2023 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE CY 2022 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP

Surgical Specialty Group (1)	Estimated CY 2022 ASC Payments (in Millions) (2)	Estimated CY 2023 Percent Change (3)
Total	\$5,858	3
Eye	\$1,789	1
Nervous System	\$1,200	4
Musculoskeletal	\$999	6
Gastrointestinal	\$896	2

Surgical Specialty Group (1)	Estimated CY 2022 ASC Payments (in Millions) (2)	Estimated CY 2023 Percent Change (3)
Cardiovascular	\$262	1
Genitourinary	\$215	3

Table 85 shows the estimated impact of the updates to the revised ASC payment system on aggregate ASC payments for selected surgical procedures during CY 2023. The table displays 30 of the procedures receiving the greatest estimated CY 2022 aggregate Medicare payments to ASCs. The HCPCS codes are sorted in descending order by estimated CY 2022 program payment.

- Column 1–CPT/HCPCS code.
- Column 2–Short Descriptor of the HCPCS code.
- Column 3–Estimated CY 2022 ASC Payments were calculated using CY 2021 ASC utilization (the most recent full year of ASC utilization) and the CY 2022 ASC payment rates.

The estimated CY 2022 payments are expressed in millions of dollars.

- Column 4–Estimated CY 2023 Percent Change reflects the percent differences between the estimated ASC payment for CY 2022 and the estimated payment for CY 2023 based on the proposed update.

TABLE 86 : ESTIMATED IMPACT OF THE FINAL CY 2023 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS Code (1)	Short Descriptor (2)	Estimated CY 2022 ASC Payment (in millions) (3)	Estimated CY 2023 Percent Change (4)
66984	Xcapsl ctrc rmvl w/o ecp	\$1,196	2
63685	Insrt/redo spine n generator	\$300	3
45380	Colonoscopy and biopsy	\$235	3
45385	Colonoscopy w/lesion removal	\$191	3
27447	Total knee arthroplasty	\$182	4
63650	Implant neuroelectrodes	\$174	9
43239	Egd biopsy single/multiple	\$160	1
64483	Njx aa&/strd tfrm epi l/s 1	\$106	2
66991	Xcapsl ctrc rmvl insj 1+	\$98	0
64590	Insrt/redo pn/gastr stimul	\$95	7
66982	Xcapsl ctrc rmvl cplx wo ecp	\$91	2
27130	Total hip arthroplasty	\$81	6
64635	Destroy lumb/sac facet jnt	\$77	1

CPT/HCPCS Code (1)	Short Descriptor (2)	Estimated CY 2022 ASC Payment (in millions) (3)	Estimated CY 2023 Percent Change (4)
29827	Sho arthrs srg rt&tr cuf rpr	\$72	2
J1097	Phenylep ketorolac opth soln	\$71	-4
64493	Inj paravert f jnt l/s 1 lev	\$66	2
36902	Intro cath dialysis circuit	\$65	3
G0105	Colorectal scrn; hi risk ind	\$60	3
66821	After cataract laser surgery	\$60	4
C9740	Cysto impl 4 or more	\$51	1
62323	Njx interlaminar lmbr/sac	\$45	0
22869	Insj stablj dev w/o dcprn	\$43	6
27279	Arthrodesis sacroiliac joint	\$42	28
45378	Diagnostic colonoscopy	\$37	3
G0121	Colon ca scrn not hi rsk ind	\$36	3
64561	Implant neuroelectrodes	\$35	7
15823	Revision of upper eyelid	\$35	-1
64721	Carpal tunnel surgery	\$34	1
65820	Relieve inner eye pressure	\$32	1
J1096	Dexametha opth insert 0.1 mg	\$32	0

c. Estimated Effects of Proposed ASC Payment System Policies on Beneficiaries

We estimate that the proposed CY 2023 update to the ASC payment system would be generally positive (that is, result in lower cost-sharing) for beneficiaries with respect to the new procedures proposed to be designated as office-based for CY 2023. First, other than certain preventive services where coinsurance and the Part B deductible is waived to comply with sections 1833(a)(1) and (b) of the Act, the ASC coinsurance rate for all procedures is 20 percent. This contrasts with procedures performed in HOPDs under the OPSS, where the beneficiary is responsible for copayments that range from 20 percent to 40 percent of the procedure payment (other than for certain preventive services), although the majority of HOPD procedures have a 20-percent copayment. Second, in almost all cases, the ASC payment rates under the ASC payment system are lower than payment rates for the same procedures under the OPSS. Therefore, the beneficiary coinsurance amount under the ASC payment system will almost always be less than the OPSS copayment amount for the same services. (The only exceptions will be if the ASC coinsurance amount exceeds the hospital inpatient deductible since the statute requires that OPSS copayment amounts not exceed the hospital inpatient deductible. Therefore, in limited circumstances, the ASC coinsurance amount may exceed the hospital inpatient

deductible and, therefore, the OPSS copayment amount for similar services.) Beneficiary coinsurance for services migrating from physicians' offices to ASCs may decrease or increase under the ASC payment system, depending on the particular service and the relative payment amounts under the MPFS compared to the ASC. While the ASC payment system bases most of its payment rates on hospital cost data used to set OPSS relative payment weights, services that are performed a majority of the time in a physician office are generally paid the lesser of the ASC amount according to the standard ASC ratesetting methodology or at the nonfacility practice expense based amount payable under the PFS. For those additional procedures that we proposed to designate as office-based in CY 2023, the beneficiary coinsurance amount under the ASC payment system generally will be no greater than the beneficiary coinsurance under the PFS because the coinsurance under both payment systems generally is 20 percent (except for certain preventive services where the coinsurance is waived under both payment systems).

3. Accounting Statements and Tables

As required by OMB Circular A-4 (available on the Office of Management and Budget website at:

<https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/OMB/circulars/a004/a-4.html>), we have prepared accounting statements to illustrate the impacts of the OPSS and ASC

changes in this proposed rule. The first accounting statement, Table 87, illustrates the classification of expenditures for the CY 2023 estimated hospital OPSS incurred benefit impacts associated with the proposed CY 2023 OPD fee schedule increase. The second accounting statement, Table 88, illustrates the classification of expenditures associated with the proposed 2.7 percent CY 2023 update to the ASC payment system, based on the provisions of this proposed rule and the baseline spending estimates for ASCs. Both tables classify most estimated impacts as transfers. Table 89 includes the annual estimated impact of hospital OQR and ASCQR programs, and the prior authorization process.

TABLE 87: ACCOUNTING STATEMENT: CY 2023 ESTIMATED HOSPITAL OPPS TRANSFERS FROM CY 2022 TO CY 2023 ASSOCIATED WITH THE CY 2023 HOSPITAL OUTPATIENT OPD FEE SCHEDULE INCREASE

Category	Transfers
Annualized Monetized Transfers	\$1,790 million
From Whom to Whom	Federal Government to outpatient hospitals and other providers who receive payment under the hospital OPPS

TABLE 88: ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2022 TO CY 2023 AS A RESULT OF THE PROPOSED CY 2023 UPDATED TO THE ASC PAYMENT SYSTEM

Category	Transfers
Annualized Monetized Transfers	\$110 million
From Whom to Whom	Federal Government to Medicare Providers and Suppliers
Total	\$110 million

TABLE 89: ESTIMATED COSTS IN CY 2023

CATEGORY	Costs
Burden	\$-11,688,943 million*
Regulatory Familiarization	\$17.204 million**

*The annual estimate includes the impact of Hospital OQR and ASCQR Programs, and the Prior Authorization Process.

** Regulatory familiarization costs occur upfront only.

4. Effects of Changes in Requirements for the Hospital OQR Program

a. Background

We refer readers to the CY 2018 OPPS/ASC final rule (82 FR 59492 through 59494) for the previously estimated effects of changes to the Hospital Outpatient Quality Reporting (OQR) Program for the CY 2018, CY 2019, and CY 2021 payment determinations. Of the 3,356 hospitals that met eligibility requirements for the CY 2022 payment determination, we determined that 88 hospitals did not meet the requirements to receive the full annual Outpatient Department (OPD) fee schedule increase factor.

b. Impact of CY 2023 OPPS/ASC Proposed Rule Policies

We do not anticipate that the CY 2023 Hospital OQR Program proposed policies will impact the number of facilities that will receive payment reductions. In this proposed rule, we propose to-- (1) add an additional targeting criterion to the validation selection policy beginning

with the CY 2023 reporting period; (2) align the patient encounter quarters with the calendar year beginning with the CY 2024 reporting period; and (3) change reporting for the OP-31 measure from mandatory to voluntary beginning with the CY 2025 payment determination.

As shown in Table 81 in section XXIII.B.4 (Collection of Information) of this proposed rule, we estimate a total information collection burden decrease for 3,350 OPPS hospitals of -325,847 hours at a cost of -\$15,138,852 annually associated with our proposed policies and updated burden estimates for the CY 2025 reporting period/CY 2027 payment determination and subsequent years, compared to our currently approved information collection burden estimates. We refer readers to section XXIII.B of this proposed rule (information collection requirements) for a detailed discussion of the calculations estimating the changes to the information collection burden for submitting data to the Hospital OQR Program. We do not believe the proposed policies will have any further economic impact beyond information collection burden.

5. Effects of Requirements for the ASCQR Program

a. Background

In section XV of this proposed rule, we discuss our proposed policies affecting the Ambulatory Surgical Center Quality Reporting (ASCQR) Program. For the CY 2022 payment determination, of the 5,386 ASCs that met eligibility requirements, we determined that 290 ASCs did not meet the requirements to receive the full annual payment update under the ASC fee schedule.

b. Impact of CY 2023 OPPS/ASC Proposed Policies

In section XVI of this proposed rule, we propose to change reporting for the ASC-11 measure from mandatory to voluntary beginning with the CY 2023 reporting period. As shown in Table 82 in section XXIII.C.3.e (Collection of Information), we estimate a total information collection burden decrease for 4,646 ACSs of -72,107 hours at a cost of -\$3,350,091 annually associated with our proposed policies and updated burden estimates for the CY 2025 reporting period/CY 2027 payment determination and subsequent years, compared to our currently

approved information collection burden estimates. We refer readers to section XXIII.C of the preamble of this proposed rule (information collection requirements) for a detailed discussion of the calculations estimating the changes to the information collection burden for submitting data to the ASCQR Program. We do not believe the proposed policy will have any further economic impact beyond information collection burden.

6. Effects of Requirements for the Rural Emergency Hospitals (REH) Program

a. Background

In section XVIII.A of this proposed rule, we discuss our proposed policies to provide payment to REHs, including the following proposals: (1) the payment rate for an REH service would be calculated using the OPPS prospective payment rate for the equivalent covered OPD service increased by 5 percent; (2) the additional 5 percent payment for REH services, above the amount that would be paid for covered OPD services, would not be subject to a copayment; (3) For CY 2023, the monthly facility payment that each REH will receive would be determined by first calculating the total amount that CMS determines was paid to all CAHs under Title 18 of the Act in CY 2019 minus the estimated total amount that would have been paid under Title 18 to CAHs in CY 2019 if payment were made for inpatient hospital, outpatient hospital, and skilled nursing facility services under the applicable prospective payment systems for such services during CY 2019. The difference is divided by the number of CAHs enrolled in Medicare in CY 2019 to calculate the annual amount of this additional facility payment per individual REH. The annual payment amount is then divided by 12 to calculate the monthly facility payment that each REH will receive.

b. Impact of CY 2023 OPPS/ASC Proposed Rule REH Policies

For CY 2023, we have determined there are 1,716 CAHs and rural subsection (d) hospitals with 50 or fewer beds that are eligible to convert to become an REH in the nation. A

study³⁶⁰ estimated that 68 eligible providers or approximately 4 percent of all eligible providers would become a REH in CY 2023, and we use this number of REHs for our impact analyses. We acknowledge that the number of conversions could be less than or significantly greater than this estimate.

We developed a percentile analysis estimating how much revenue from rendering medical services a provider would lose or gain during CY 2023 if it decided to convert to a REH. We estimated that a provider in the 95th percentile of total annual REH medical service payment would receive an additional \$2,089,700 in Medicare payments. We estimated that a provider in the 100th percentile of total annual REH medical service payment would receive an additional \$3,362,560 in Medicare payments. Since a REH provider conversion rate of 4 percent falls between the 95th percentile and the 100th percentile of total annual REH medical service payment spending, we took the average of the additional spending for the 95th and 100th percentiles to determine the additional medical service spending for each provider converting to a REH in CY 2023 would be \$2,726,130. Since we do not have any information on individual providers that may convert, nor do we have any information on characteristics of regions where REH conversions may be more likely, our best assumption regarding the impact of the REH policy is that providers who anticipate the most financial benefit from converting to an REH would be the most likely providers to convert.

Next, we determined the annual facility payment amount for a provider that converts to an REH in CY 2023. The proposed monthly facility payment for CY 2023 is \$268,294. When this amount is multiplied by 12 months, the total annual facility payment is equal to \$3,219,524. To determine the total impacts of the REH policy, we need to multiply the additional medical service spending amount of \$2,726,130 by 68 providers which equals \$185,376,820. Next, we multiply the total annual facility payment amount of \$3,219,524 by 68 providers which equals

³⁶⁰ “How Many Hospitals Might Convert to a Rural Emergency Hospital (REH)?” July 2021. Pink, GH et. al. *Findings Brief – NC Rural Health Research Program*.

\$218,927,610. Finally, we combine the two amounts together, and we obtain a final estimate of the impacts of the REH provider policy of an additional \$404,304,430 in Medicare payments.

7. Effects of Rural Emergency Hospitals (REH) Physician Self-Referral Law Updates

The physician self-referral law provisions related to REHs are discussed in section XVII.E. of this proposed rule.

As discussed in section XVIII.E.3 of this proposed rule, we propose a new exception at § 411.356(c)(4) for ownership or investment interests held by physicians (or immediate family members of physicians) in an REH. If all the requirements of the proposed exception are satisfied, the physician's (or immediate family member's) ownership or investment interest in the REH would not constitute a financial relationship for purposes of the physician self-referral law, and the referral and billing prohibitions of the physician self-referral law would not apply.

All the hospitals that are eligible to convert to an REH are either critical access hospitals or small rural hospitals and, therefore, are currently considered "hospitals" for purposes of the physician self-referral law. We believe that most physician-owned entities that are not publicly traded currently rely on the rural provider and whole hospital exceptions in our regulations at § 411.356(c)(1) and (3), respectively. The proposed REH exception includes program integrity requirements similar to those under the rural provider and whole hospital exceptions. Thus, we anticipate that the requirements of the proposed REH exception would result in no additional burden to a physician-owned REH and would protect against program or patient abuse. We believe that the proposed REH exception would ensure that the physician self-referral law does not inhibit access to medically necessary designated health services furnished by REHs that are owned or invested in by physicians (or their immediate family members) or thwart the underlying goal of section 125 of the CAA to safeguard or expand such access.

As discussed in section XVIII.E.5 of this proposed rule, we also propose to revise certain existing exceptions applicable to compensation arrangements involving specific types of providers to make them applicable to compensation arrangements to which an REH is a party.

Specifically, we propose to revise the exceptions for physician recruitment at § 411.357(e), obstetrical malpractice insurance subsidies at § 411.357(r), retention payments in underserved areas at § 411.357(t), electronic prescribing items and services at § 411.357(v), assistance to compensate a nonphysician practitioner at § 411.357(x), and timeshare arrangements at § 411.357(y) to also permit an REH to provide remuneration to a physician (or an immediate family member of a physician) if all requirements of the applicable exception are satisfied. All the proposed revisions would ensure that exceptions that may already be used by existing CAHs and small rural hospitals eligible to undergo conversion to an REH remain available to REHs. We believe that the continued availability of these exceptions could be important to ensuring access to necessary designated health services and other care furnished by an REH.

8. REH Enrollment

The only impacts of our proposed REH enrollment policies are the information collection requirements associated with the facility's completion and submission of a Form CMS-855A change of information application to convert from a CAH or hospital (as defined in section 1886(d)(1)(B) of the Act) to an REH. These are addressed in detail in section XXIII.G of this proposed rule. As explained in that section, we estimate a Year 1 burden of 68 hours (68 applications x 1 hour per application) at a cost of \$2,784 (based on an hourly wage estimate of \$40.94). Over a 3-year period, this results in an annual burden of 23 hours at a cost of \$928.

9. Effects of Addition of a New Service Category for Hospital Outpatient Department (OPD)

Prior Authorization Process

a. Overall Impact

In the CY 2020 OPPS/ASC final rule with comment period, we established a prior authorization process for certain hospital OPD services using our authority under section 1833(t)(2)(F) of the Act, which allows the Secretary to develop "a method for controlling unnecessary increases in the volume of covered OPD services" (84 FR 61142,

November 12, 2019).³⁶¹ As part of the CY 2021 OPPTS/ASC final rule (CMS-1736-FC), we added additional service categories to the prior authorization process (85 FR 85866, December 29, 2020). The regulations governing the prior authorization process are located in subpart I of 42 CFR part 419, specifically at §§ 419.80 through 419.89.

In accordance with § 419.83(b), we propose to require prior authorization for a new service category: Facet Joint Interventions. We propose adding the service category to § 419.83(a)(3). We also propose that the prior authorization process for the additional service category would be effective for dates of services on or after March 1, 2023. The addition of the service category is consistent with our authority under section 1833(t)(2)(F) of the Act and is based upon our determination that there has been an unnecessary increase in the volume of these services.

The overall economic impact on the health care sector to require prior authorization for the additional service category is dependent on the number of claims affected. Table 90, Overall Economic Impact on the Health Sector, lists an estimate of the overall economic impact on the health sector for the new service category. The values populating this table were obtained from the cost reflected in Table 91, Annual Private Sector Costs, and Table 92, Estimated Annual Administrative Costs to CMS. Together, Tables 91 and 92 combine to convey the overall economic cost impact to the health sector for the new service category, which is illustrated in Table 90. It should be noted that due to the March start date for prior authorization for the new service category, year one includes only 10 months of prior authorization requests.

Based on the estimate, the overall economic cost impact would be approximately \$22 million in the first year based on 10 months for the new service category. The 5-year impact would be approximately \$127.4 million, and the 10-year impact would be approximately \$259.2 million. The 5- and 10-year impacts account for year one, including only 10 months.

³⁶¹ See also Correction Notice issued January 3, 2020 (85 FR 224).

Additional administrative paperwork costs to private sector providers and an increase in Medicare spending to conduct reviews combine to create the financial impact; however, this impact is offset by Medicare savings. Annually, we estimate an overall Medicare savings of \$65.3 million. We believe there are likely to be other benefits that would result from the prior authorization requirement for the new service category, though many of those benefits are difficult to quantify. For instance, we would expect to see savings in the form of reduced unnecessary utilization, fraud, waste, and abuse, including a reduction in improper Medicare fee-for-service payments (we note that not all improper payments are fraudulent). We are soliciting public comments on the potential increased costs and benefits associated with this proposed provision for the new service category.

TABLE 90: OVERALL ECONOMIC COST IMPACT ON THE HEALTH SECTOR

	Year 1	5 Years	10 Years
Private Sector Costs	\$5,987,841	\$34,524,944	\$70,196,322
Medicare Costs	\$16,018,431	\$92,881,139	\$188,959,524
Total Economic Impact to Health Sector	\$22,006,272	\$127,406,083	\$259,155,846

According to the RFA’s use of the term, most suppliers and providers are small entities. Likewise, the vast majority of physician and nurse practitioner (NP) practices are considered small businesses according to the SBA’s size standards of having total revenues of \$10 million or less in any 1 year. While the economic costs and benefits are substantial in the aggregate, the economic impact on individual entities compliant with Medicare program coverage and utilization rules and regulations would be relatively small. We estimate that 90 to 95 percent of providers who provide these services are small entities under the RFA definition. The rationale behind requiring prior authorization is to control unnecessary increases in the volume of covered OPD services. The impact on providers not in compliance with Medicare coverage, coding, and payment rules and regulations could be significant, as the proposed rule would change the billing practices of those providers. We believe that the purpose of the statute and this rule is to avoid

unnecessary increases in utilization of OPD services. Therefore, we do not view decreased revenues from the additional OPD service category subject to unnecessary utilization by providers to be a condition that we must mitigate. We believe that the effect would be minimal on providers who are compliant with Medicare coverage, coding, and payment rules and requirements. Adding the new service category would offer additional protection to a provider's cash flow as the provider would know in advance if the Medicare requirements are met.

b. Anticipated Specific Cost Effects

1. Private Sector Costs

We do not believe that this rule would significantly affect the number of legitimate claims submitted for the new service category. However, we would expect a decrease in the overall amount paid for the services resulting from a reduction in unnecessary utilization of the services requiring prior authorization.

We estimate that the private sector's per-case time burden attributed to submitting documentation and associated clerical activities in support of a prior authorization request for the additional service category would be equivalent to that of submitting documentation and clerical activities associated with prepayment review, which is 0.5 hours. We would apply this time burden estimate to initial submissions and resubmissions.

TABLE 91: YEAR 1 (10 MONTH) PRIVATE SECTOR COSTS

Activity	Responses Per Year (i.e., number of reviewed claims)	Time Per Response (hours) or Dollar Cost	Total Burden Per Year (hours)	Total Burden Costs Per Year Using Loaded Rate
Fax and Electronic Submitted Requests-Initial Submissions	162,169	0.5	81,085	\$2,777,955
Fax and Electronic Submitted Requests-Resubmissions	53,213	0.5	26,606	\$911,532
Mailed in Requests-Initial Submissions	69,501	0.5	34,751	\$1,190,552

Mailed in Requests-Resubmissions	22,805	0.5	11,403	\$390,657
Mailing Costs	92,306	5		\$461,532
Provider Demonstration-Education	2,487	3	7,461	\$255,614
Total			161,305	\$5,987,841

2. Administrative Costs to CMS

CMS would incur additional costs associated with processing the prior authorization requests for the new service category. We use the range of potentially affected cases (submissions and resubmissions) and multiply it by \$50, the estimated cost to review each request. The combined cost also includes other elements such as appeals, education, outreach, and system changes.

TABLE 92: YEAR 1 (10 MONTH) ESTIMATED ADMINISTRATIVE COSTS TO CMS

Service Category	Estimated Year One Administrative Cost (10 Months)
Facet Joint Interventions- 10 Codes	\$16,018,431

3. Estimated Beneficiary Costs

We would expect a reduction in the utilization of the new Medicare OPD service category when such utilization does not comply with one or more of Medicare's coverage, coding, and payment rules. While there may be an associated burden on beneficiaries while they wait for the prior authorization decision; we are unable to quantify that burden. Although the rule would permit utilization that is medically necessary, OPD services that are not medically necessary may still provide convenience or usefulness for beneficiaries; any rule-induced loss of such convenience or usefulness constitutes a cost of the rule that we lack data to quantify.

Additionally, beneficiaries may have out-of-pocket costs for those services that are determined not to comply with Medicare requirements and thus, are not eligible for Medicare payment. We lack the data to quantify these costs as well.

c. Estimated Benefits

There would be quantifiable benefits for this rule because we expect a reduction in the unnecessary utilization of the new Medicare OPD service category subject to prior authorization. It is difficult to project the exact decrease in unnecessary utilization; however, based on a 25 percent savings percentage, we estimate that for the first ten months, there would be savings of \$54.4 million overall. Annually, we estimate an overall gross savings of \$65.3 million. This savings represents a Medicare benefit from more efficient use of health care resources while still maintaining the same health outcomes for necessary services. We would closely monitor utilization and billing practices. The expected benefits would also include changed billing practices that would also enhance the coordination of care for the beneficiary. For example, requiring prior authorization for the additional OPD services category would ensure that the primary care practitioner recommending the service and the facility collaborate more closely to provide the most appropriate OPD services to meet the needs of the beneficiary. The practitioner recommending the service would evaluate the beneficiary to determine what services are medically necessary based on the beneficiary's condition. This would require the facility to collaborate closely with the practitioner early on in the process to ensure the services are truly necessary and meet all requirements and that their supporting documentation is complete and correct. Improper payments made because the practitioner did not evaluate the patient or the patient does not meet the Medicare requirements would likely be reduced by the requirement that a provider submits clinical documentation created as part of its prior authorization request.

D. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret a rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review a rule, we assumed that the number of commenters on last year's proposed rule (18,664) will be the number of reviewers of this proposed rule. We acknowledge that this assumption may

understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers choose not to comment on the proposed rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcome any comments on the approach to estimating the number of entities that will review the proposed rule. We also recognize that different types of entities are, in many cases, affected by mutually exclusive sections of the proposed rule, and therefore, for the purposes of our estimate, we assume that each reviewer reads approximately 50 percent of the rule. We seek comments on this assumption.

Using the wage information from the BLS for medical and health service managers (Code 11-9111), we estimated that the cost of reviewing this rule is \$115.22 per hour, including overhead and fringe benefits (https://www.bls.gov/oes/current/oes_nat.htm). Assuming an average reading speed, we estimate that it would take approximately 8 hours for the staff to review half of this proposed rule. For each facility that reviewed the proposed rule, the estimated cost is \$921.76 (8 hours x \$115.22). Therefore, we estimate that the total cost of reviewing this regulation is \$17,203,729 (\$921.76 x 18,664).

E. Regulatory Flexibility Act (RFA) Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, many hospitals are considered small businesses either by the Small Business Administration's size standards with total revenues of \$41.5 million or less in any single year or by the hospital's not-for-profit status. Most ASCs and most CMHCs are considered small businesses with total revenues of \$16.5 million or less in any single year. For details, we refer readers to the Small Business Administration's "Table of Size Standards" at <http://www.sba.gov/content/table-small-business-size-standards>. As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. We do not believe

that this threshold will be reached by the requirements in this proposed rule. As a result, the Secretary has determined that this proposed rule would not have a significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has 100 or fewer beds. We estimate that this final rule with comment period would increase payments to small rural hospitals by approximately 3 percent. Therefore, it should not have a significant impact on the approximately 563 small rural hospitals. We note that the estimated payment impact for any category of small entity will depend on both the services that they provide as well as the payment policies and/or payment systems that may apply to them. Therefore, the most applicable estimated impact may be based on the specialty, provider type, or payment system.

The analysis above, together with the remainder of this preamble, provides a regulatory flexibility analysis and a regulatory impact analysis. We note that the policies established in this proposed rule apply more broadly to OPPS providers and do not specifically focus on small rural hospitals. As a result, the impact on those providers may depend more significantly on their case mix of services provided, since the broader impact on the hospital category is more dependent on the OPD update factor, as indicated in the impact table.

F. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2022, that threshold level is currently approximately \$165 million. This proposed rule does not mandate any requirements for State, local, or tribal governments, or for the private sector.

G. Conclusion

The changes we propose in this proposed rule would affect all classes of hospitals paid under the OPSS as well as affect both CMHCs and ASCs. We estimate that most classes of hospitals paid under the OPSS would experience a modest increase or a minimal decrease in payment for services furnished under the OPSS in CY 2023. Table 84 demonstrates the estimated distributional impact of the OPSS budget neutrality requirements that would result in a 2.9 percent increase in payments for all services paid under the OPSS in CY 2023, after considering all of the changes to APC reconfiguration and recalibration, as well as the OPD fee schedule increase factor, wage index changes, including the frontier State wage index adjustment, estimated payment for outliers, changes to the pass-through payment estimate, proposed exception for rural SCHs from the clinic visit policy for services furnished at off campus PBDs, and proposed adjustment for the additional resource costs of acquiring domestic NIOSH-approved surgical N95 respirators. However, some classes of providers that are paid under the OPSS would experience more significant gains or losses in OPSS payments in CY 2023.

The updates we are making to the ASC payment system for CY 2023 would affect each of the approximately 5,900 ASCs currently approved for participation in the Medicare program. The effect on an individual ASC would depend on its mix of patients, the proportion of the ASCs patients who are Medicare beneficiaries, the degree to which the payments for the procedures offered by the ASC are changed under the ASC payment system, and the extent to which the ASC provides a different set of procedures in the coming year than in previous years. Table 85 demonstrates the estimated distributional impact among ASC surgical specialties of the productivity-adjusted hospital market basket update factor of 2.7 percent for CY 2023.

H. Federalism Analysis

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct costs on

State and local governments, preempts State law, or otherwise has federalism implications. We have examined the OPPS and ASC provisions included in this proposed rule in accordance with Executive Order 13132, Federalism, and have determined that they will not have a substantial direct effect on State, local or tribal governments, preempt State law, or otherwise have a federalism implication. As reflected in Table 84 of this proposed rule, we estimate that OPPS payments to governmental hospitals (including State and local governmental hospitals) would increase by 2.8 percent under this proposed rule. While we do not know the number of ASCs or CMHCs with government ownership, we anticipate that it is small. The analyses we have provided in this section of this proposed rule, in conjunction with the remainder of this document, demonstrate that this proposed rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866, the RFA, and section 1102(b) of the Act.

This proposed rule would affect payments to a substantial number of small rural hospitals and a small number of rural ASCs, as well as other classes of hospitals, CMHCs, and ASCs, and some effects may be significant. However, as noted in section XXV, this proposed rule should not have a significant effect on small rural hospitals.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on July 6, 2022.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping, rural areas, X-rays.

42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 411

Diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 413

Diseases, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

1. The authority citation for part 405 continues to read as follows:

Authority: 42 U.S.C. 263a, 405(a), 1302, 1320b-12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

2. Section 405.1801 is amended by revising paragraph (b)(2)(ii) to read as follows:

§ 405.1801 Introduction.

* * * * *

(b) * * *

(2) * * *

(ii) Some of these nonprovider entities are required to file periodic cost reports and are paid on the basis of information furnished in these reports. Except as provided at § 413.420(g), these nonprovider entities may not obtain a contractor hearing or a Board hearing under section 1878 of the Act or this subpart.

* * * * *

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

3. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

4. Section 410.27 is amended by:

a. Revising paragraphs (a)(1)(iv)(A) and (B); and

b. Removing paragraph (a)(1)(iv)(D).

The revisions read as follows:

§ 410.27 Therapeutic outpatient hospital or CAH services and supplies incident to a physician's or nonphysician practitioner's service: Conditions.

(a) * * *

(1) * * *

(iv) * * *

(A) For services furnished in the hospital or CAH, or in an outpatient department of the hospital or CAH, both on and off-campus, as defined in § 413.65 of this chapter, general supervision means the procedure is furnished under the physician's or nonphysician practitioner's overall direction and control, but the physician's or nonphysician practitioner's presence is not required during the performance of the procedure.

(B) Certain therapeutic services and supplies may be assigned either direct supervision or personal supervision.

(1) For purposes of this section, direct supervision means that the physician or nonphysician practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room when the procedure is performed. For pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, direct supervision must be furnished by a doctor of medicine or a doctor of osteopathy, as specified in §§ 410.47 and 410.49, respectively. Until the later of the end of the calendar year in which the PHE as defined in § 400.200 of this chapter ends or December 31, 2021, the presence of the physician includes virtual presence through audio/video real-time communications technology (excluding audio-only);

(2) Personal supervision means the physician or nonphysician practitioner must be in attendance in the room during the performance of the procedure;

* * * * *

5. Section 410.28 is amended by revising paragraph (e) to read as follows:

§ 410.28 Hospital or CAH diagnostic services furnished to outpatients: Conditions.

* * * * *

(e) Medicare Part B makes payment under section 1833(t) of the Act for diagnostic services furnished by or under arrangements made by the participating hospital only when the diagnostic services are furnished under one of the three levels of supervision (as defined in

paragraphs (e)(1) through (3) of this section) specified by CMS for the particular service by a physician or, to the extent that they are authorized to do so under their scope of practice and applicable State law, by a nonphysician practitioner (physician assistant, nurse practitioner, clinical nurse specialist, certified nurse-midwife or certified registered nurse anesthetist).

(1) *General supervision.* General supervision means the procedure is furnished under the physician's or nonphysician practitioner's overall direction and control, but the physician's or nonphysician practitioner's presence is not required during the performance of the procedure. Under general supervision at a facility accorded provider-based status, the training of the nonphysician personnel who actually perform the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the facility.

(2) *Direct supervision.* (i) For services furnished directly or under arrangement in the hospital or in an on-campus or off-campus outpatient department of the hospital, as defined in § 413.65 of this chapter, "direct supervision" means that the physician or nonphysician practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room where the procedure is performed.

(ii) For services furnished under arrangement in nonhospital locations, "direct supervision" means the physician or nonphysician practitioner must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room when the procedure is performed.

(iii) Until the later of the end of the calendar year in which the PHE as defined in § 400.200 of this chapter ends or December 31, 2021, the presence of the physician or nonphysician practitioner under paragraphs (e)(2)(i) and (ii) of this section includes virtual presence through audio/video real-time communications technology (excluding audio-only).

(3) *Personal supervision.* Personal supervision means the physician or nonphysician practitioner must be in attendance in the room during the performance of the procedure.

* * * * *

6. Section § 410.40 is amended by revising paragraphs (f)(1), (2), and (5) to read as follows:

§ 410.40 Coverage of ambulance services.

* * * * *

(f) * * *

(1) From any point of origin to the nearest hospital, CAH, REH, or SNF that is capable of furnishing the required level and type of care for the beneficiary's illness or injury. The hospital or CAH or REH must have available the type of physician or physician specialist needed to treat the beneficiary's condition.

(2) From a hospital, CAH, REH, or SNF to the beneficiary's home.

* * * * *

(5) During a Public Health Emergency, as defined in § 400.200 of this chapter, a ground ambulance transport from any point of origin to a destination that is equipped to treat the condition of the patient consistent with any applicable State or local Emergency Medical Services protocol that governs the destination location. Such destinations include, but are not limited to, alternative sites determined to be part of a hospital, critical access hospital, REH (effective January 1, 2023), or skilled nursing facility, community mental health centers, federally qualified health centers, rural health clinics, physician offices, urgent care facilities, ambulatory surgical centers, any location furnishing dialysis services outside of an ESRD facility when an ESRD facility is not available, and the beneficiary's home.

* * * * *

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

7. The authority citation for part 411 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395w-101 through 1395w-152, 1395hh, and 1395nn.

8. Section 411.351 is amended by revising the definition of “Rural area” and adding a definition for “Rural emergency hospital” to read as follows:

§ 411.351 Definitions.

* * * * *

Rural area means an area that is not an urban area as defined at § 412.64(b) of this chapter.

Rural emergency hospital has the meaning set forth in section 1861(kkk)(2) of the Act and § 419.91 of this chapter.

* * * * *

9. Section 411.356 is amended by adding paragraph (c)(4) to read as follows:

§ 411.356 Exceptions to the referral prohibition related to ownership or investment interests.

* * * * *

(c) * * *

(4) A rural emergency hospital, in the case of designated health services that are furnished by such rural emergency hospital, if all of the following requirements are satisfied:

(i) The entity is enrolled in Medicare as a rural emergency hospital.

(ii) The ownership or investment interest is in the entire rural emergency hospital and not merely in a distinct part or department of the rural emergency hospital.

(iii) The rural emergency hospital does not directly or indirectly condition any ownership or investment interests held or to be held by a physician (or an immediate family member of a physician) on the physician making or influencing referrals to the rural emergency hospital or otherwise generating business for the rural emergency hospital.

(iv) The rural emergency hospital does not offer any ownership or investment interests to a physician (or an immediate family member of a physician) on terms more favorable than the terms offered to a person that is not a physician (or an immediate family member of a physician).

(v) Neither the rural emergency hospital nor any owner of or investor in the rural emergency hospital directly or indirectly provides loans or financing for any investment in the rural emergency hospital by a physician (or an immediate family member of a physician).

(vi) Neither the rural emergency hospital nor any owner of or investor in the rural emergency hospital directly or indirectly guarantees a loan, makes a payment toward a loan, or otherwise subsidizes a loan for a physician (or an immediate family member of a physician) that is related to acquiring any ownership or investment interest in the rural emergency hospital.

(vii) Ownership or investment returns are distributed to each owner of or investor in the rural emergency hospital in an amount that is directly proportional to the ownership or investment interest in the rural emergency hospital of such owner or investor.

(viii) Physicians (or immediate family members of physicians) who have ownership or investment interests in the rural emergency hospital do not directly or indirectly receive any guaranteed receipt of or right to purchase other business interests related to the rural emergency hospital, including the purchase or lease of any property under the control of any other owner of or investor in the rural emergency hospital or located near the premises of the rural emergency hospital.

(ix) The rural emergency hospital does not offer a physician (or an immediate family member of a physician) the opportunity to purchase or lease any property under the control of the rural emergency hospital or any other owner of or investor in the rural emergency hospital on more favorable terms than the terms offered to a person that is not a physician (or an immediate family member of a physician).

10. Section 411.357 is amended by revising paragraphs (e)(6), (r)(2) introductory text, (r)(2)(ii) through (v), (t)(5), (v)(1)(i), (x)(7), and (x)(8) and adding paragraph (y)(10) to read as follows:

§ 411.357 Exceptions to the referral prohibition related to compensation arrangements.

* * * * *

(e) * * *

(6)(i) This paragraph (e) applies to remuneration provided by a federally qualified health center, rural health clinic, or rural emergency hospital in the same manner as it applies to remuneration provided by a hospital.

(ii) The “geographic area served” by a federally qualified health center, rural health clinic, or rural emergency hospital is the area composed of the lowest number of contiguous or noncontiguous zip codes from which the federally qualified health center, rural health clinic, or rural emergency hospital draws at least 90 percent of its patients, as determined on an encounter basis. The geographic area served by the federally qualified health center, rural health clinic, or rural emergency hospital may include one or more zip codes from which the federally qualified health center, rural health clinic, or rural emergency hospital draws no patients, provided that such zip codes are entirely surrounded by zip codes in the geographic area described above from which the federally qualified health center, rural health clinic, or rural emergency hospital draws at least 90 percent of its patients.

* * * * *

(r) * * *

(2) A payment from a hospital, federally qualified health center, rural health clinic, or rural emergency hospital that is used to pay for some or all of the costs of malpractice insurance premiums for a physician who engages in obstetrical practice as a routine part of his or her medical practice, if all of the following conditions are met:

* * * * *

(ii) The arrangement is set out in writing, is signed by the physician and the hospital, federally qualified health center, rural health clinic, or rural emergency hospital providing the payment, and specifies the payment to be made by the hospital, federally qualified health center, rural health clinic, or rural emergency hospital and the terms under which the payment is to be provided.

(iii) The arrangement is not conditioned on the physician's referral of patients to the hospital, federally qualified health center, rural health clinic, or rural emergency hospital providing the payment.

(iv) The hospital, federally qualified health center, rural health clinic, or rural emergency hospital does not determine the amount of the payment in any manner that takes into account the volume or value of referrals by the physician or any other business generated between the parties.

(v) The physician is allowed to establish staff privileges at any hospital(s), federally qualified health center(s), rural health clinic(s), or rural emergency hospital(s) and to refer business to any other entities (except as referrals may be restricted under an employment arrangement or services arrangement that complies with § 411.354(d)(4)).

* * * * *

(t) * * *

(5) *Application to other entities.* This paragraph (t) applies to remuneration provided by a federally qualified health center, rural health clinic, or rural emergency hospital in the same manner as it applies to remuneration provided by a hospital. For purposes of paragraph (t), the geographic area served by a federally qualified health center, rural health clinic, or rural emergency hospital has the meaning set forth in section (e)(6)(ii) of this section.

* * * * *

(v) * * *

(1) * * *

(i) Hospital or rural emergency hospital to a physician who is a member of its medical staff;

* * * * *

(x) * * *

(7)(i) This paragraph (x) may be used by a hospital, federally qualified health center, rural health clinic, or rural emergency hospital only once every 3 years with respect to the same referring physician.

(ii) Paragraph (x)(7)(i) of this section does not apply to remuneration provided by a hospital, federally qualified health center, rural health clinic, or rural emergency hospital to a physician to compensate a nonphysician practitioner to provide NPP patient care services if—

(A) The nonphysician practitioner is replacing a nonphysician practitioner who terminated his or her employment or contractual arrangement to provide NPP patient care services with the physician (or the physician organization in whose shoes the physician stands) within 1 year of the commencement of the employment or contractual arrangement; and

(B) The remuneration provided to the physician is provided during a period that does not exceed 2 consecutive years as measured from the commencement of the compensation arrangement between the nonphysician practitioner who is being replaced and the physician (or the physician organization in whose shoes the physician stands).

(8)(i) This paragraph (x) applies to remuneration provided by a federally qualified health center, rural health clinic, or rural emergency hospital in the same manner as it applies to remuneration provided by a hospital.

(ii) The “geographic area served” by a federally qualified health center, rural health clinic, or rural emergency hospital has the meaning set forth in paragraph (e)(6)(ii) of this section.

(y) * * *

(10) This paragraph (y) applies to remuneration provided by a rural emergency hospital in the same manner as it applies to remuneration provided by a hospital.

* * * * *

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

11. The authority citation for part 412 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

12. Section 412.1 is amended by revising paragraph (a)(1)(iv) to read as follows:

§ 412.1 Scope of part.

(a) * * *

(1) * * *

(iv) Additional payments are made for outlier cases, bad debts, indirect medical education costs, for serving a disproportionate share of low-income patients, and for the additional resource costs of domestic National Institute for Occupational Safety and Health approved surgical N95 respirators.

* * * * *

13. Section 412.2 is amended by adding paragraph (f)(10) to read as follows:

§ 412.2 Basis of payment.

* * * * *

(f) * * *

(10) A payment adjustment for the additional resource costs of domestic National Institute for Occupational Safety and Health approved surgical N95 respirators as specified in § 412.113 of subpart H.

* * * * *

14. Section 412.100 is amended by revising paragraph (b) to read as follows:

§ 412.100 Special treatment: Kidney transplant programs.

* * * * *

(b) *Costs of kidney acquisition.* Kidney acquisition costs include allowable costs incurred in the acquisition of a kidney from a living or a deceased donor by the hospital, or from a deceased donor by an organ procurement organization. These costs are listed in § 413.402(b) of this chapter.

15. Section 412.113 is amended by adding paragraph (f) to read as follows:

§ 412.113 Other payments.

* * * * *

(f) *Additional resource costs of domestic National Institute for Occupational Safety and Health approved surgical N95 respirators.* (1) For cost reporting periods beginning on or after January 1, 2023, a payment adjustment to a hospital for the additional resource costs of domestic National Institute for Occupational Safety and Health approved surgical N95 respirators is made as described in paragraph (f)(2) of this section.

(2) The payment adjustment is based on the estimated difference in the reasonable cost incurred by the hospital for domestic National Institute for Occupational Safety and Health approved surgical N95 respirators purchased during the cost reporting period as compared to other National Institute for Occupational Safety and Health approved surgical N95 respirators purchased during the cost reporting period.

16. Section 412.190 is amended by revising paragraph (c) to read as follows:

§ 412.190 Overall Hospital Quality Star Rating.

* * * * *

(c) *Frequency of publication and data used.* The Overall Star Rating are published once annually using data publicly reported on Hospital Compare or its successor website from a quarter within the previous 12 months.

* * * * *

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

17. The authority citation for part 413 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395m, 1395x(v), 1395x(kkk), 1395hh, 1395rr, 1395tt, and 1395ww.

18. Section 413.1 is amended by adding paragraph (a)(1)(ii)(L) and revising paragraph (a)(2)(i) to read as follows:

§ 413.1 Introduction.

(a) * * *

(1) * * *

(ii) * * *

(L) Section 1834(x) of the Act authorizes payment for services furnished by Rural Emergency Hospitals (REHs) and establishes the payment methodology.

(2) * * *

(i) Hospitals, critical access hospitals (CAHs), and rural emergency hospitals (REHs);

* * * * *

19. Section 413.13 is amended by adding paragraph (c)(2)(vii) to read as follows:

§ 413.13 Amount of payment if customary charges for services furnished are less than reasonable costs.

* * * * *

(c) * * *

(2) * * *

(vii) *Services furnished by a rural emergency hospital (REH)*. Services furnished by a rural emergency hospital are subject to the payment methodology set forth in part 419, subpart K.

* * * * *

20. Section 413.24 is amended by revising paragraphs (f)(4)(i) and (ii) and (f)(4)(iv)(A).
to read as follows:

§ 413.24 Adequate cost data and cost finding.

* * * * *

(f) * * *

(4) * * *

(i) As used in this paragraph, “provider” means a hospital, rural emergency hospital, skilled nursing facility, home health agency, hospice, organ procurement organization, histocompatibility laboratory, rural health clinic, federally qualified health center, community mental health center, or end-stage renal disease facility.

(ii) Effective for cost reporting periods beginning on or after October 1, 1989 for hospitals; cost reporting periods ending on or after February 1, 1997 for skilled nursing facilities and home health agencies; cost reporting periods ending on or after December 31, 2004 for hospices, and end-stage renal disease facilities; cost reporting periods ending on or after March 31, 2005 for organ procurement organizations, histocompatibility laboratories, rural health clinics, Federally qualified health centers, and community mental health centers; and cost reporting periods beginning on or after January 1, 2023 for rural emergency hospitals, a provider is required to submit cost reports in a standardized electronic format. The provider's electronic program must be capable of producing the CMS standardized output file in a form that can be read by the contractor's automated system. This electronic file, which must contain the input data required to complete the cost report and to pass specified edits, must be forwarded to the contractor for processing through its system.

* * * * *

(iv)(A) Effective as specified in paragraphs (f)(4)(iv)(A)(1) through (5) and except as provided in paragraph (f)(4)(iv)(C) of this section, a provider must submit a hard copy of a settlement summary, if applicable, which is a statement of certain worksheet totals found within the electronic file, and the certification statement described in paragraph (f)(4)(iv)(B) of this section signed by its administrator or chief financial officer certifying the accuracy of the electronic file or the manually prepared cost report.

(1) For hospitals, effective for cost reporting periods ending on or after September 30, 1994;

(2) For skilled nursing facilities and home health agencies, effective for cost reporting periods ending on or after February 1, 1997;

(3) For hospices and end-stage renal disease facilities, effective for cost reporting periods ending on or after December 31, 2004;

(4) For organ procurement organizations, histocompatibility laboratories, rural health clinics, Federally qualified health centers, and community mental health centers, effective for cost reporting periods ending on or after March 31, 2005; and

(5) For rural emergency hospitals, effective for cost reporting periods beginning on or after January 1, 2023.

* * * * *

21. Section 413.198 is amended by revising paragraph (b)(4)(ii) to read as follows:

§ 413.198 Recordkeeping and cost reporting requirements for outpatient maintenance dialysis.

* * * * *

(b) * * *

(4) * * *

(ii) Section 413.420, Payment to independent organ procurement organizations and to histocompatibility laboratories for kidney acquisition costs;

* * * * *

22. Section 413.400 is amended by revising the definitions of “Hospital-based organ procurement organization (HOPO)”, “Transplant hospital”, “Transplant hospital/HOPO (TH/HOPO)”, and “Transplant program” to read as follows:

§ 413.400 Definitions.

* * * * *

Hospital-based organ procurement organization (HOPO) means an organ procurement organization that is considered a department of the TH and reports organ acquisition costs it incurs on the TH's Medicare cost report.

* * * * *

Transplant hospital (TH) means a hospital that furnishes organ transplants and other medical and surgical specialty services required for the care of transplant patients.

Transplant hospital/HOPO (TH/HOPO) refers to a TH, or a TH that operates a HOPO (as previously defined in this section) and performs organ procurement activities as one entity reported on the TH's Medicare cost report.

Transplant program means an organ-specific transplant program within a TH (as defined in this section).

* * * * *

23. Section 413.402 is amended by revising paragraphs (a), (b)(3), (4), and (7), (b)(8)(i) and (ii), and (d)(2)(ii) to read as follows:

§ 413.402 Organ acquisition costs.

(a) *Costs related to organ acquisition.* Costs recognized in paragraph (b) of this section are allowable costs incurred in the acquisition of organs from a living donor or a deceased donor

by the hospital, or from a deceased donor by an OPO. Additionally, there are administrative and general costs that may be allowable and included on the cost report for an OPO or TH/HOPO.

(b) * * *

(3) Other costs associated with excising organs, such as general routine and special care services (for example, intensive care unit or critical care unit services), provided to the living or deceased donor.

(4) Operating room and other inpatient ancillary services applicable to the living or deceased donor.

* * * * *

(7) Surgeons' fees for excising deceased organs (currently limited to \$1,250 for kidneys).

(8) * * *

(i) Excised organ to the TH; and

(ii) Deceased donor to procure organs when it is necessary to preserve clinical outcomes or to avoid loss of potentially transplantable organs.

* * * * *

(d) * * *

(2) * * *

(ii) Transportation costs of the deceased donor after organ procurement for funeral services or for burial.

* * * * *

24. Section 413.404 is amended by revising paragraphs (a)(2), (b)(2), (b)(3) introductory text, (b)(3)(i) introductory text, (b)(3)(i)(A) through (C), (b)(3)(ii) introductory text, (b)(3)(ii)(A) and (B), (b)(3)(ii)(C) introductory text, (b)(3)(ii)(C)(1) through (3), (c)(1)(i) and (ii), (c)(2)(i) through (iv), and (c)(3) to read as follows:

§ 413.404 Standard acquisition charge.

(a) * * *

(2) The SAC represents the average of the total organ acquisition costs associated with procuring either deceased donor organs or living donor organs, by organ type.

* * * * *

(b) * * *

(2) When a TH/HOPO furnishes an organ to another TH or IOPO, it must bill the receiving TH or IOPO its SAC by organ type, or the hospital's standard departmental charges that are reduced to cost.

(3) A TH must establish SACs for living donor organs. A TH/HOPO must establish SACs for deceased donor organs.

(i) Living donor SAC for THs –

(A) *Definition.* The living donor SAC is an average organ acquisition cost that a TH incurs to procure an organ from a living donor.

(B) *Establishment of living donor SAC.* A TH must establish a living donor SAC before the TH bills its first living donor transplant to Medicare.

(C) *Calculating the living donor SAC—(1) Initial living donor SAC.* A TH calculates its initial living donor SAC for each living donor organ type as follows:

(i) By estimating the reasonable and necessary organ acquisition costs it expects to incur for services furnished to living donors, and pre-admission services furnished to recipients of living donor organs during the hospital's cost reporting period.

(ii) By dividing the estimated amount described in paragraph (b)(3)(i)(C)(1)(i) of this section by the projected number of usable living donor organs to be procured by the TH during the TH's cost reporting period.

(2) *Subsequent living donor SAC.* A TH calculates its subsequent years' living donor SAC for each living donor organ type as follows:

(i) By using the TH's actual organ acquisition costs for the living donor organ type from the prior year's Medicare cost report, adjusted for any changes in the current year.

(ii) Dividing the costs in paragraph (b)(3)(i)(C)(2)(i) of this section by the actual number of usable living donor organs procured by the TH during that prior cost reporting period.

* * * * *

(ii) *Deceased donor SAC for TH/HOPOs—(A) Definition.* The deceased donor SAC is an average cost that a TH/HOPO incurs to procure a deceased donor organ.

(B) *Calculating the deceased donor SAC—(1) Initial deceased donor SAC.* A TH/HOPO calculates its initial deceased donor SAC for each deceased donor organ type as follows:

(i) By estimating the reasonable and necessary costs it expects to incur to procure deceased donor organs, combined with the expected costs of acquiring deceased donor organs from OPOs or other THs.

(ii) By dividing the estimated amount described in paragraph (b)(3)(ii)(B)(1)(i) of this section by the projected number of usable deceased donor organs to be procured by the TH/HOPO within the TH's cost reporting period.

(2) *Subsequent deceased donor SAC.* A TH/HOPO calculates its subsequent years' deceased donor SAC for each deceased donor organ type as follows:

(i) By using the TH's actual organ acquisition costs for the deceased donor organ type from the prior year's Medicare cost report, adjusted for any changes in the current year.

(ii) By dividing the costs in paragraph (b)(3)(ii)(B)(2)(i) of this section by the actual number of usable deceased donor organs procured by the TH/HOPO during that prior cost reporting period.

(C) *Costs to develop the deceased donor SAC.* Costs that may be used to develop the deceased donor SAC include, but are not limited to the following:

(1) Costs of organs acquired from other THs or OPOs.

(2) Costs of transportation as specified in § 413.402(b)(8).

(3) Surgeons' fees for excising deceased donor organs (currently limited to \$1,250 for kidneys).

* * * * *

(c) * * *

(1) * * *

(i) Estimating the reasonable and necessary costs it expects to incur for services furnished to procure deceased donor non-renal organs during the IOPO's cost reporting period; and

(ii) Dividing the amount estimated in paragraph (c)(1)(i) of this section by the projected number of deceased donor non-renal organs the IOPO expects to procure within its cost reporting period.

* * * * *

(2) * * *

(i) *General.* An IOPO's contractor establishes the kidney SAC based on an estimate of, initial year projected or subsequent years' actual, reasonable and necessary costs the IOPO expects to incur to procure deceased donor kidneys during the IOPO's cost reporting period, divided by the, initial year projected or subsequent years' actual, number of usable deceased donor kidneys the IOPO expects to procure.

(ii) *Initial year.* The contractor develops the IOPO's initial kidney SAC based on the IOPO's budget information.

(iii) *Subsequent years.* The contractor computes the kidney SAC for subsequent years using the IOPO's costs related to kidney acquisition that were incurred in the prior cost reporting period and dividing those costs by the number of usable deceased donor kidneys procured during that cost reporting period. The kidney SAC amount is the interim payment made by the TH or other OPO to the IOPO, as set forth in § 413.420(d)(1).

(iv) *SAC adjustments.* The IOPO's contractor may adjust the kidney SAC during the year, if necessary, for cost changes.

* * * * *

(3) *Billing SACs for organs generally.* When an IOPO obtains an organ from another IOPO, the receiving IOPO is responsible for paying the procuring IOPO's SAC. The receiving IOPO uses its SAC for each organ type and not the procuring IOPO's SAC when billing the TH receiving the organ.

25. Section 413.412 is amended by revising the section heading and paragraphs (c) and (d) to read as follows:

§ 413.412 Intent to transplant, and counting en bloc, research, and unusable organs.

* * * * *

(c) *Research organs.* (1) For Medicare cost allocation purposes, organs used for research are not counted as Medicare usable organs or as total usable organs in the ratio used to calculate Medicare's share of organ acquisition costs (except pancreata for islet cell transplants as specified in § 413.406(a)).

(2) OPOs and THs must reduce their costs to procure organs for research from total organ acquisition costs on the Medicare cost report.

(d) *Counting of unusable organs.* (1) An organ is not counted as a Medicare usable organ or a total usable organ in the ratio used to calculate Medicare's share of organ acquisition costs if a surgeon determines, upon initial inspection or after removal of the organ, that the organ is not viable and not medically suitable for transplant and is therefore unusable.

(2) OPOs and THs include the cost to procure unusable organs, as described in paragraph (d)(1) of this section, in total organ acquisition costs reported on their Medicare cost report.

26. Section 413.414 is amended by revising paragraphs (a), (b), (c) introductory text, (c)(1) and (2), and (c)(3)(i) and (ii) to read as follows:

§ 413.414 Medicare secondary payer and organ acquisition costs.

(a) *General principle.* If a Medicare beneficiary has a primary health insurer other than Medicare and that primary health insurer has primary liability for the transplant and organ acquisition costs, the Medicare Program may share a liability for organ acquisition costs as a

secondary payer to the TH that performs the transplant in certain instances. To determine whether Medicare has liability to the TH that performs the transplant as a secondary payer for organ acquisition costs, it is necessary for the TH that performs the transplant to review the TH's agreement with the primary insurer.

(b) *Medicare has no secondary payer liability for organ acquisition costs.* If the primary insurer's agreement requires the TH to accept the primary insurer's payment as payment in full for the transplant and the associated organ acquisition costs, Medicare has zero liability as a secondary payer with no payment obligation for the transplantation costs or the organ acquisition costs, and the organ at issue is not a Medicare usable organ.

(c) *Medicare may have secondary payer liability for organ acquisition costs.* When the primary insurer's agreement does not require the TH that performs the transplant to accept the payment from the primary insurer as payment in full, and the payment the TH receives from the primary insurer for the transplant and organ acquisition costs is insufficient to cover the entire cost, Medicare may have a secondary payer liability to the TH that performs the transplant for the organ acquisition costs.

(1) To determine whether Medicare has a secondary payer liability for the organ acquisition costs, it is necessary for the TH that performs the transplant to submit a bill to its contractor and to compare the total cost of the transplant, including the transplant DRG amount and the organ acquisition costs, to the payment received from the primary payer.

(2) If the payment from the primary payer is greater than the cost of the transplant DRG and the organ acquisition costs, there is no Medicare liability and the TH must not count the organ as a Medicare usable organ.

(3) * * *

(i) The TH must pro-rate the payment from the primary payer between the transplant DRG payment and the organ acquisition payment.

(ii) Only the TH that performs the transplant counts the organ as a Medicare usable organ.

* * * * *

27. Section 413.416 is amended by revising paragraphs (a), (b), (c) introductory text, (c)(2) through (4), (d) introductory text, and (d)(1) to read as follows:

§ 413.416 Organ acquisition charges for kidney-paired exchanges.

(a) *Initial living donor evaluations.* When a recipient and donor elect to participate in a kidney paired exchange, the costs of the initial living donor evaluations are incurred by the originally intended recipient's TH, regardless of whether the living donor actually donates to their originally intended recipient, a kidney paired exchange recipient, or does not donate at all.

(b) *Additional tests after a match.* In a kidney paired exchange, regardless of whether an actual donation occurs, once the donor and recipient are matched, any additional tests requested by the recipient's TH and performed by the donor's TH, are billed to the recipient's TH as charges reduced to cost (using the donor's TH's cost to charge ratio) and included as acquisition costs on the recipient TH's Medicare cost report.

(c) *Procurement and transport of a kidney.* When a donor's TH procures and furnishes a kidney to a recipient's TH all of the following are applicable:

* * * * *

(2)(i) The donor's TH bills the recipient's TH.

(ii) The donor's TH bills its charges reduced to cost, or bills its applicable kidney SAC for the reasonable costs associated with procuring, packaging, and transporting the kidney.

(3) The donor's TH records the costs described in paragraph (c)(2)(ii) of this section on its Medicare cost report as kidney acquisition costs and offsets any payments received from the recipient's TH against its kidney acquisition costs.

(4) The recipient's TH records as part of its kidney acquisition costs -

(i) The amounts billed by the donor's TH for the reasonable costs associated with procuring, packaging, and transporting the organ; and

(ii) Any additional testing performed and billed by the donor's TH.

(d) *Donor's procurement occurs at recipient TH.* In a kidney-paired exchange—

(1) When a donor's TH does not procure a kidney, but the donor travels to the recipient's TH for the organ procurement, the reasonable costs associated with the organ procurement are included on the Medicare cost report of the recipient's TH; and

* * * * *

28. Section 413.418 is revised to read as follows:

§ 413.418 Amounts billed to organ procurement organizations for hospital services provided to deceased donors and included as organ acquisition costs.

(a) *General.* A donor community hospital (a Medicare-certified non-TH) and a TH incur costs for hospital services attributable to a deceased donor or a donor whose death is imminent. Organ acquisition costs include hospital services authorized by the OPO when there is consent to donate, and declaration of death has been made or death is imminent and these services must be provided prior to declaration of death. These costs must not be part of medical treatment that primarily offers a medical benefit to the patient as determined by a healthcare team.

(b) *Amounts billed for organ acquisition costs.* For cost reporting periods beginning on or after February 25, 2022, when a donor community hospital or TH incurs costs for services furnished to a deceased donor, as authorized by the OPO, the donor community hospital or TH must bill the OPO the lesser of its customary charges that are reduced to cost by applying its most recently available hospital specific cost-to-charge ratio for the period in which the service was rendered, or a negotiated rate.

29. Section 413.420 is amended by revising paragraphs (a), (c)(1)(ii), (iv), and (v), (d), and (e)(2)(i) and (ii) to read as follows:

§ 413.420 Payment to independent organ procurement organizations and

histocompatibility laboratories for kidney acquisition costs.

(a) *Principle.* (1) Covered services furnished by IOPOs and histocompatibility laboratories in connection with kidney acquisition and transplantation are reimbursed under the principles for determining reasonable cost contained in this part.

(2) Services furnished by IOPOs and histocompatibility laboratories, that have an agreement with the Secretary in accordance with paragraph (c) of this section, are paid directly by the TH using a kidney SAC (for an IOPO) or contractor-established rates (for a histocompatibility laboratory). (The reasonable costs of services furnished by IOPOs or laboratories are reimbursed in accordance with the principles contained in §§ 413.60 and 413.64.)

* * * * *

(c) * * *

(1) * * *

(ii) To permit CMS to designate a contractor to determine the interim reimbursement rate, payable by the THs for services provided by the IOPO or laboratory, and to determine Medicare's reasonable cost based upon the cost report filed by the IOPO or laboratory.

* * *

(iv) To pay to CMS amounts that have been paid by CMS to THs and that are determined to be in excess of the reasonable cost of the services provided by the IOPO or laboratory.

(v) Not to charge any individual for items or services for which that individual is entitled to have payment made under section 1881 of the Act.

* * * * *

(d) *Interim reimbursement.* (1) THs with approved kidney transplant programs pay the IOPO or histocompatibility laboratory for their pre-transplantation services on the basis of an interim rate established by the contractor for that IOPO or laboratory.

(2) The interim rate is a kidney SAC or contractor established rates, based on costs associated with procuring a kidney for transplantation, incurred by an IOPO or laboratory respectively, during its previous fiscal year. If there is not adequate cost data to determine the initial interim rate, the contractor determines it according to the IOPO's or laboratory's estimate of its projected costs for the fiscal year.

(3) Payments made by THs on the basis of interim rates are reconciled directly with the IOPO or laboratory after the close of its fiscal year, in accordance with paragraph (e) of this section.

(4) Information on the interim rate for all IOPOs and histocompatibility laboratories must be disseminated to all THs and contractors.

(e) * * *

(2) * * *

(i) *Retroactive adjustment.* A retroactive adjustment in the amount paid under the interim rate is made in accordance with § 413.64(f).

(ii) *Lump sum adjustment.* If the determination of reasonable cost reveals an overpayment or underpayment resulting from the interim reimbursement rate paid to THs, a lump sum adjustment is made directly between that contractor and the IOPO or laboratory.

* * * * *

PART 416—AMBULATORY SURGICAL SERVICES

30. The authority citation for part 416 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

31. Section 416.166 is amended by revising paragraph (d)(1) to read as follows:

§ 416.166 Covered surgical procedures.

* * * * *

(d) * * *

(1) *Pre-proposed rule CPL recommendation process.* On or after January 1, 2024, an

external party may recommend a surgical procedure by March 1 of a calendar year for the list of ASC covered surgical procedures for the following calendar year.

* * * * *

32. Section 416.172 is amended by adding paragraph (h) to read as follows:

§ 416.172 Adjustments to national payment rates.

* * * * *

(h) *Special payment for certain code combinations—(1) Eligibility.* A code combination is eligible for the payment specified in paragraph (h)(2) of this section if the code combination is—

(i) Eligible for a C-APC complexity adjustment under the OPPS; and

(ii) Comprised of a separately payable surgical procedure, that is listed on the ASC Covered Procedures list (§ 416.166), and one or more packaged add-on codes that are listed on the ASC covered procedures or ancillary services lists (§ 416.164(b)).

(2) *Calculation of payment.* (i) Except as specified in paragraph (h)(2)(ii) of this section, CMS calculates the payment for code combinations that meet the eligibility requirements in paragraph (h)(1) of this section by applying the methodology specified in § 416.171(a) to the OPPS C-APC complexity-adjusted relative weights.

(ii) For primary procedures assigned device-intensive status that are a component of a code combination that is eligible for payment under paragraph (h)(2) of this section, the primary procedure of the code combination retains its device-intensive status, and—

(A) The device portion is equivalent to the device portion of the device-intensive APC under the OPPS (§ 419.44(b)); and

(B) The non-device portion is calculated in accordance with the methodology specified in § 416.171(a).

33. Section 416.174 is amended by revising paragraph (a) to read as follows:

§ 416.174 Payment for non-opioid pain management drugs and biologicals that function as supplies in surgical procedures.

(a) Eligibility for separate payment for non-opioid pain management drugs and biologicals. Beginning on or after January 1, 2022, a non-opioid pain management drug or biological that functions as a surgical supply is eligible for separate payment for an applicable calendar year if CMS determines it meets the following requirements through that year's rulemaking:

(1) The drug is approved under a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FDCA), under an abbreviated new drug application under section 505(j), or, in the case of a biological product, is licensed under section 351 of the Public Health Service Act. The product has an FDA approved indication for pain management or analgesia.

(2) The per-day cost of the drug or biological estimated by CMS for the year exceeds the OPPS drug packaging threshold set for such year through notice and comment rulemaking.

(3) The drug or biological does not have transitional pass-through payment status under § 419.64. In the case where a drug or biological otherwise meets the requirements under § 416.174 and has transitional pass-through payment status that expires during the calendar year, the drug or biological will qualify for separate payment as specified in paragraph (a) during such calendar year on the first day of the next calendar year quarter following the expiration of its pass-through status.

(4) The drug or biological is not already separately payable in the OPPS or ASC payment system under a policy other than the one specified in this section.

* * * * *

PART 419—PROSPECTIVE PAYMENT SYSTEMS FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

34. The authority citation for part 419 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395l(t), and 1395hh.

35. Part 419 is amended by revising the heading to read as set forth above.

36. Section 419.43 is amended by adding paragraph (j) to read as follows:

§ 419.43 Adjustments to national program payment and beneficiary copayment amounts.

* * * * *

(j) *Additional resource costs of domestic National Institute for Occupational Safety and Health approved surgical N95 respirators—(1) General rule.* For cost reporting periods beginning on or after January 1, 2023, CMS provides for a payment adjustment for the additional resource costs of domestic National Institute for Occupational Safety and Health approved surgical N95 respirators as described in paragraph (j)(2) of this section.

(2) *Amount of adjustment.* The payment adjustment is based on the estimated difference in the reasonable cost incurred by the hospital for domestic National Institute for Occupational Safety and Health approved surgical N95 respirators purchased during the cost reporting period as compared to other National Institute for Occupational Safety and Health approved surgical N95 respirators purchased during the cost reporting period.

(3) *Budget neutrality.* CMS establishes the payment adjustment under paragraph (j)(2) of this section in a budget neutral manner.

37. Section 419.46 is amended by revising paragraph (f)(3)(iv) and adding paragraph (f)(3)(v) to read as follows:

§ 419.46 Participation, data submission, and validation requirements under the Hospital Outpatient Quality Reporting (OQR) Program.

* * * * *

(f) * * *

(3) * * *

(iv) Any hospital that passed validation in the previous year but had a two-tailed confidence interval that included 75 percent; or

(v) Any hospital with a two-tailed confidence interval that is less than 75 percent, and that had less than four quarters of data due to receiving an ECE for one or more quarters.

* * * * *

38. Section 419.47 is added to read as follows:

§ 419.47 Coding and Payment for Category B Investigational Device Exemption (IDE)

Studies

(a) *Creation of a new HCPCS code for Category B IDE Studies.* CMS will create a new HCPCS code, or revise an existing HCPCS code, to describe a Category B IDE study, which will include both the treatment and control arms, related device(s) of the study, as well as routine care items and services, as specified under 42 CFR 405.201, when CMS determines that:

(1) The Medicare coverage IDE study criteria in 42 CFR 405.212 are met; and

(2) A new or revised code is necessary to preserve the scientific validity of such a study, such as by preventing the unblinding of study.

(b) *Payment for Category B IDE Studies.* Where CMS creates a new HCPCS code or revises an existing HCPCS code under paragraph (a) of this section, CMS will:

(1) Make a single packaged payment for the HCPCS code that includes payment for the investigational device, placebo control, and routine care items and services of a Category B IDE study, as specified under 42 CFR 405.201; and

(2) Calculate the single packaged payment rate for the HCPCS code based on the average resources utilized for each study participant, including the frequency with which the investigational device is used in the study population.

39. Section 419.83 is amended by revising paragraphs (a)(3) and (b) to read as follows:

§ 419.83 List of hospital outpatient department services requiring prior authorization.

(a) * * *

(3) The Facet Joint Interventions service category requires prior authorization beginning for service dates on or after March 1, 2023.

(b) *Adoption of the list of services and technical updates.* (1) CMS will adopt the list of hospital outpatient department service categories requiring prior authorization and any updates or geographic restrictions through formal notice-and-comment rulemaking.

(2) Technical updates to the list of services, such as changes to the name of the service or CPT code, will be published on the CMS website.

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40. Subpart K is added to read as follows:

Subpart K - Payments to Rural Emergency Hospitals (REHs)

Sec.

419.90 Basis and scope of subpart.

419.91 Definitions.

419.92 Payment to rural emergency hospitals.

419.93 Payment for an off-campus provider-based department of a rural emergency hospital.

419.94 Preclusion of administrative and judicial review.

Subpart K - Payments to Rural Emergency Hospitals (REHs)

§ 419.90 Basis and scope of subpart.

(a) *Basis.* This subpart implements sections 1861(kkk) and 1834(x) of the Act, which establish the rural emergency hospital Medicare provider type and the payment requirements applying to such entities.

(b) *Scope.* This subpart describes the methodologies used to determine payment for REH services and the monthly facility payment amount paid to REHs.

§ 419.91 Definitions.

As used in this subpart -

Rural Emergency Hospital or *REH* means an entity as defined in § 485.502 of this chapter.

Rural Emergency Hospital (REH) Services means all covered outpatient department (OPD) services, as defined in section 1833(t)(1)(B) of the Act, excluding services described in section 1833(t)(1)(B)(ii), furnished by an REH that would be paid under the OPDS when

provided in a hospital paid under the OPPTS for outpatient services, provided that such services are furnished consistent with the conditions of participation in §§ 485.510 through 485.544 of this chapter.

§ 419.92 Payment to rural emergency hospitals.

(a) *Payment for REH services—(1) Medicare payment.* A rural emergency hospital that furnishes a REH service on or after January 1, 2023, is paid an amount equal to the amount of payment that would otherwise apply under section 1833(t) of the Act for the equivalent covered OPD service, increased by 5 percent.

(2) *Beneficiary copayment.* The beneficiary copayment for a REH service is the amount determined under section 1833(t)(8) of the Act for the equivalent covered OPD service, excluding the 5 percent payment increase described in paragraph (a)(1) of this section.

(b) *Monthly facility payment.* Effective January 1, 2023, REHs are paid a monthly facility payment equal to 1/12 of the annual additional facility payment amount described in paragraphs (b)(1) and (2) of this section.

(1) *Calculation of monthly facility payment for 2023.* For calendar year 2023, the annual additional facility payment amount is:

(i) The total amount that the Secretary determines was paid by the Medicare program and from beneficiary copayments to all critical access hospitals in calendar year 2019; minus—

(ii) The estimated total amount that the Secretary determines would have been paid by the Medicare program and from beneficiary copayments to critical access hospitals in calendar year 2019 if payment were made for inpatient hospital, outpatient hospital, and skilled nursing facility services under the applicable prospective payment systems for such services during calendar year 2019; divided by—

(iii) The total number of critical access hospitals enrolled in Medicare in calendar year 2019.

(2) *Calculation of monthly facility payment for 2024 and subsequent years.* For calendar year 2024 and each subsequent calendar year, the amount of the additional annual facility payment is the amount of the preceding year's additional annual facility payment, increased by the hospital market basket percentage increase as described under section 1886(b)(3)(B)(iii) of the Act.

(3) *Recording and Reporting the use of the monthly facility payment.* A rural emergency hospital receiving the monthly facility payment must maintain detailed information as specified by the Secretary as to how the facility has used the monthly facility payments and must make this information available to the Secretary upon request.

(c) *Payment for services furnished by an REH that do not meet the definition of REH services.* A service furnished by an REH that does not meet the definition of an REH service under § 419.91, including a hospital service that is excluded from payment under the OPPS as described in § 419.22, is paid for under the payment system applicable to the service, provided the requirements for payment under that system are met.

(1) *Payment for ambulance services.* Ambulance services furnished by an entity owned and operated by a rural emergency hospital are paid under the ambulance fee schedule as described at section 1834(l) of the Act.

(2) *Payment for post-hospital extended care services.* Post-hospital extended care services furnished by a rural emergency hospital that has a unit that is a distinct part licensed as a skilled nursing facility are paid under the skilled nursing facility prospective payment system described at section 1888(e) of the Act.

§ 419.93 Payment for an off-campus provider-based department of a rural emergency hospital.

(a) Items and services furnished by an off-campus provider-based department of an REH, as defined in paragraph (b) of this section, are not applicable items and services under sections 1833(t)(1)(B)(v) and (t)(21) of the Act and are paid as follows:

(1) REH services furnished by an off-campus provider-based department of an REH are paid as described in § 419.92(a)(1).

(2) Services that do not meet the definition of REH services that are furnished by an off-campus provider-based department of an REH are paid as described under § 419.92(c).

(b) For the purpose of this section, “off-campus provider-based department of an REH” means a “department of a provider” (as defined at § 413.65(a)(2) of this chapter) that is not located on the campus (as defined in § 413.65(a)(2) of this chapter) or within the distance described in such definition from a “remote location of a hospital” (as defined in § 413.65(a)(2) of this chapter) that meets the requirements for provider-based status under § 413.65 of this chapter.

§ 419.94 Preclusion of administrative and judicial review.

There is no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the following:

(a) The determination of whether a rural emergency hospital meets the requirements of this subpart.

(b) The determination of payment amounts under this subpart.

(c) The requirements established by this subpart.

PART 424-CONDITIONS FOR MEDICARE PAYMENT

41. The authority for part 424 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

42. Amend § 424.518 by revising paragraph (a)(1)(viii) to read as follows:

§ 424.518 Screening levels for Medicare providers and suppliers.

(a) * * *

(1) * * *

(viii) Hospitals, including critical access hospitals, rural emergency hospitals, Department of Veterans Affairs hospitals, and other federally owned hospital facilities.

* * * * *

43. Add § 424.575 to read as follows:

§ 424.575 Rural emergency hospitals.

(a) A rural emergency hospital (as defined in § 485.502 of this chapter) must comply with all applicable provisions in this subpart in order to enroll and maintain enrollment in Medicare.

(b) A provider that is currently enrolled in Medicare as a critical access hospital or a hospital (as defined in section 1886(d)(1)(B) of the Act) converts its existing enrollment to that of a rural emergency hospital (as defined in § 485.502 of this chapter) via a Form CMS-855A change of information application per § 424.516 rather than a Form CMS-855A initial enrollment application.

Dated: July 14, 2022.

Xavier Becerra,

Secretary,

Department of Health and Human Services.

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