

U.S. Department of Labor

Office of Inspector General—Office of Audit

REPORT TO THE OFFICE OF WORKERS' COMPENSATION PROGRAMS



OWCP DID NOT ENSURE BEST PRICES AND ALLOWED INAPPROPRIATE, POTENTIALLY LETHAL PRESCRIPTIONS IN THE FECA PROGRAM

This report was prepared by Harper, Rains, Knight & Company under contract to the U.S. Department of Labor, Office of Inspector General, and, by acceptance, it becomes a report of the Office of Inspector General.

A handwritten signature in cursive script that reads "Carolyn R. Hantry".

U.S. Department of Labor
Assistant Inspector General for Audit

DATE ISSUED: MARCH 31, 2023
REPORT NUMBER: 03-23-001-04-431



BRIEFLY...

OWCP DID NOT ENSURE BEST PRICES AND ALLOWED INAPPROPRIATE, POTENTIALLY LETHAL PRESCRIPTIONS IN THE FECA PROGRAM

March 31, 2023

WHY OIG CONDUCTED THE AUDIT

The Department of Labor's Office of Workers' Compensation Programs (OWCP) provides workers' compensation coverage to approximately 2.6 million federal and postal workers through the Federal Employees' Compensation Act (FECA) program. Recent Office of Inspector General audit work found OWCP had not done enough to ensure it paid the best price for prescription drugs in the FECA program. Specifically, the audits noted OWCP lacked a pharmacy benefit manager to help contain costs and had not determined if alternative prescription drug pricing methodologies would be more competitive.

WHAT OIG DID

The OIG contracted with the independent certified public accounting firm of Harper, Rains, Knight & Company, P.A. (HRK) to conduct an audit to answer the following:

Has OWCP effectively managed pharmaceutical spending in the FECA program?

To answer this question, HRK's audit included: analyzing 6 years of pharmaceutical data covering Fiscal Year 2015 through Fiscal Year 2020; interviewing OWCP management; reviewing OWCP policies, procedures, and other documentation; and comparing the FECA program to industry best practices and other workers' compensation programs.

WHAT OIG FOUND

HRK found OWCP did not effectively manage pharmaceutical spending in the FECA program from Fiscal Year 2015 through Fiscal Year 2020. Specifically, OWCP did not pay the best available prices for prescription drugs. HRK identified up to \$321.26 million in excess spending during the audit period. In addition, OWCP did not effectively monitor pharmaceutical policy changes to ensure implementation, resulting in claimants receiving thousands of inappropriate prescriptions and potentially lethal drugs, including 1,330 prescriptions for fast-acting fentanyl after issuing a policy that restricted its use.

HRK also found OWCP failed to timely identify and address emerging issues and did not perform sufficient oversight of prescription drugs that are highly scrutinized and rarely covered in workers' compensation programs. As a result, OWCP spent hundreds of millions of dollars on drugs that may not have been necessary or appropriate for FECA claimants.

Finally, HRK found OWCP lacked sufficient clinical expertise and guidelines to ensure appropriate pharmaceutical decisions, which could negatively impact claimants' health, recovery, and return to work.

WHAT OIG RECOMMENDED

HRK made 10 recommendations to OWCP to strengthen management of pharmaceuticals in the FECA program, specifically regarding: evaluating alternate pricing methodologies, ensuring implementation of and adherence to policies, identifying emerging issues by developing and implementing an ongoing pharmaceutical monitoring program, ensuring sufficient clinical expertise among FECA staff, and using evidence-based clinical guidelines to inform prescription drug coverage policies. OWCP generally agreed with the recommendations.

READ THE FULL REPORT

<https://www.oig.dol.gov/public/reports/oa/2023/03-23-001-04-431.pdf>

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INSPECTOR GENERAL'S REPORT

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The U.S. Department of Labor Office of Inspector General contracted with the independent certified public accounting firm of Harper, Rains, Knight & Company, P.A. (HRK) to conduct a performance audit the Office of Workers' Compensation Programs' (OWCP) management of pharmaceutical spending in the Federal Employees' Compensation Act (FECA) program.

The OIG monitored HRK's work to ensure it met professional standards and contractual requirements. HRK's independent audit was conducted in accordance with generally accepted government auditing standards.

HRK was responsible for the auditors' evaluation and the conclusions expressed in the report while the Office of Inspector General reviewed HRK's report and supporting documentation.

PURPOSE

OWCP's FECA program provides workers' compensation coverage to approximately 2.6 million federal and postal workers around the world for employment-related injuries and occupational diseases. In Fiscal Year (FY) 2015 and FY 2016, a sharp increase in pharmaceutical¹ spending for the FECA program raised concerns. Subsequent Office of Inspector General work found OWCP had not done enough to ensure it paid the best prices for prescription

¹ Relating to medicinal drugs, or their preparation, use, or sale

drugs, specifically noting the lack of a pharmacy benefit manager² to help contain costs and the failure to determine if alternative prescription drug pricing methodologies would be more competitive.³

In response, OWCP took a number of actions to reduce pharmaceutical spending, including implementing controls on prescriptions for compounded drugs⁴ and for opioids. According to data provided by OWCP, it significantly decreased total compounded drug spending from almost \$256 million in FY 2016 to less than \$176,000 in FY 2020 and reduced opioid spending from over \$86 million in FY 2016 to approximately \$29 million in FY 2020.⁵ However, the Office of Inspector General remained concerned about OWCP's ability to effectively manage the cost, as well as the use, of pharmaceuticals in the FECA program. For instance, we noted that, despite the reduction in compounded drug costs, spending on other prescription drugs (i.e., non-compounded) rose almost 10 percent from FY 2015 to FY 2020.

Given these concerns, we contracted with HRK to conduct a performance audit to answer the following question:

Has OWCP effectively managed pharmaceutical spending in the FECA program?

To answer this question, HRK's audit included: analyzing 6 years of pharmaceutical data covering FY 2015 through FY 2020; interviewing OWCP management; reviewing OWCP policies, procedures, and other documentation; and performing comparative analyses of the FECA program and industry best practices and other workers' compensation programs.

RESULTS

HRK found OWCP did not effectively manage pharmaceutical spending in the FECA program from FY 2015 through FY 2020. Specifically, OWCP did not pay the best available prices for prescription drugs. HRK identified up to

² Pharmacy Benefit Managers are third-party administrators of prescription drug programs, primarily responsible for: developing and maintaining formularies, which include an approved listing of prescriptions; negotiating discounts and rebates with drug manufacturers; and processing and paying prescription drug claims.

³ OWCP Must Continue Strengthening Management of FECA Pharmaceuticals, Including Opioids, Report No. 03-10-002-04-431 (May 14, 2019), <https://www.oig.dol.gov/public/reports/oa/2019/03-19-002-04-431.pdf>

⁴ Generally, compounding is a practice in which a licensed pharmacist or physician combines ingredients of a drug to create a medication tailored to the needs of an individual patient.

⁵ HRK calculated these values differently than OWCP. The values used throughout this report are HRK's calculations unless otherwise specified.

\$321.26 million in excess spending during the audit period (see Exhibit 1, Table 5 for questioned costs that the audit team identified). In addition, OWCP did not effectively monitor pharmaceutical policy changes to ensure implementation, resulting in claimants receiving thousands of inappropriate prescriptions⁶ and potentially lethal drugs, including 1,330 prescriptions for fast-acting fentanyl after issuing a policy that restricted its use.

HRK also found OWCP failed to timely identify and address emerging issues and did not perform sufficient oversight of prescription drugs that are highly scrutinized and rarely covered in workers' compensation programs. As a result, OWCP spent hundreds of millions of dollars on drugs that may not have been necessary or appropriate for FECA claimants.

Finally, HRK found OWCP lacked sufficient clinical expertise and guidelines to ensure appropriate pharmaceutical decisions, which could negatively impact claimants' health, recovery, and return to work.



Carolyn R. Hantz
Assistant Inspector General for Audit

⁶ Inappropriate prescriptions are prescriptions that are not properly authorized and may be wasteful, unnecessary, or even dangerous for FECA claimants.



CONTRACTOR PERFORMANCE AUDIT REPORT

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We were engaged by the U.S. Department of Labor Office of Inspector General (OIG) to conduct a performance audit of the Office of Workers' Compensation Programs' (OWCP) management of pharmaceutical spending in the Federal Employees' Compensation Act (FECA) program for the period covering Fiscal Year (FY) 2015 through FY 2020. We conducted the audit to answer the following question:

Has OWCP effectively managed pharmaceutical spending in the FECA program?

To accomplish our objective, we: analyzed pharmaceutical data from FY 2015 through FY 2020; conducted interviews with OWCP management; reviewed policies, procedures, and contractual agreements; and identified, collected, reviewed, and summarized relevant research documents, reports, papers, training documents, and related information. Additionally, we performed comparative analyses between the FECA program's policies and performance and industry best practices and other workers' compensation programs.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

RESULTS

Based on the results of our work, we found OWCP did not effectively manage pharmaceutical spending in the FECA program from FY 2015 through FY 2020. Specifically, OWCP did not pay the best available prices for prescription drugs; we identified up to \$321.26 million in excess spending during the audit period. In addition, OWCP did not effectively monitor pharmaceutical policy changes to ensure implementation, resulting in claimants receiving thousands of inappropriate prescriptions and potentially lethal drugs, including 1,330 prescriptions for fast-acting fentanyl after issuing a policy that restricted its use.

We also found OWCP failed to timely identify and address emerging issues and did not perform sufficient oversight of prescription drugs that are highly scrutinized and rarely covered in workers' compensation programs. As a result, OWCP spent hundreds of millions of dollars on drugs that may not have been necessary or appropriate for FECA claimants.⁷

Finally, OWCP lacked sufficient clinical expertise and guidelines to ensure appropriate pharmaceutical decisions, which could negatively impact claimants' health, recovery, and return to work.

OWCP DID NOT PAY THE BEST AVAILABLE PRICES FOR PRESCRIPTION DRUGS

OWCP did not pay the best prices for prescription drugs in the FECA program because it did not have a process to ensure its pricing was competitive with other comparable payers in the industry. For example, OWCP did not compare its pricing to publicly available pricing benchmarks. In 2017, the OIG reported⁸ that OWCP lacked controls to ensure the prices it paid for drugs were fair and reasonable, noting OWCP had not effectively evaluated costs or pricing methodologies. In addition, OWCP also did not capitalize on additional ways to reduce pharmaceutical spending, such as taking advantage of manufacturer rebates. Although OWCP believed its pricing was competitive with other workers' compensation programs, it did not identify alternate pricing methodologies or

⁷ Under FECA, a federal employee or postal worker who has sustained a work-related injury or disease is eligible to file claims for benefits such as medical care, wage loss replacement, and help in returning to work.

⁸ Interim Report on Audit of Pharmaceutical Management in DOL Benefit Programs - OWCP Needs Better Controls Over Compounded Prescription Drugs, Report No. 03-17-001-04-431 (May 23, 2017), <https://www.oig.dol.gov/public/reports/oa/2017/03-17-001-04-431.pdf>

other opportunities that could have reduced pharmaceutical spending because it did not have processes to do so. As a result, OWCP did not realize up to \$321.26 million in savings of taxpayer dollars during the audit period.

As a steward of federal funds, OWCP has a responsibility to realize the best prices possible. The Federal Chief Information Officers Handbook provides Chief Information Officers, agency heads, and other senior leaders a collection of resources focused on issues related to management in the federal government.⁹ One of the policies and initiatives the handbook addresses is the President's Management Agenda, which lays out a long-term vision for modernizing the federal government in key areas that will improve the ability of agencies to deliver mission outcomes, provide excellent service, and effectively steward taxpayer dollars on behalf of the American people.

It states, in part:

Effective stewardship of taxpayer funds is a crucial responsibility of Government, from preventing fraud to maximizing impact. Taxpayer dollars must go to effective programs that produce results efficiently.¹⁰

Further, OWCP's Vision Statement states the agency "will serve as a responsible steward of the resources entrusted to it."

Prescription drug prices vary widely in the market, and using multiple pricing lists to compare and identify the lowest prices is a pricing strategy that can reduce overall pharmaceutical spending and aid in saving taxpayer dollars.¹¹ We compared the prices OWCP paid to two publicly available benchmark pricing lists—the Affordable Care Act Federal Upper Limit (ACA FUL)¹² and National

⁹ U.S. Chief Information Officers Council, Federal Chief Information Officers Handbook, last accessed November 16, 2022, <https://www.cio.gov/handbook/policies-initiatives/pma/>

¹⁰ U.S. Chief Information Officers Council, Federal Chief Information Officers Handbook, last accessed November 16, 2022, Chapter 6.1, <https://www.cio.gov/handbook/policies-initiatives/pma/>

¹¹ For more information on pricing, please see: Kaiser Family Foundation, "Pricing and Payment for Medicaid Prescription Drugs" (January 23, 2020), last accessed August 29, 2022, <https://www.kff.org/medicaid/issue-brief/pricing-and-payment-for-medicare-prescription-drugs/>.

¹² For more information on ACA FUL, please see: Medicaid.gov, "Federal Upper Limit: Affordable Care Act Federal Upper Limit" (page last updated March 10, 2021), last accessed August 29, 2022, <https://www.medicare.gov/medicaid/prescription-drugs/federal-upper-limit/index.html>.

Average Drug Acquisition Cost (NADAC)¹³—and to a proprietary Maximum Allowable Cost (MAC)¹⁴ price list. We found the prices OWCP paid for prescription drugs were not competitive, and we identified excess spending of up to \$321.26 million over the audit period.

OWCP PRESCRIPTION DRUG PRICING WAS NOT COMPETITIVE

During the audit period, OWCP relied on its fee schedule, based on Average Wholesale Price (AWP),¹⁵ to set the prices it paid for pharmaceuticals in the FECA program. The OIG’s 2019 report¹⁶ stated that OWCP officials believed FECA’s pharmaceutical pricing was competitive with other workers’ compensation programs. However, we found OWCP paid significantly higher prices for certain prescription drugs when compared: to the ACA FUL price list, to a NADAC-equivalent price list similar to the State of California’s fee schedule, and to a proprietary MAC price list. These three comparative analyses identified excess spending in the respective amounts of \$85.96 million, \$161.64 million, and \$321.26 million.

COMPARATIVE ANALYSIS: FECA PRICING AND ACA FUL PRICING

The ACA FUL is a drug pricing benchmark, based on a formula described in the Affordable Care Act, used by Medicaid and designed to make the government a “prudent buyer – and reduce Medicaid expenditures.”¹⁷ It can serve as a

¹³ For more information on NADAC, please see: Centers for Medicaid & Medicare Services, “Methodology for Calculating the National Average Drug Acquisition Cost (NADAC) for Medicaid Covered Outpatient Drugs” (January 2021), last accessed August 29, 2022, <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/ful-nadac-downloads/nadacmethodology.pdf>.

¹⁴ For more information on MAC pricing, please see: Academy of Managed Care Pharmacy, “Maximum Allowable Cost (MAC) Pricing” (October 28, 2021), last accessed August 29, 2022, <https://www.amcp.org/policy-advocacy/policy-advocacy-focus-areas/where-we-stand-position-statements/maximum-allowable-cost-mac-pricing>.

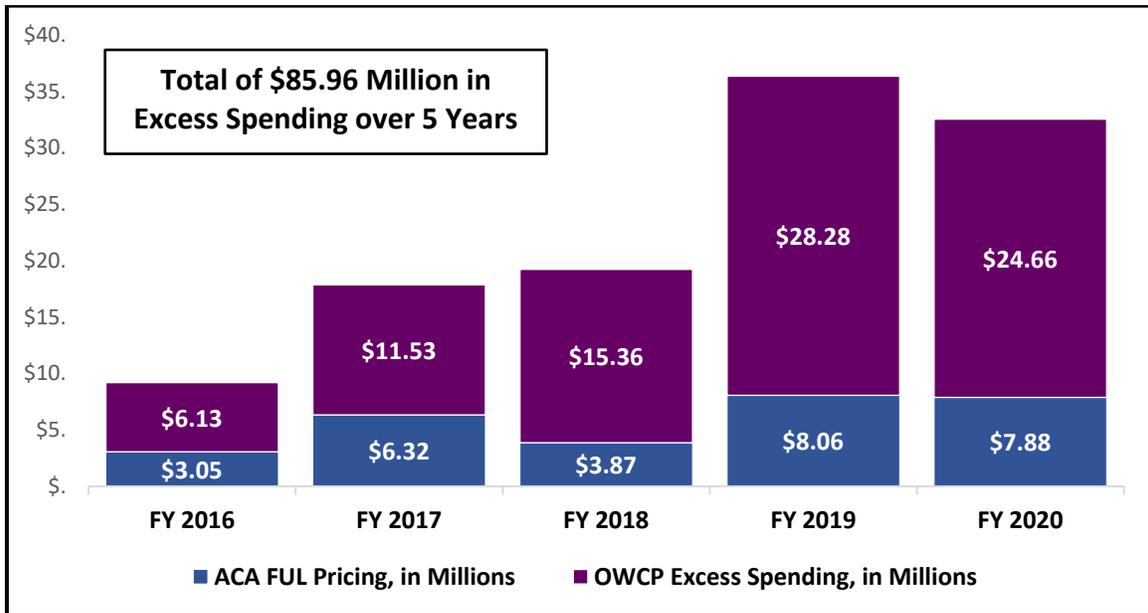
¹⁵ AWP is a prescription drug pricing benchmark used throughout the healthcare industry. Although it describes the average price paid to buy a drug from a wholesaler, it does not include discounts/rebates and is not a true representation of actual market prices paid. For more information on AWP, please see: Drugs.com, “Average Wholesale Price (AWP) as a Pricing Benchmark” (last updated January 27, 2022), last accessed August 29, 2022, <https://www.drugs.com/article/average-wholesale-price-awp.html>.

¹⁶ OWCP Must Continue Strengthening Management of FECA Pharmaceuticals, Including Opioids, Report No. 03-10-002-04-431 (May 14, 2019), <https://www.oig.dol.gov/public/reports/oa/2019/03-19-002-04-431.pdf>

¹⁷ Kaiser Family Foundation, “Pricing and Payment for Medicaid Prescription Drugs,” (January 23, 2020), last accessed August 29, 2022, <https://www.kff.org/medicaid/issue-brief/pricing-and-payment-for-medicaid-prescription-drugs/>

maximum cost list for prescription drugs available for purchase at retail community pharmacies nationwide. For each year from FY 2016 through FY 2020, we identified the top 10 drugs for which OWCP paid more than the ACA FUL price; in these 5 years, we identified a total of 17 unique drugs, for which OWCP paid \$115.14 million. Had OWCP paid ACA FUL prices for those 17 drugs, it could have saved \$85.96 million from FY 2016 through FY 2020 (see Figure 1).

Figure 1: Excess FECA Pharmaceutical Spending Using ACA FUL Price List, FY 2016–FY 2020



Source: OIG graphic representation of HRK comparative analysis

Of this total \$85.96 million in excess spending, OWCP could have saved \$51 million on 4 prescription drugs:

- diclofenac solution 1.5 percent,¹⁸
- celecoxib capsule 200 milligram (MG),¹⁹

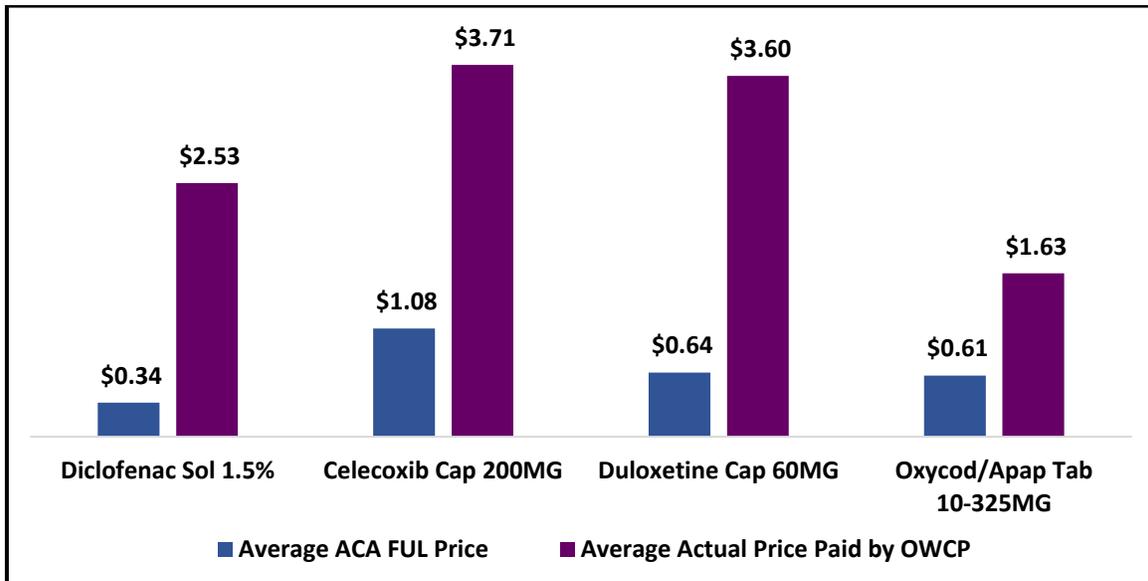
¹⁸ According to the Mayo Clinic, diclofenac is a nonsteroidal anti-inflammatory drug, used to treat mild or moderate pain that helps to relieve the symptoms of arthritis.

¹⁹ According to the Mayo Clinic, celecoxib is also a nonsteroidal anti-inflammatory drug, used to treat mild or moderate pain including from arthritis, including a type of arthritis that affects joints in the spine.

- duloxetine capsule 60MG,²⁰ and
- oxycodone/acetaminophen (Oxycod/Apap) tablet 10-325MG.²¹

For example, ACA FUL listed an average price of \$0.64 for a 60MG duloxetine capsule over the audit period while OWCP paid an average of \$3.60, generating an average potential savings of \$2.96 per unit (see Figure 2).

Figure 2: \$51 Million in Excess Spending from 4 Prescription Drugs, Comparative Analysis of Prices Paid: FECA Program to ACA FUL List



Source: OIG graphic representation of HRK comparative analysis

COMPARATIVE ANALYSIS: FECA PRICING AND NADAC PRICING

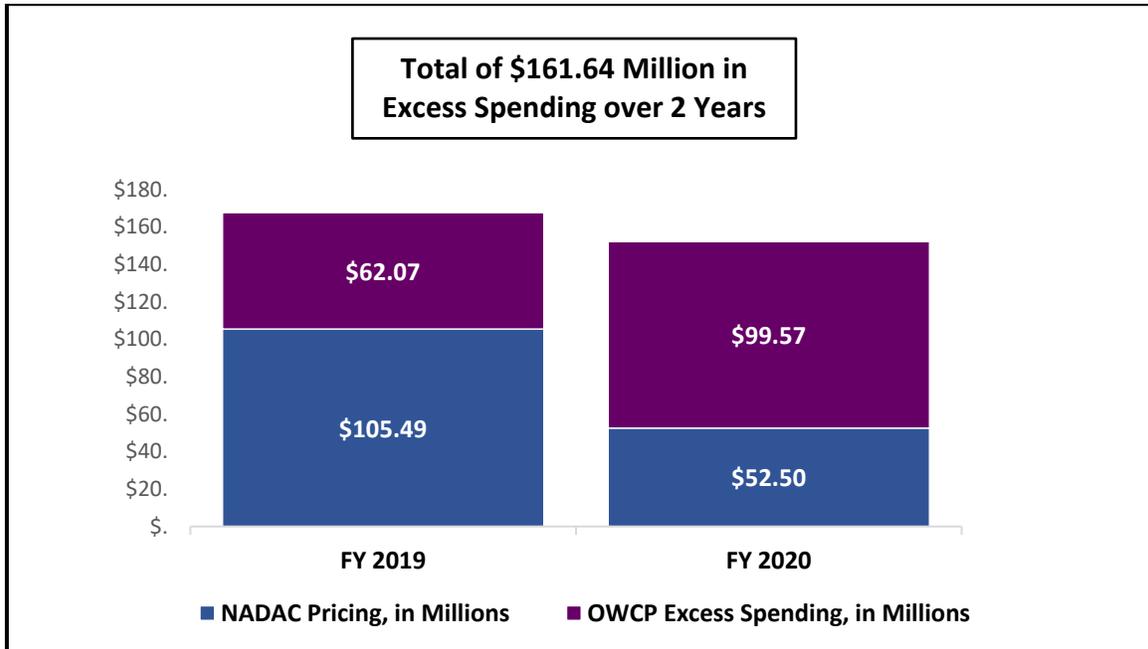
NADAC is a pricing benchmark developed by the Centers for Medicare & Medicaid Services based on actual acquisition costs paid by retail pharmacies. It is updated weekly and has been used, for example, by the State of California as the basis for its publicly available fee schedule. For all drugs that had a

²⁰ According to the Mayo Clinic, duloxetine is used to treat depression and anxiety as well as pain caused by nerve damage associated with diabetes and pain related to muscles and bones.

²¹ According to the Mayo Clinic, oxycodone and acetaminophen combination is used to relieve pain severe enough to require opioid treatment and when other pain medicines did not work well enough or cannot be tolerated.

NADAC price available for FY 2019 and FY 2020,²² we used NADAC-equivalent pricing²³ to recalculate OWCP-paid claims and identified \$161.64 million in excess spending out of \$319.63 million in spending for those 2 years (see Figure 3).

Figure 3: Excess FECA Pharmaceutical Spending Using NADAC-Equivalent Price List, FY 2019–FY 2020



Source: OIG graphic representation of HRK comparative analysis

COMPARATIVE ANALYSIS: FECA PRICING AND COMMERCIAL MAC LIST PRICING

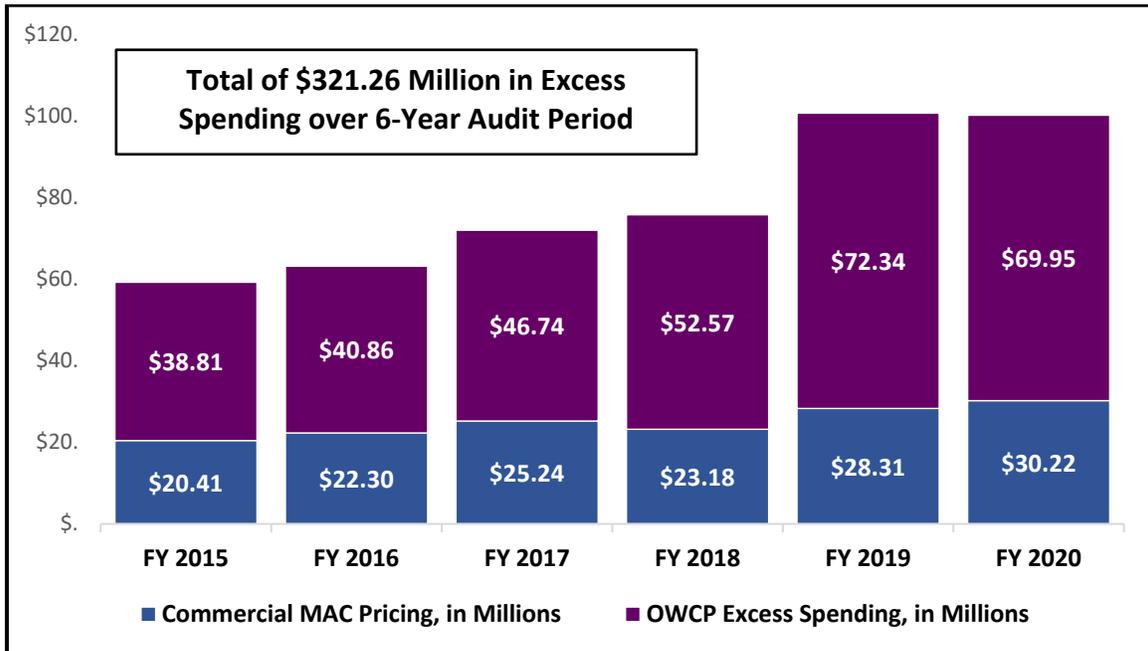
A MAC list serves as a ceiling price list to help ensure organizations and consumers do not overpay for prescription drugs. Prescription drug prices generally decrease over time for a variety of reasons. A properly administered

²² We did not use earlier data because the white paper establishing the NADAC to AWP pricing equivalency was not published until November 2018.

²³ NADAC-equivalent prices were derived from an actuarial analysis of NADAC to AWP pricing equivalencies. For more information, please see “Milliman White Paper – NADAC-plus: An Emerging Paradigm in Pharmacy Pricing?” (November 2018), last accessed September 3, 2022, <https://us.milliman.com/-/media/milliman/importedfiles/uploadedfiles/insight/2018/nadac-plus.ashx>.

MAC list accounts for and reflects these decreases in cost over time to prevent overspending. In our third comparative analysis, we compared OWCP’s prices paid for prescription drugs to a proprietary list with prices representative of a commercial MAC price list.²⁴ For the 6-year audit period, had OWCP paid prices consistent with commercial prices, it could have saved \$321.26 million out of almost \$470.93 million in spending (see Figure 4).

Figure 4: Excess FECA Pharmaceutical Spending Using a Commercial MAC Price List, FY 2015–FY 2020



Source: OIG graphic representation of HRK comparative analysis

²⁴ To perform this comparison, the audit team utilized multiple pricing sources in an algorithm to calculate a pricing value that reflected the current market, specific to the prescription drug and the date of the analysis. The values used in the calculation included survey-based pricing, federal and state pricing lists, various retail pricing sources, acquisition costs, and pricing experience from analysis of other clients. These were used to determine a market competitive price for all multi-source drugs and many brand products.

OWCP DID NOT INCORPORATE REBATES FROM DRUG MANUFACTURERS INTO THE FECA PHARMACEUTICAL PROGRAM

Prescription drug manufacturers commonly provide rebates to Pharmacy Benefit Managers (PBM) or rebate vendors, either of which can pass them on in full or in part to payers. According to the Academy of Managed Care Pharmacy, a national professional association of pharmacists and other health care practitioners, rebates represent a way to negotiate prescription drug discounts and are a key strategy used to drive down overall prescription drug costs.²⁵ Because of the impact rebates can have on savings for high-cost brand name prescription drugs, pharmaceutical management programs generally negotiate a contract with a PBM or rebate vendor that leverages rebate dollars to offset pharmaceutical costs.

By law, state Medicaid agencies are entitled to manufacturer rebates for prescription drugs provided to Medicaid beneficiaries. The Medicaid Drug Rebate Program requires drug manufacturers to pay rebates in exchange for drug coverage. The rebates are shared between the states and the federal government to offset the overall cost of prescription drugs under Medicaid. Medicare Part D also takes advantage of rebates.

Health Affairs, a peer-reviewed journal of health policy that has been cited by government officials and national media, reported that prescription drug rebates can sometimes reach 50 percent or more of list price and total Medicare Part D drug spending offset by rebates on brand name drugs in 2018 was 25 percent.²⁶

Even though incorporating rebates can result in substantial savings, OWCP indicated it did not incorporate prescription drug manufacturer rebates in the FECA pharmaceutical program. According to OWCP officials, the FECA program never had a mechanism, or a contract, to incorporate rebates for pharmacy expenditures during the audit period. In FY 2018, the FECA program began the procurement process for a PBM that would be contractually required to obtain certain levels of AWP discounts. The contract was awarded in February 2021, and, as part of this contract, OWCP receives data on pharmaceutical rebates the PBM obtains. However, OWCP does not get those monies on top of AWP discounts. While OWCP officials indicated it was likely that the PBM vendor

²⁵ Academy of Managed Care Pharmacy, “Pharmaceutical Manufacturer Rebates,” (June 17, 2021), last accessed September 3, 2022, <https://www.amcp.org/policy-advocacy/policy-advocacy-focus-areas/where-we-stand-position-statements/pharmaceutical-manufacturer-rebates>

²⁶ Health Affairs Blog, “Sharing Drug Rebates with Medicare Part D Patients: Why And How,” (September 14, 2020), last accessed September 3, 2022, <https://www.healthaffairs.org/doi/10.1377/forefront.20200911.841771/full/>

considered rebates in their AWP discounts when bidding, they did not provide any evidence that this occurred. OWCP officials also stated they do not plan to modify the PBM contract, which expires in March 2026, to require that the PBM seek rebates on behalf of the U.S. Department of Labor but will consider it for the next contract.

**OWCP’S LACK OF PROCESS TO ENSURE
COMPETITIVE PRICING RESULTED IN UP TO
\$321.26 MILLION IN EXCESS SPENDING**

Although OWCP believed its pricing was competitive with other workers’ compensation programs, it did not identify alternate pricing methodologies or other opportunities that could have reduced pharmaceutical spending because it did not have processes to do so. For example, OWCP did not have a process or requirement to:

- identify other available pricing models;
- ensure its pricing was competitive with others in the industry, such as comparing its pricing to the ACA FUL, NADAC, state fee schedules, market research, and comparable payers; or
- take advantage of manufacturer rebates.

Additionally, OWCP could have changed the rates it paid at any time through a policy change; however, as of September 30, 2020, OWCP had not changed its rates since July 1, 2016 (see Figure 5).

Figure 5: Tools to Ensure Competitive Prices for Prescription Drugs



Source: OIG graphic representation of HRK analysis

By failing to ensure competitive pricing in the FECA pharmaceutical program, OWCP did not realize up to \$321.26 million in savings of taxpayer dollars during the audit period. Overall, this was almost 20 percent of the \$1.63 billion OWCP spent on prescription drugs for FECA claimants during the audit period.

OWCP FAILED TO ENSURE CLAIMANTS RECEIVED ONLY APPROPRIATE PRESCRIPTIONS

OWCP issued significant policy and process changes related to claimant prescriptions prior to and during the audit period. Although these changes were intended to improve claimant safety and save costs, OWCP did not ensure the changes were properly implemented. This occurred because OWCP did not effectively monitor its bill pay vendor, who was responsible for implementing

these changes. As a result, OWCP allowed claimants to receive thousands of inappropriate prescriptions and potentially lethal drugs, which could have caused serious harm to claimants.

For example, OWCP paid for more than 98 percent (1,330 of 1,348) of prescriptions for fast-acting fentanyl, a potentially lethal and extremely addictive drug, without evidence of required cancer diagnoses. Additionally, OWCP paid for 25,037 non-maintenance early-fill prescriptions²⁷ and 473 convenience kits—which package multiple medications or items together although the individual items can be purchased at a lower cost—without prior authorization.

Further, OWCP paid for 12 Schedule II drug prescriptions with supplies that exceeded the amount allowed by OWCP policy. Schedule II drugs, which include fentanyl, are controlled substances that are considered dangerous and carry a high risk for psychological or physical dependence, abuse, and addiction. In each instance, OWCP paid for these prescription drugs in contravention of its policies.

OWCP PAID FOR 1,330 FAST-ACTING FENTANYL PRESCRIPTIONS AGAINST ITS POLICY

On May 3, 2011, OWCP published FECA Bulletin No. 11-05, which required fast-acting fentanyl prescriptions be denied unless claimants had been diagnosed with a type of cancer not specifically excluded by the bulletin. However, during the audit period, 98.7 percent (1,330 of 1,348) of the fast-acting fentanyl prescriptions OWCP paid for went to claimants without evidence of one of the eligible cancer diagnoses.

Fentanyl is an extremely potent synthetic opioid. In 2020, over 56,000 overdose deaths in the United States involved synthetic opioids other than methadone, primarily fentanyl.²⁸ Of particular concern is Transmucosal Immediate-Release Fentanyl (TIRF). Dispensed as a lozenge on a stick, TIRF is used to manage breakthrough pain in adults with cancer who are routinely taking other opioid pain medicines around-the-clock. This fast-acting formulation is highly addictive. Outside of its U.S. Food and Drug Administration-approved use for treatment of cancer-related pain, TIRF presents an unacceptably high risk for addiction.

²⁷ Non-maintenance prescriptions are prescriptions that do not treat chronic or long-term conditions. Early-fill prescriptions are defined as prescriptions filled on a date prior to when 75 percent of the prescription timeline has elapsed.

²⁸ National Institutes of Health, National Institute on Drug Abuse, “Overdose Death Rates” (January 20, 2022), last accessed September 1, 2022, <https://nida.nih.gov/research-topics/trends-statistics/overdose-death-rates>

Recognizing this risk, OWCP established a policy that required a work-related cancer diagnosis for fast-acting fentanyl products. FECA Bulletin 11-05 stated:

A new medication authorization automatic processing rule is being implemented whereby prescriptions for fast-acting fentanyl products will [be denied] unless the claimant has an accepted work-related condition of cancer. Note, however, that not all cancers will meet the criteria for the authorization of fentanyl. The following cancers will not be covered: non-melanoma cancers of the skin and *carcinoma in situ*. Also, benign tumors, by definition, are not cancer; thus, fentanyl use is not authorized.

While the number of TIRF prescriptions decreased from 487 in FY 2015 to 31 in FY 2020, none of these prescriptions should have been dispensed per OWCP guidance (see Table 1).

Table 1: TIRF Prescriptions without a Required Cancer Diagnosis, FY 2015–FY 2020

Fiscal Year	TIRF Prescriptions without Required Cancer Diagnosis
2015	487
2016	351
2017	230
2018	153
2019	78
2020	31
TOTAL	1,330

Source: HRK analysis of FECA pharmaceutical data

As the audit period did not include data prior to FY 2015, we do not know how many more fast-acting fentanyl prescriptions OWCP may have approved and paid for in contravention of FECA Bulletin 11-05 in the more than 3 years between May 2011 and September 2014.

OWCP PAID FOR 25,037 NON-MAINTENANCE EARLY-FILL PRESCRIPTIONS WITHOUT PRIOR AUTHORIZATIONS

On December 14, 2018, OWCP published FECA Circular No. 19-01, a policy that established limits on filling non-maintenance medications for the treatment of work-related injuries or illnesses. Non-maintenance medications are used to treat conditions that are not chronic or long-term. Specifically, this policy:

- limited filling prescriptions for non-maintenance medications to a 30-day supply,
- prohibited refills (early-fills) until 75 percent of the prescription timeline had passed, and
- required prior authorization by the OWCP Chief Medical Officer or designee to have the policy waived.

However, OWCP paid for 25,037 of 48,059 (52 percent) non-maintenance early-fill prescriptions without a required prior authorization after the policy became effective.²⁹ Filling non-maintenance prescriptions early has both clinical and financial impacts. Claimants who fill non-maintenance medications prior to 75 percent completion of the prescription receive a higher volume of prescription drug therapy than medically authorized, increasing the risk of possible misuse or abuse. Financially, failure to follow its policy resulted in OWCP paying for prescriptions at a higher frequency and volume than necessary.

OWCP APPROVED 473 CONVENIENCE KITS WITHOUT A PRIOR AUTHORIZATION

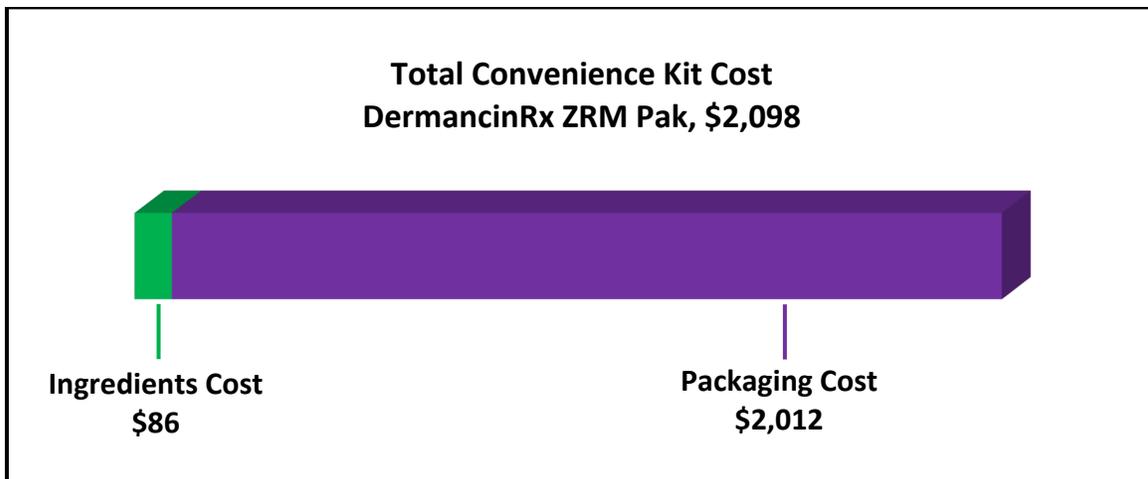
On February 14, 2018, OWCP published FECA Circular No. 18-05, to document its policy on payment for certain combination medications and convenience kits—packages that include multiple medications or items that are used together or mixed by the patient at home. OWCP had identified a trend in dispensing of convenience kits, which may have emerged as a possible substitute for traditional compounding where, generally, two or more medications are mixed

²⁹ For our analysis, we used Medi-Span to identify non-maintenance prescription drugs; OWCP used First Databank's definition. In our experience, Medi-Span classifies fewer prescription drugs as non-maintenance, and, if we had used First Databank's classification, the analysis would have produced a higher number of non-maintenance medications that should not have been paid. More information about Medi-Span is available here: <https://www.wolterskluwer.com/en/solutions/medi-span/medi-span>. More information about First Databank is available here: <https://interactive.fdbhealth.com/fdb-medknowledge-brochure-landing>.

together by a pharmacist. OWCP found that ingredients in these combination medications and convenience kits could be obtained individually at a lower cost.

For example, OWCP identified one convenience kit, DermacinRx ZRM Pak, that contained a lidocaine 5% patch and dimethicone 5% cream. In FY 2016, OWCP paid a total of \$86 for the two ingredients purchased individually but paid \$2,098 for the same ingredients when packaged together in a kit, meaning that OWCP paid \$2,012 for packaging or “convenience” alone (see Figure 6).

Figure 6: Proportion of Ingredients Cost in One Convenience Kit, DermacinRx ZRM Pak



Source: OIG graphic representation of HRK analysis

Additionally, OWCP determined that, because convenience kits usually have a separate National Drug Code from the individual ingredients in the kit, convenience kits can be used to bypass OWCP’s process to determine medical necessity.

Accordingly, FECA Circular No. 18-05 established a policy to automatically deny authorization and payment when:

1. OWCP has determined that the items in the kit/medication can typically be obtained separately and/or at a lower cost and there is a reasonable commercially available alternative or substitute; or
2. the primary use is for a condition not normally caused by a workers’ compensation injury.

The circular does allow for exceptions with prior authorization from the district director.

However, OWCP approved 473 of 487 (97 percent) convenience kit prescriptions, totaling \$1,034,281, without the required prior authorization, after implementation of the policy, from February 14, 2018, through FY 2020.

OWCP APPROVED 12 SCHEDULE II CONTROLLED PRESCRIPTIONS WITH GREATER THAN 30-DAY SUPPLY

On April 22, 2020, OWCP issued Customer Service Request³⁰ 12727 to its medical bill pay contractor to update pharmaceutical controls in response to the COVID-19 pandemic. The updated controls were implemented to accommodate pharmacies and claimants with prescription drug needs during the pandemic. However, the Customer Service Request kept in place a 30-day maximum supply limit for Schedule II prescriptions. Examples of Schedule II drugs include fentanyl, oxycodone, hydrocodone, and various formulations of morphine.

We found OWCP approved 12 of 55,250 Schedule II controlled prescriptions with a greater than 30-day supply after issuing the business rule in Customer Service Request 12727. While 12 is a small number of exceptions, these are dangerous drugs that could result in additional harm to already injured workers, and, therefore, it is critical OWCP ensures its bill pay vendor is not bypassing the authorized supply limits.

OWCP'S INEFFECTIVE MONITORING OF ITS BILL PAY VENDOR RESULTED IN CLAIMANTS RECEIVING THOUSANDS OF INAPPROPRIATE PRESCRIPTIONS

These issues occurred because OWCP did not effectively monitor its bill pay vendor to ensure policy changes were appropriately implemented. OWCP contracted with its bill pay vendor to provide pharmacy bill processing services for the FECA program, relying too heavily on the vendor for responsibilities related to implementing OWCP's policy changes. Further, OWCP did not perform sufficient post-implementation reviews to ensure changes were fully implemented and operating as intended. Management stated that OWCP evaluated the vendor's performance by checking a sample of bills to ensure payments were accurate. However, the bills sampled were relatively small compared to the entire population of medical bill payments, and the tests were not specifically designed to catch prescriptions that were paid against OWCP's policy changes. OWCP's

³⁰ Customer Service Requests, known as CSRs, are technical directives and protocols from OWCP to its bill pay vendor.

failure to effectively monitor its bill pay vendor resulted in claimants receiving thousands of inappropriate prescriptions and potentially lethal drugs such as fentanyl during the audit period.

OWCP FAILED TO TIMELY IDENTIFY AND ADDRESS EMERGING ISSUES AND DID NOT PERFORM SUFFICIENT OVERSIGHT OF HIGHLY SCRUTINIZED AND RARELY COVERED PRESCRIPTION DRUGS

OWCP failed to timely identify and address emerging issues—such as dramatic increases in opioid use and compounded drug spending—until after they became critical concerns. OWCP also did not perform sufficient oversight of prescription drugs that are highly scrutinized and rarely covered in workers’ compensation programs. These problems occurred because OWCP did not have an ongoing monitoring and alert program to identify changes in prescription costs, trends, and other emerging issues. As a result, OWCP spent hundreds of millions of dollars on drugs that may not have been necessary or appropriate for FECA claimants. Had OWCP developed an effective ongoing pharmaceutical monitoring and alert program, it may have been able to identify and address emerging issues and implement controls much sooner, thereby saving hundreds of millions of dollars.

OWCP FAILED TO TIMELY IDENTIFY AND ADDRESS DRAMATIC INCREASES IN SPENDING FOR OPIOIDS AND COMPOUNDS

OWCP failed to address problematic issues—such as dramatic increases in opioid use and compounded drug spending—until after they became critical problems. The OIG previously reported on these issues in 2017³¹ and 2019.³² For example, OWCP did not institute controls to mitigate opioid usage until the end of 2016, years after many commercial insurers, third-party administrators,

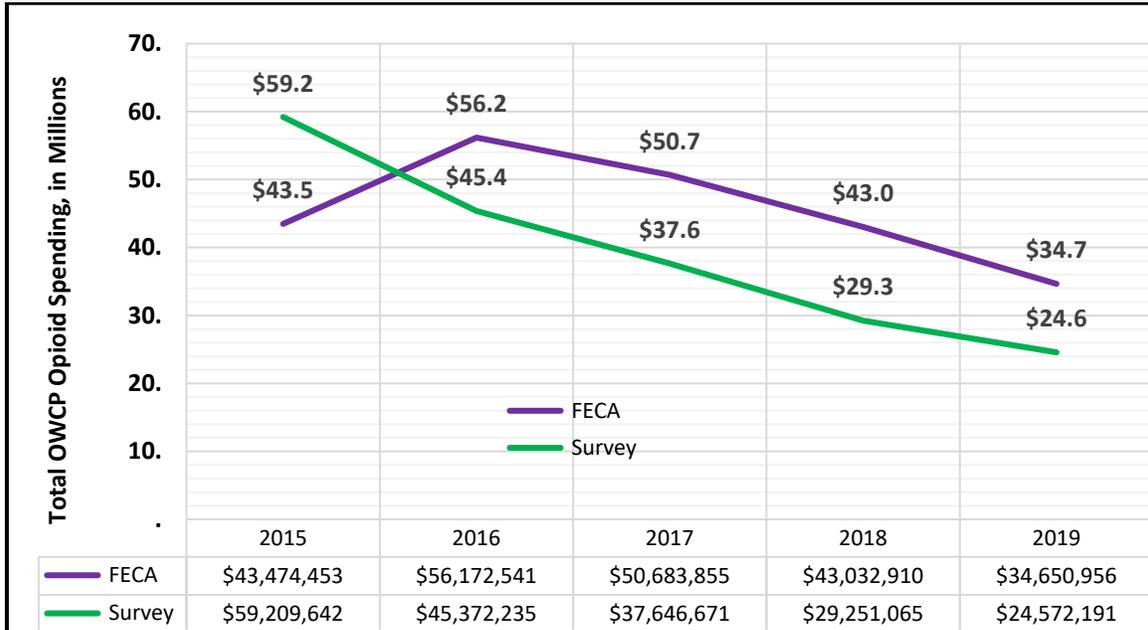
³¹ Interim Report on Audit of Pharmaceutical Management in DOL Benefit Programs - OWCP Needs Better Controls Over Compounded Prescription Drugs, Report No. 03-17-001-04-431 (May 23, 2017), <https://www.oig.dol.gov/public/reports/oa/2017/03-17-001-04-431.pdf>

³² OWCP Must Continue Strengthening Management of FECA Pharmaceuticals, Including Opioids, Report No. 03-10-002-04-431 (May 14, 2019), <https://www.oig.dol.gov/public/reports/oa/2019/03-19-002-04-431.pdf>

and large employers had done so.³³ The results of an annual survey sent to executives and senior management at 19 workers’ compensation payers that inquired about prescription drug management showed a majority of respondents enacted policies designed to mitigate opioid usage dating back to 2011.³⁴ In FY 2016, OWCP showed an almost 30 percent increase in opioid spending over the prior year³⁵ while other workers’ compensation payers reported an average decrease of 23.4 percent from FY 2015 to FY 2016.

After implementing controls, OWCP’s opioid spending decreased in FY 2017 and subsequent years although the overall decline during the audit period was less than what was reported by survey respondents (see Figure 7).

Figure 7: Comparative Analysis of Opioid Spending, FECA Program and Survey Respondents, FY 2015–FY 2019



Source: OIG graphic representation of HRK analysis of FECA pharmaceutical data and CompPharma annual survey data

From FY 2015 through FY 2019, OWCP opioid spending in the FECA program declined by 20.3 percent while, during the same time period, survey respondents’ opioid spending declined by 58.5 percent. However, after OWCP implemented

³³ Insurance Journal, “Opioid Epidemic Plagues Workers’ Comp,” (May 17, 2013), last accessed September 14, 2022, <https://www.insurancejournal.com/news/national/2013/05/17/292528.htm>

³⁴ CompPharma confidential data from its 2012 survey, which was based on 2011 data

³⁵ The audit team calculated opioid spending figures based on its analysis of FECA pharmaceutical data provided by OWCP.

controls in FY 2017, it saw a similar rate of decline (31.6 percent) compared to survey respondents (34.7 percent). This indicates the \$12.7 million increase in opioid spending from FY 2015 to FY 2016 was unnecessary and caused by OWCP's failure to timely identify the opioid issue and take appropriate action to mitigate it.

OWCP also failed to address the increased use and cost of compounded drugs until October 2016, 3 years after other workers' compensation payers began to act.³⁶ By 2013, 72 percent of survey respondents identified compounded drugs as an emerging issue of concern and 11 of 25 respondents specifically referenced compound management initiatives to control costs.³⁷

Further, in March 2016, the United States Postal Service (USPS) OIG issued a report³⁸ noting it had brought the issue of escalating medical costs to OWCP's attention more than a year before, in January 2015, and was informed the increase was "simply the law of averages catching up." The report also noted that TRICARE (the military health insurance program), as well as other state and private entities, implemented restrictions on compounded drugs in 2015.

In FY 2016, OWCP paid \$214 million for compounded drugs. After implementing controls to address this issue in FY 2017, OWCP spending on compounded drugs dropped 94 percent to \$12.5 million (see Figure 8).³⁹

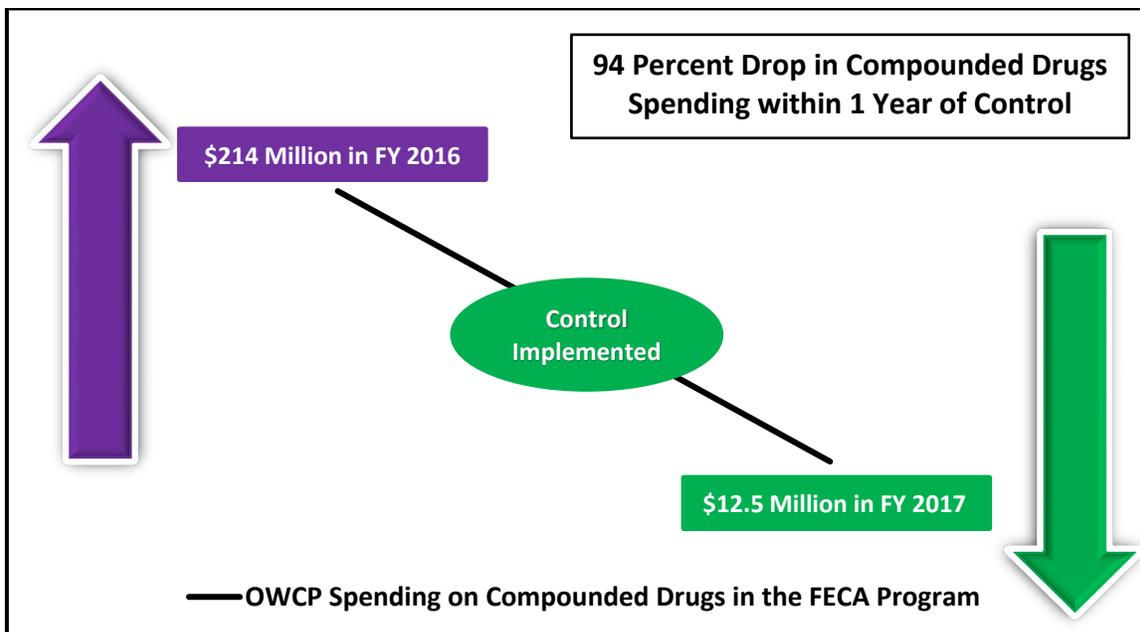
³⁶ CompPharma, "Prescription Drug Management in Workers' Compensation The Eleventh Annual Survey Report (2013 data)," (December 8, 2014), last accessed August 30, 2022, <https://comppharma.com/wp-content/uploads/2016/09/CompPharmaPayerSurvey2014Public-1.pdf>

³⁷ CompPharma confidential data from its 2014 survey, which was based on 2013 data

³⁸ Office of Inspector General, United States Postal Service, "Workers' Compensation Compound Drug Costs," Management Advisory Report No. HR-MA-16-003, (March 14, 2016), last accessed August 30, 2022, <https://www.uspsoidg.gov/reports/audit-reports/management-advisory-workers-compensation-compound-drug-costs>

³⁹ The audit team calculated compounded drug spending figures based on its analysis of FECA pharmaceutical data provided by OWCP.

Figure 8: Compounded Drug Spending before and after Control Implementation



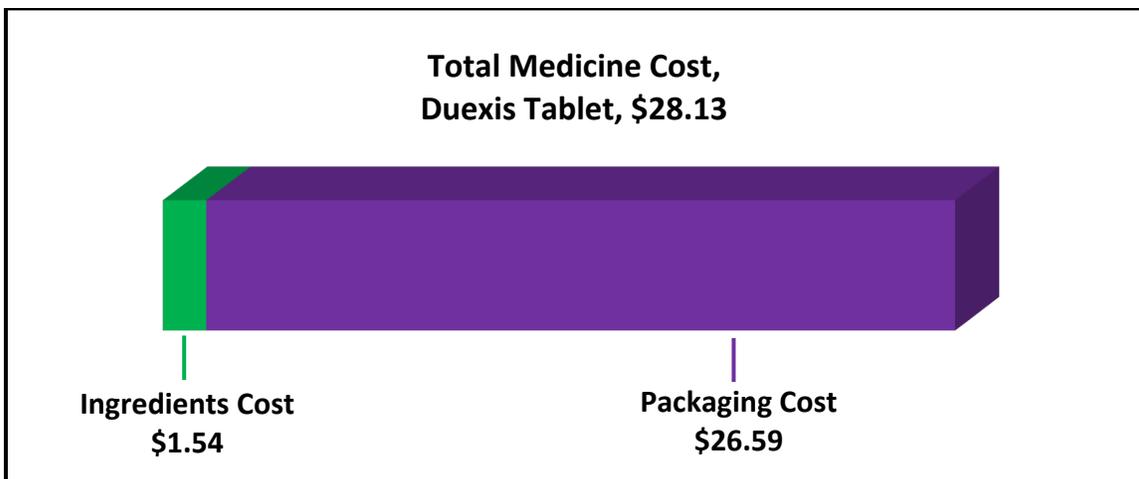
Source: OIG graphic representation of HRK analysis

Had OWCP been able to identify the issue and implement controls much sooner, it could have potentially saved hundreds of millions of dollars.

OWCP FAILED TO IDENTIFY HIGHLY SCRUTINIZED AND RARELY COVERED DRUGS

OWCP did not perform sufficient oversight of prescription drugs that are highly scrutinized or rarely covered by other workers' compensation programs. These drugs can be allowable in certain situations but require close oversight because they are intended to treat conditions not commonly associated with work-related injuries. Additionally, some combination medicines are highly scrutinized because they combine two inexpensive generic medications into a single tablet at a significantly higher cost without additional clinical value. For example, during the audit period, OWCP paid for Duexis, Vimovo, and diclofenac/misoprostol. Duexis combines ibuprofen, a nonsteroidal anti-inflammatory drug, and famotidine, which is used to treat ulcers and heartburn. OWCP paid \$1.54 total for those two ingredients separately, but paid \$28.13 per unit for Duexis (see Figure 9).

Figure 9: Proportion of Ingredients Cost in One Highly Scrutinized Therapy, Duexis Tablet



Source: OIG graphic representation of HRK analysis

Notably, in 2018, OWCP added Duexis and Vimovo to the FECA program’s prescription drug exclusion list but only after it had spent \$21 million on these drugs.⁴⁰ Other examples that warrant additional oversight include drugs such as Enbrel and Humira, which are used to treat auto-immune diseases that are unlikely to arise from a work-related injury.

In total, we identified 10 highly scrutinized or rarely covered drugs for which OWCP paid during the audit period, accounting for over \$28 million in potential waste (see Table 2).

⁴⁰ U.S. Department of Labor, Office of Workers’ Compensation Programs, “DFEC List of National Drug Codes (NDCs) That Will Deny,” last accessed August 30, 2022, https://www.dol.gov/agencies/owcp/FECA/not_covered_ndc

Table 2: Ten Highly Scrutinized or Rarely Covered Workers' Compensation Drugs for which OWCP Paid, FY 2015–FY 2020

Pharmaceutical Therapy	Common Uses⁴¹	Total Cost
Duexis tablet	To relieve symptoms of rheumatoid arthritis	\$19,170,940
Vimovo tablet	To relieve symptoms of certain types of arthritis in adults and children	\$2,008,453
Viagra tablet	To treat male sexual function problems	\$1,700,051
Enbrel injection	To treat certain types of arthritis caused by an auto-immune disease	\$1,528,923
Humira pen injection	To reduce pain and swelling due to certain types of arthritis and to treat certain skin disorders such as plaque-type psoriasis	\$1,428,801
Enlyte capsule	A multi-vitamin with iron that may be useful for patients at risk of depression	\$1,042,614
Diclofenac/Misoprostol tablet	To reduce pain, swelling, and joint stiffness from arthritis	\$381,404
Sildenafil tablet	To treat male sexual function problems	\$380,860
Basaglar injection	To treat diabetes	\$378,245
Omega-3-acid capsule	A fish oil supplement that may reduce the risk of heart disease	\$352,386
TOTAL		\$28,372,677

Source: HRK analysis of FECA pharmaceutical data

⁴¹ While these prescription drugs might be used for myriad purposes, this table provides a plain language description of common uses.

**OWCP’S LACK OF AN EFFECTIVE
PHARMACEUTICAL MONITORING AND ALERT
PROGRAM RESULTED IN POTENTIALLY
HUNDREDS OF MILLIONS OF DOLLARS SPENT ON
UNNECESSARY PRESCRIPTION DRUGS**

We requested—but OWCP did not provide—documentation, materials, or other evidence that it had an effective ongoing pharmaceutical monitoring and alert program. To ensure management has quality information and appropriate internal controls in place to address program risks and changes, an effective pharmaceutical monitoring and alert program would use key data elements to identify changes in prescription drug usage, such as prescribing patterns, prescription drug utilization, new and novel prescription drugs, and sourcing of prescription drugs. It should also identify fluctuations in costs for specific prescription drugs and other changes in costs. Additionally, OWCP did not perform prescription-claim-level reviews to ensure prescriptions were paid at the appropriate cost basis.

Since internal control is a dynamic process that has to be adapted continually to the risks and changes an entity faces, monitoring of the internal control system is essential in helping internal control remain aligned with changing objectives, environment, laws, resources, and risks. The U.S. Government Accountability Office’s (GAO) “Standards for Internal Control in the Federal Government” states that management should establish and operate monitoring activities to monitor the internal control system and evaluate the results.⁴² The GAO standards also state that management should use quality information to achieve the entity’s objectives.⁴³

OWCP used a pharmaceutical dashboard and related reports developed by a third-party contractor that provided some useful high-level information on overall trends related to pharmaceutical spending and some detail on two broad classes/types of medications, namely compounds and opioids. The reports also contained some insights into more granular issues, including compounding pharmacies, patients receiving compounds and trends over time, opioid usage across a broad population, top providers by spending, and some prescription drugs that may be inappropriate.

However, the reports did not address key monitoring program elements, such as:

⁴² GAO’s “Standards for Internal Control in the Federal Government,” (GAO-14-704G) September 2014, Principle 16

⁴³ GAO’s “Standards for Internal Control in the Federal Government,” (GAO-14-704G) September 2014, Principle 13

- breaking spending down by prescription drug class;
- effectively identifying new/emerging prescription drugs;
- providing insights into issues such as TIRF, convenience kits, and non-maintenance medications;
- identifying best practices, high/low performing claims examiners and medical benefit examiners, problematic prescribers, emerging issues, and training needs; or
- effectively preventing improper payments since they are retrospective, as opposed to monitoring claims before they are paid.

To reduce risks and ensure quality information needed for effective monitoring of internal controls, an ongoing pharmaceutical monitoring and alert program would use key data elements. Management can better identify and quickly adapt to changes, trends, and other emerging issues using data elements such as:

- an over-the-counter indicator;
- a maintenance indicator;
- ingredient costs paid; and
- another payer amount, which is used to indicate if other payers (i.e., group health or Medicare) are involved in drug reimbursement (see Exhibit 2 for a list of common data elements and each element's importance in pharmaceutical management).

More specifically, these data elements can be used to track contractual pricing compliance, to identify the use of new or expensive drugs, to uncover payments for drugs not related to a specific occupational injury/illness, and for myriad other purposes. OWCP management indicated OWCP did not use these data elements to monitor the FECA program. When asked why, OWCP management stated these fields were not readily available from their bill pay vendor.

In addition, OWCP did not perform prescription-claim-level reviews. Although OWCP tested a random sample of claims as part of its oversight of the bill pay vendor, this testing was not performed at the claim level to determine if OWCP was paying claims at the appropriate cost basis. For example, if a generic drug was improperly categorized by the bill pay vendor as a brand drug, then it could be billed at the higher brand rate; this would be a claim payment at an inappropriate cost basis. Performing prescription-claim-level reviews is a form of monitoring that could reduce or prevent payments being made at an inappropriate cost basis.

Had OWCP developed an effective ongoing pharmaceutical monitoring and alert program, it may have been able to timely identify emerging issues and implement more effective controls, thereby saving hundreds of millions of dollars.

OWCP LACKED SUFFICIENT CLINICAL EXPERTISE AND GUIDELINES TO ENSURE APPROPRIATE PHARMACEUTICAL DECISIONS

OWCP also lacked sufficient clinical expertise and guidelines to ensure appropriate pharmaceutical decisions in the FECA program. OWCP lacked sufficient pharmaceutical and medical expert staff and sometimes relied on claims examiners for pharmaceutical claims decisions including appropriateness of a given prescription drug; however, OWCP did not provide adequate training to staff assigned to pharmaceutical duties. It also relied on internally developed spreadsheets (referred to as “treatment suites”) instead of on evidence-based clinical guidelines to ensure appropriate prescriptions.

This occurred because management did not ensure a sufficient level of expertise required for decision-making on pharmaceutical claims, leading to a significant shortage of clinicians and inadequate staff training. Decisions to approve inappropriate medications can result in adverse health consequences for claimants and increased claim duration and costs.

OWCP LACKED SUFFICIENT CLINICAL EXPERTISE

During the audit period, OWCP lacked sufficient clinical expertise in both staff and training. The FECA program did not have a dedicated full-time medical director or dedicated full-time pharmacist. Further, agency claims examiners typically lacked pharmaceutical or medical backgrounds. OWCP did not have a formal, ongoing prescription drug-specific training program for staff involved in decisions regarding pharmaceutical claims.

The FECA program spent an estimated \$188 million on prescription drugs in FY 2020 but did not have a dedicated full-time medical director in FY 2020 or at any other time during the audit period. During most of the audit period, OWCP had two physicians—one serving as OWCP’s Chief Medical Officer (a title comparable to a medical director)—that divided their time between all four OWCP workers’ compensation programs. The Chief Medical Officer stated the Energy Workers program took up most of their time. In FY 2020, the other physician resigned and OWCP was left with only the Chief Medical Officer being responsible for all four OWCP programs.

For comparison to other workers’ compensation payers, one large third-party administrator with roughly equivalent annual pharmaceutical spending has six

full-time physicians, including a medical director, on staff and one insurer with an estimated one-third of FECA’s annual pharmaceutical spending has five full-time physicians, including a medical director. Additionally, a small regional insurer with less than \$6 million, estimated, in annual pharmaceutical spending has one full-time medical director as does a small state fund with an estimated \$4 million in annual pharmaceutical spending (see Table 3).

Table 3: Comparison of the Number of Medical Directors and Physicians Employed by Workers’ Compensation Payers

Workers’ Compensation Payer	Estimated Annual Pharmaceutical Spending	Number of Full-Time Medical Directors and Physicians
Third Party Administrator	Roughly \$188 million	6
An Insurer	Roughly \$62 million	5
FECA	\$188 million	1-2
Regional Insurer	\$6 million	1
State Fund	\$4 million	1

Source: CompPharma industry interviews, 2021 and 2022

Additionally, OWCP did not have a pharmacist on staff until May 2018 and remained with only one full-time pharmacist until August 2021 when OWCP hired a second full-time pharmacist. During the audit period, OWCP’s Chief Pharmacist served all four OWCP programs.

For comparison, two of the top five worker’s compensation payers by estimated annual pharmaceutical spending (Top 5 National Payer) had eight and five full-time pharmacists on staff, respectively.⁴⁴ The first Top 5 National Payer spent about \$132 million or about \$56 million less than the FECA program. The second Top 5 National Payer spent about \$82 million or about \$106 million less than the FECA program. One state fund that spent about \$39 million had two full-time pharmacists, and another state fund that spent about \$12 million had 1 full-time pharmacist on staff (see Table 4).

⁴⁴ All monetary references in this paragraph are estimated figures for FY 2020 pharmaceutical spending.

Table 4: Comparison of the Number of Pharmacists Employed by Workers' Compensation Payers

Payer	FY 2020 Pharmaceutical Spending	Number of Full Time Pharmacists
Top 5 National Payer	\$132 million	8
Top 5 National Payer	\$82 million	4
State Fund	\$39 million	2
FECA	\$188 million	0-2
State Fund	\$12 million	1

Source: CompPharma industry interviews conducted in 2021 and 2022

OWCP delegated decisions related to pharmaceutical claims to claims examiners, who typically have no pharmaceutical or medical backgrounds, rather than to physicians or pharmacists. This included medical benefit examiners, who are claims examiners with specific responsibilities in managing opioid prescriptions. According to the position description, claims examiners' duties include "[evaluating] a wide variety of medical evidence (e.g., medical documents, medical reports, diagnostic reports, etc.) submitted in support of medication authorization requests...[and reviewing] evidence to determine the facts for a claimant's medical prescriptions and dosage, where appropriate."

However, OWCP had no formal ongoing prescription drug-specific training program for staff assigned to pharmaceutical duties. Instead, OWCP management indicated physicians occasionally held discussions with staff focused on specific cases. Additionally, it provided some training to medical benefit examiners on compounded drugs and opioids, but it lacked documentation showing employee attendance or comprehension of the trainings provided. It also lacked documentation of any follow-up study to assess the trainings' effectiveness.

Finally, there was little involvement of OWCP clinical experts in the development or management of the FECA pharmaceutical program. For example, the OWCP Chief Pharmacist indicated he had little input into the prior authorization process that was developed shortly after the pharmacist was hired in May 2018, and he was rarely consulted on medical benefit examiners' handling of letters of medical necessity for opioids or compounds. Additionally, OWCP had no clinical group—such as a pharmacy therapeutics committee—to comprehensively review medications for their clinical and financial benefits and decide whether OWCP should approve and pay for certain prescription drugs.

OWCP RELIED ON INTERNALLY DEVELOPED SPREADSHEETS INSTEAD OF EVIDENCE-BASED GUIDELINES

To determine which treatments to cover, the FECA program relied on internally developed spreadsheets called treatment suites that matched specific injuries or illnesses to appropriate medical procedures and prescription drugs. Alternatively, evidence-based guidelines use a critical appraisal of scientific evidence to identify the most beneficial treatments.⁴⁵ They also serve to identify treatments that are unsupported by good science and highlight ineffective, dangerous, and wasteful practices.

Additionally, for organizations who pay for healthcare services, such evidence-based guidelines can improve efficiency and save money. OWCP's Chief Medical Officer and Chief Pharmacist agreed OWCP needed to transition from treatment suites to evidence-based guidelines, such as those available from the American College of Occupational and Environmental Medicine,⁴⁶ which have been adopted by the State of California, or the Official Disability Guidelines,⁴⁷ which have been adopted by nine other state workers compensation programs.

OWCP'S INSUFFICIENT EMPHASIS ON CLINICAL EXPERTISE RESULTED IN INCREASED RISK OF INAPPROPRIATE PHARMACEUTICAL DECISIONS

Because OWCP management underestimated the level of clinical expertise required to make appropriate decisions on pharmaceutical claims, there was a significant shortage of clinicians and staff training in the FECA program. Also, the FECA program relied on treatment suites instead of evidence-based guidelines. This under-emphasis on clinical expertise in managing the FECA pharmaceutical program increased the risk of inappropriate pharmaceutical decisions, which could negatively impact claimants' health, recovery, and return to work, leading to adverse health consequences, increased claim duration, and added costs for employing agencies.

⁴⁵ National Institutes of Health, National Library of Medicine, "Potential benefits, limitations, and harms of clinical guidelines," (February 20, 1999), last accessed August 30, 2022, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1114973/>

⁴⁶ For more information on the American College of Occupational and Environmental Medicine's guidelines, please see its "Guidelines" webpage, last accessed August 30, 2022, <https://acoem.org/Guidance-and-Position-Statements/Guidelines>.

⁴⁷ For more information on Official Disability Guidelines, please see: "ODG for Workers' Compensation: Industry-Leading Medical Treatment & Return-to-Work Guidelines," last accessed August 30, 2022, <https://www.mcq.com/odg/workers-comp-guidelines/>.

CONCLUSION

We recognize OWCP has taken recent actions to improve its management of the FECA pharmaceutical program, including implementing controls on prescriptions for compounded drugs and opioids. OWCP achieved a greater than 99 percent reduction in compounded drug spending and significantly reduced opioid spending from FY 2016 to FY 2020. Despite these accomplishments, we found OWCP did not effectively manage pharmaceutical spending during the audit period and remains challenged in effectively managing the cost and use of prescription drugs in the FECA program.

We note that, after the audit period, OWCP implemented a PBM to help manage its pharmaceutical program and control costs. During our audit, OWCP officials acknowledged problems existed but stated the new PBM would address them. While using a PBM instead of a bill pay vendor to process prescriptions may improve the FECA pharmaceutical program, it is by no means a total solution. Though certainly a positive program improvement, the implementation of a PBM does not negate our report recommendations. To obtain the best available prices, OWCP must ensure appropriate definitions for elements such as drug categorization, dispensing channels, audit rights, access to data, and pricing methodology—including the extent to which rebates are incorporated.

Having a PBM is only part of OWCP's pharmaceutical program and does not relieve OWCP from additional pharmaceutical management responsibilities. Workers' compensation payers need to set policy, make coverage decisions, ensure policy changes are successfully implemented, and monitor their PBM's performance. Mistakes, overpayments, and inappropriate prescriptions can occur, and the FECA program needs sufficient staff and processes to ensure errors do not occur and, in the event errors do occur, to catch and correct errors in near real-time.

RECOMMENDATIONS

We recommend the Director of the Office of Workers' Compensation Program:

1. Implement a process to ensure competitive prices for the FECA program by regularly evaluating alternate pricing methodologies and other sources—including publicly available benchmark price lists, state fee schedules, market research, and comparable payers—and updating its pricing methodology as appropriate.
2. Implement a process to collect drug manufacturer rebates.

3. Implement a process to review the effectiveness of policy changes, including: (a) documented assessment of prescription information after any changes in the authorization, approval, and/or adjudication process to ensure desired changes are achieved; and (b) documented solutions for any performance gaps identified during the review, including follow-up testing.
4. Implement an ongoing pharmaceutical monitoring and alert program to identify and closely monitor significant changes in costs, prescribing patterns, utilization, sources, and new and novel prescription drugs.
5. Establish internal controls that identify prescription drugs payment and management issues in near-real-time, including: (a) reviewing all system data fields provided by Pharmacy Benefit Managers and bill pay vendor(s); (b) determining any additional data fields/elements needed to monitor pharmaceutical spending and track trends over time; (c) ensuring a recurring process to receive and immediately review data from the Pharmacy Benefit Managers and bill pay vendor(s); and (d) using that data review to report regularly to management, medical director, and staff pharmacists for collaborative identification of current and emerging issues.
6. Implement a technology solution to perform ongoing prescription-claim-level reviews in near real-time—including contractual adherence by the Pharmacy Benefit Manager, prescription drug pricing discounts, and rebate guarantees—as well as to validate prescription drug pricing methodology.
7. Adopt one or more of the widely used and thoroughly vetted evidence-based clinical guidelines, such as those from the American College of Occupational and Environmental Medicine and Official Disability Guidelines, in place of treatment suites.
8. Develop and deliver ongoing formal training for staff involved in making pharmaceutical decisions, with documentation of participation and post-training evaluation.
9. Add pharmacists and physicians to provide oversight of the FECA program and other necessary functions not assigned to the Pharmacy Benefit Manager.
10. Ensure medical and pharmaceutical experts participate in the development, monitoring, maintenance, improvement, and evaluation of the FECA pharmaceutical program.

SUMMARY OF OWCP'S RESPONSE

OWCP generally agreed with Recommendations 2, 3, and 9. OWCP maintained that the remaining seven recommendations were already implemented, largely due to its implementation of a PBM. OWCP noted that the audit covered FY 2015 through FY 2020, which was before OWCP executed a contract with a

PBM, and, therefore, in its view, the report does not reflect the current state of the FECA pharmaceutical program.

We acknowledge that the implementation of a PBM, which was one of sixteen recommendations the OIG made in its 2017 report,⁴⁸ may have already helped to improve the FECA pharmaceutical program. However, OWCP must still address the issues identified in this report to ensure responsible stewardship of taxpayer dollars and the safety of program beneficiaries.

For example, for Recommendation 1, OWCP should implement a process to evaluate alternate pricing methodologies ahead of its planned market research for future procurements in 2025. Although the PBM implementation has resulted in significant cost savings to date, a PBM is not a fiduciary and is only required to ensure OWCP obtains the price discounts established by the contract. If OWCP can identify opportunities to achieve greater cost savings for taxpayers during the current contract, it should consider modifying the contract or opting to not exercise the remaining option years. OWCP needs additional controls to ensure it is able to identify those cost-saving opportunities and prevent spending on unnecessary or overpriced prescription drugs.

Also, in response to Recommendation 8, OWCP indicated that medical benefit examiners and claims examiners only make administrative decisions, not clinical decisions. As we noted in our report, our audit work found these staff were making pharmaceutical benefit decisions, which can involve significant complexity. Claims examiners' duties include independently examining and adjudicating medical treatment requests, including authorization requests for pharmaceuticals such as opioids and compounded medications. As such, we continue to see the need for ongoing, formal training for these staff, with documentation of participation and post-training evaluation.

Moving forward, OWCP must monitor both the FECA program and any third-party vendors, including the PBM, to ensure prices are competitive; policies are appropriately implemented; and emerging issues, mistakes, overpayments, and inappropriate prescriptions are timely identified and addressed.

Management's response to the draft report is included in its entirety in Appendix B.

⁴⁸ Interim Report on Audit of Pharmaceutical Management in DOL Benefit Programs - OWCP Needs Better Controls Over Compounded Prescription Drugs, Report No. 03-17-001-04-431 (May 23, 2017), <https://www.oig.dol.gov/public/reports/oa/2017/03-17-001-04-431.pdf>

We appreciate the cooperation and courtesies OWCP extended us during this audit.

Harper, Rains, Knight & Company, P.A.

Harper, Rains, Knight & Company, P.A.
Washington, DC
March 28, 2023

EXHIBIT 1: QUESTIONED COSTS

Table 5: Questioned Costs⁴⁹

Description	Area of Issue	Amount
Unreasonable or unnecessary expenditures	OWCP Controls	\$321,261,486

Source: OIG-generated based on HRK comparative analysis

⁴⁹ As defined by the Inspector General Act of 1978, as amended, questioned costs include alleged violations of law, regulations, contracts, grants, or agreements; costs not supported by adequate documentation; or the expenditure of funds for an intended purpose that was unnecessary or unreasonable.

EXHIBIT 2: COMMON DATA ELEMENTS NOT READILY AVAILABLE TO OWCP'S PHARMACEUTICAL MANAGEMENT

Data Element	Importance to Pharmaceutical Management in Workers' Compensation
Incentive Fee Paid	Pharmacies receive a fee for administering vaccines, which should not be relevant to workers' compensation; if this data element is populated, it is likely improperly billed.
Other Payer Amount	This data element indicates coordinating of benefits or alternative insurance billed at pharmacy, which should not be relevant to workers' compensation; if this data element is populated, it is likely improperly billed.
Professional Fee Paid to Provider	Pharmacies receive a fee for administering vaccines or compounds, which should not be relevant to workers' compensation; if this data element is populated, it is likely improperly billed.
Pharmacy Paid Dispensing Fee	This data element can be used in analyzing the difference between the amount paid to the pharmacy and the amount billed to OWCP.
Pharmacy Paid Sales Tax	This data element can be used in analyzing the difference between the amount paid to the pharmacy and the amount billed to OWCP.
Pharmacy Paid Incentive Fee Paid	This data element can be used in analyzing the difference between the amount paid to the pharmacy and the amount billed to OWCP.
Pharmacy Paid Ingredient Cost	This data element can be used in analyzing the difference between the amount paid to the pharmacy and the amount billed to OWCP.
Ingredient Cost Paid	This data element can be used to determine contract adherence and to analyze the market competitiveness of pricing.
Co Pay Amount	This data element indicates coordinating of benefits or alternative insurance billed at pharmacy, which should not be relevant to workers' compensation; if this data element is populated, it is likely improperly billed.

Data Element	Importance to Pharmaceutical Management in Workers' Compensation
Dispensing Fee	This data element can be used to determine contract adherence and to analyze the market competitiveness of pricing.
Retail/Mail Order Indicator	This data element tracks the channel used to distribute the prescription. This can be used to ensure appropriate pricing discounts are applied.
Formulary Indicator	This data element is used to track whether a medication is covered by the payer's formulary.
Single Source Generic Code	This data element can be used to analyze the utilization of higher cost generic drugs.
Maintenance Indicator	This data element indicates whether a prescription is used for an acute injury or a preventative medication. This can be used to analyze waste and abuse and can aid in coordination of care.
Specialty Indicator	This data element can be used to analyze the utilization of higher cost specialty drugs.
Over-the-Counter (OTC) Indicator	This data element can be used to analyze the utilization of over-the-counter drugs.
Prior Authorization Type	This data element gives the rationale for the prior authorization. This can be used to identify the level of effort associated with reviewing the prior authorization request.
Pharmacy Chain ID	This data element indicates the pharmacy chain used to fill a prescription and can be used to identify out-of-network claims.
Pharmacy Class Code	This data element indicates the broader pharmacy class used to fill a prescription. This can be used to ensure prescriptions are filled within preferred networks to help drive down costs.
Amount Attributed to Product Selection (Formulary Status)	This data element identifies the cost paid by a claimant when choosing a higher cost brand drug when a generic is available.
Origin Code	This indicates the method by which the pharmacy received the prescription, showing whether the prescription was filled in accordance with appropriate policies and pricing.

APPENDIX A: SCOPE AND METHODOLOGY

SCOPE

We were engaged by the OIG to conduct a performance audit of the effectiveness of OWCP's management of FECA pharmaceutical spending for the period covering FY 2015 through FY 2020.

METHODOLOGY

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

To accomplish our objective, we analyzed pharmaceutical data from FY 2015 through FY 2020; conducted interviews with OWCP management; reviewed policies, procedures, and contractual agreements; and identified, collected, reviewed, and summarized relevant research documents, reports, training documents and information, and papers. Additionally, we compared the FECA program's policies and performance to industry best practices and other workers' compensation programs.

We analyzed the FY 2015 to FY 2020 pharmaceutical data based on the OWCP guidance in place for each FY. Additionally, we analyzed the pharmaceutical data to compare to industry best practices and to identify potential areas for improvement and potential cost savings. We did not perform any sampling of the OWCP data.

We performed structured interviews with OWCP management, the OWCP Chief Medical Officer, and the FECA Program's Chief Pharmacist. These interviews were performed to obtain an understanding of the processes and procedures in place and how those processes and procedures are developed. The interviews were also conducted to verify and clarify observations we made during the performance audit.

We performed analysis of the policies and procedures identified during the interviews as well as our own research. Our research included reading OWCP reports, guidance in the form of FECA bulletins and circulars, and publicly available published papers on the subject matter. We then compared the OWCP

policies, procedures, and guidance to industry best practices in place in the workers' compensation space.

Due to the subject matter, we contracted with subject matter experts from HealthPlan Data Solutions and CompPharma LLC.

HealthPlan Data Solutions is a pharmacy analytics platform that leverages leading-edge technologies and pharmacy reimbursement expertise to drive out over-spending and deficiencies in contract compliance, design, and terms in the pharmaceutical distribution channel. HealthPlan Data Solutions performed analysis on 100 percent of paid prescription claims during the audit period and reprocessed each claim according to OWCP-defined utilization criteria, plan design exclusions, and numerous pricing methodologies.

CompPharma LLC is a consultancy focused on pharmaceutical program management and improvement in workers' compensation programs. CompPharma LLC conducted much of the research and comparisons regarding industry standards, staffing best practices, reimbursement, and the clinical management of pharmacy benefits. In addition, CompPharma LLC provided insight into program management, industry metrics and the reporting and management thereof, and the case for and use of evidence-based guidelines.

DATA RELIABILITY

In conducting this audit, we relied on data provided by OWCP's bill pay vendor. To assess the reliability of this information, we performed tests for obvious errors in completeness, compared it to other sources where possible, and confirmed our understanding of the data through interviews and walkthroughs with agency officials. We note the OIG issued an alert memorandum in September 2022⁵⁰ that concluded OWCP's medical bill processing data were of undetermined reliability. However, based on the work we performed, we determined the specific pharmaceutical data we used for this audit was sufficiently reliable to support our audit conclusions, findings, and recommendations.

⁵⁰ Alert Memorandum: The Office of Workers' Compensation Programs' Workers' Compensation Medical Bill Process System Data Were of Undetermined Reliability, Report No. 23-22-002-04-001 (September 26, 2022), <https://www.oig.dol.gov/public/reports/oa/2022/23-22-002-04-001.pdf>

INTERNAL CONTROLS

In performing the audit, we evaluated OWCP’s internal controls over FECA pharmaceutical spending for reasonable assurance that pharmaceutical spending was performed in accordance with federal and internal requirements. Our consideration of internal controls for FECA pharmaceutical spending would not necessarily disclose all matters that might be significant deficiencies or material weaknesses. Because of inherent limitations in internal controls, misstatements, losses, or noncompliance may nevertheless occur and not be detected. Because this was a performance audit, our audit was not designed to provide an opinion on the internal controls of OWCP. Accordingly, we provide no such opinions.

CRITERIA

- Federal Employees’ Compensation Act 5 U.S.C. 8101 *et seq.*
- Federal Employees Program Procedure Manual
- FECA Bulletin 11-05, Usage Guidelines for Fentanyl Products
- FECA Bulletin 17-01, Compounded Medication Prescribing Guidelines
- FECA Circular 18-05, Medication “Convenience” Kits and Combination Medications
- Customer Service Request 12727 – Business rule, which implemented restrictions on Schedule II drugs
- Federal Chief Information Officers Handbook
- GAO, Standards for Internal Control in the Federal Government

PRIOR RELEVANT COVERAGE

During the last 6 years, the OIG has issued two reports of significant relevance to the subject of this report. Those reports are the following:

1. Interim Report on Audit of Pharmaceutical Management in DOL Benefit Programs - OWCP Needs Better Controls Over Compounded Prescription Drugs, Report No. 03-17-001-04-431 (May 23, 2017), available at: <https://www.oig.dol.gov/public/reports/oa/2017/03-17-001-04-431.pdf>; and
2. OWCP Must Continue Strengthening Management of FECA Pharmaceuticals, Including Opioids, Report No. 03-19-002-04-431 (May 14, 2019), available at: <https://www.oig.dol.gov/public/reports/oa/2019/03-19-002-04-431.pdf>.

Additionally, a relevant March 14, 2016, USPS-OIG report (No. HR-MA-16-003) entitled “Management Advisory - Workers’ Compensation Compound Drug Costs,” is available at: <https://www.uspsoig.gov/reports/audit-reports/management-advisory-workers-compensation-compound-drug-costs>.

APPENDIX B: AGENCY'S RESPONSE TO THE REPORT

U.S. Department of Labor

Office of Workers' Compensation Programs
Washington, D.C. 20210



March 16, 2023

MEMORANDUM FOR: CAROLYN R. HANTZ
Assistant Inspector General for Audit

FROM: CHRISTOPHER J. GODFREY
Director of Workers' Compensation Programs

CHRISTOPHER
GODFREY

Digitally signed by CHRISTOPHER
GODFREY
Date: 2023.03.15 15:55:39 -04'00'

SUBJECT: Draft Report: OWCP Did Not Ensure Best Prices and
Allowed Inappropriate, Potentially Lethal Prescriptions in the
FECA Program, No. 03-23-001-04-431

The purpose of this memo is to provide a response from the Office of Workers' Compensation Programs (OWCP) to the subject draft report by the Office of the Inspector General (OIG) regarding the Federal Employees' Compensation Act (FECA) Program's pharmaceutical management. I want to emphasize that this report does not reflect the *current* pharmaceutical management program within the FECA program. As this audit covers the period 2015-2020, before OWCP executed a contract with a pharmacy benefit manager (PBM), many of the recommendations have already been addressed or were in the process of being addressed before this audit began. The OWCP has addressed each OIG Recommendation indicating the status of the recommendation below.

OIG RECOMMENDATION #1: "Implement a process to ensure competitive prices for the FECA program by regularly evaluating alternate pricing methodologies and other sources—including state fee schedules, ACA FUL, NADAC, MAC lists, market research, and comparable payers—and updating its pricing methodology as appropriate."

OWCP Response: OWCP has already implemented a process to "ensure competitive pricing" through a competitive acquisition process. On February 5, 2021, the U.S. Department of Labor's Office of the Senior Procurement Executive awarded a five-year contract to a pharmacy benefit manager (PBM) for the FECA program following a competitive solicitation process that resulted in the selection of the firm (among several competitors) whose proposal offered the Government the best value to the Government, considering among other factors the pricing offered by the offerors. This contract guaranteed pharmaceutical pricing for the FECA program that was substantially lower than the FECA pharmacy fee schedule in place at the time. Implementation of the PBM by the

FECA program saved federal agencies approximately \$87.9 million on medications year over year between Fiscal Year 2021 and Fiscal Year 2022. That contract (including its price reductions) is currently in place. As OWCP continues its market research as part of future procurements, OWCP will incorporate a process to evaluate alternative pricing methods, such as those recommended, and to include such alternative pricing methods, as appropriate, in future PBM contract solicitations beginning in 2025.

OIG RECOMMENDATION #2: “Implement a process to collect drug manufacturer rebates.”

OWCP Response: The OWCP agrees to evaluate whether the collection of drug manufacturer rebates is in the best interest of the Government during the next pharmacy benefit manager (PBM) solicitation. On February 5, 2021, the U.S. Department of Labor’s Office of the Senior Procurement Executive (OSPE) awarded a five-year contract to a PBM for the FECA program. This contract guaranteed pricing that was substantially lower than the FECA pharmacy fee schedule in place at the time. As part of its first PBM contract, the OWCP required and collects information on drug manufacturer rebates received by the PBM. In its market research efforts, and during the next solicitation, planned for 2025, the OWCP will explore whether direct payment or pass-through of drug manufacturer rebates to OWCP is in the best interest of the Government.

OIG RECOMMENDATION #3: “Implement a process to review the effectiveness of policy changes, including: (a) documented assessment of prescription information after any changes in the authorization, approval, and/or adjudication process to ensure desired changes are achieved; and (b) documented solutions for any performance gaps identified during the review, including follow-up testing.”

OWCP Response: The OWCP agrees with the OIG’s recommendation. On February 5, 2021, the U.S. Department of Labor’s Office of the Senior Procurement Executive awarded a five-year contract to a pharmacy benefit manager (PBM) for the FECA program. OWCP created an audit controls matrix to regularly monitor policy compliance and a quality assurance surveillance plan that monitors and reports on the overall performance of the PBM contractor. When performance gaps are identified, the OWCP documents the gaps and works with the PBM to resolve the gaps and perform necessary system testing.

OIG RECOMMENDATION #4: “Implement an ongoing pharmaceutical monitoring and alert program to identify and closely monitor significant changes in costs, prescribing patterns, utilization, sources, and new and novel prescription drugs.”

OWCP Response: This recommendation has already been implemented. On February 5, 2021, the U.S. Department of Labor's Office of Procurement Services awarded a five-year contract to a pharmacy benefit manager (PBM) for the FECA program. This contract included pharmaceutical monitoring and new drug alerts by the PBM. The PBM's account management team alerts the OWCP of changes in prescription costs, drug utilization, and prescribing patterns on a monthly and quarterly basis.

OIG RECOMMENDATION #5: "Establish internal controls that identify prescription drugs payment and management issues in near-real-time, including: (a) reviewing all system data fields provided by PBM(s) and bill pay vendor(s); (b) determining any additional data fields/elements needed to monitor pharmaceutical spending and track trends over time; (c) ensuring a recurring process to receive and immediately review data from the PBM(s) and bill pay vendor(s); and (d) using that data review to report regularly to management, medical director, and staff pharmacists for collaborative identification of current and emerging issues."

OWCP Response: This recommendation has already been implemented. On February 5, 2021, the U.S. Department of Labor's Office of Procurement Services awarded a five-year contract to a pharmacy benefit manager (PBM) for the FECA program. Subsequently, the OWCP established internal controls that identify prescription drug payment and management issues in near-real-time to include immediate data access via the PBM portal and daily pricing alerts. The OWCP receives pharmacy data from the PBM on a weekly basis and has access to the PBM's near-real-time data analytics platform. The pharmacy data received are added to the OWCP's pharmacy database, which includes data extracts from Medi-Span and the National Council for Prescription Drug Programs (NCPDP).

OIG RECOMMENDATION #6: "Implement a technology solution to perform ongoing prescription-claim-level reviews in near-real-time—including contractual adherence by the PBM, prescription drug pricing discounts, and rebate guarantees—as well as to validate prescription drug pricing methodology."

OWCP Response: This recommendation has already been implemented. On February 5, 2021, the U.S. Department of Labor's Office of Procurement Services awarded a five-year contract to a pharmacy benefit manager (PBM) for the FECA program. The OWCP currently receives data extracts from the PBM on a weekly basis, which are added to the OWCP's pharmacy database. The OWCP identifies any overpayments (deviations from contractually required pricing discounts) billed by the PBM on a quarterly basis, to be processed for collection under FECA program debt collection procedures

OIG RECOMMENDATION #7: “Adopt one or more of the widely used and thoroughly vetted evidence-based clinical guidelines, such as those from the American College of Occupational and Environmental Medicine and Official Disability Guidelines, in place of treatment suites.”

OWCP Response: This recommendation has already been implemented. On February 5, 2021, the U.S. Department of Labor’s Office of Procurement Services awarded a five-year contract to a pharmacy benefit manager (PBM) for the FECA program. This contract included the use of a Pharmacy and Therapeutics Committee to develop and maintain a drug formulary that is based on nationally recognized guidelines, including American College of Occupational and Environmental Medicine (ACOEM) and Official Disability Guidelines (ODG), and is approved by the OWCP. Treatment suites are no longer used by the FECA program in the adjudication and management of pharmacy claims.

OIG RECOMMENDATION #8: “Develop and deliver ongoing formal training for staff involved in making pharmaceutical decisions, with documentation of participation and post-training evaluation.”

OWCP Response: This recommendation has already been implemented. On February 5, 2021, the U.S. Department of Labor’s Office of Procurement Services awarded a five-year contract to a pharmacy benefit manager (PBM) for the FECA program. The PBM’s clinical pharmacists, physicians, and nurses, and OWCP clinical pharmacists and physicians make pharmaceutical decisions based on current clinical guidelines. The OWCP clinical pharmacists and physicians receive continuing education from major, nonprofit medical and pharmacy societies and attend annual meetings to stay abreast of important medical topics. The OWCP’s clinical pharmacists and physicians also have access to major medical journals and information from other federal agencies including the U.S. Food and Drug Administration (FDA). The FECA program’s medical benefit examiners and claims examiners make administrative decisions; they do not make clinical decisions.

OWCP RECOMMENDATION #9: “Add pharmacists and physicians to the FECA program for oversight and other necessary functions not assigned to the PBM.”

OWCP Response: The OWCP agrees with the OIG’s recommendation. The OWCP added a second clinical pharmacist in August of 2021, and a Deputy Chief Medical Officer in November of 2021. The OWCP recently approved the hiring of a third clinical pharmacist and a third physician and will initiate the hiring process in Fiscal Year 2023.

OWCP RECOMMENDATION #10: “Ensure medical and pharmaceutical experts participate in the development, monitoring, maintenance, improvement, and evaluation of the FECA pharmaceutical program.”

OWCP Response: This recommendation has already been implemented. On February 5, 2021, the U.S. Department of Labor’s Office of Procurement Services awarded a five-year contract to a pharmacy benefit manager (PBM) for the FECA program. Since the implementation of the pharmacy benefit manager (PBM) contract, OWCP physicians, pharmacists, and data scientists have actively collaborated with the FECA program in the development and administration of the FECA pharmacy program. The OWCP has a dedicated team within the Division of Administrative Operations (DAO), comprised of medical professionals responsible for developing policy in conjunction with the program and for providing professional oversight for the delivery of medical and pharmacy benefits. This team includes physicians, pharmacists, and data scientists who are directly managing the PBM contract, monitoring its performance, making improvements, and evaluating its overall progress in collaboration with DOL’s contracting officials as appropriate.

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