



Practitioner's Manual

AN INFORMATIONAL OUTLINE OF THE CONTROLLED SUBSTANCES ACT

Revised 2023¹

¹ This manual replaces all previous editions of the Practitioner's Manual issued by the Drug Enforcement Administration, both hard copy and electronic.

Drug Enforcement Administration
Practitioner's Manual

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This Practitioner's Manual has been prepared by the Drug Enforcement Administration (DEA), Diversion Control Division, as a guide to assist practitioners (i.e., registrants, such as physicians, dentists, veterinarians, scientific investigators, or other persons licensed, registered, or otherwise permitted, who are authorized to prescribe, dispense, and administer controlled substances) in their understanding of the federal Controlled Substances Act and its implementing regulations as they pertain to their profession.

The 2023 edition replaces all previous editions of the Practitioner's Manual issued by DEA, both hard copy and electronic.

Guidance documents, such as this document, are not binding and lack the force and effect of law, unless expressly authorized by statute or expressly incorporated into a contract, grant, or cooperative agreement.

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SECTION I - INTRODUCTION

Disclaimer

This Practitioner's Manual is intended to summarize and explain the basic requirements for prescribing, administering, and dispensing controlled substances under the Controlled Substances Act (CSA), 21 U.S.C. 801-971, and the Drug Enforcement Administration (DEA) regulations, 21 CFR Parts 1300 to End. This Practitioner's Manual is a guidance document that provides statutory and regulatory requirements as well as recommended practices. Statutory and regulatory requirements use language such as "must," "shall," or "required" include the statutory and/or regulatory citation(s). Recommended practices in this Practitioner's Manual are voluntary and use language such as "should" or "recommend" to identify these suggestions. Readers should refer to the most current versions of the CSA, DEA regulations, and Federal Register notices to obtain the most complete and accurate up-to-date statutory and regulatory information. These publications are available on the Internet through the U.S. Government Publishing Office website, <https://www.govinfo.gov>, which provides information by section, citation, and keywords. Any modifications to the law or regulations will be posted on DEA's Diversion Control Division (Diversion) website at www.DEAdiversion.usdoj.gov.

If there are errors in this Practitioner's Manual, please send notification to the following:

ODLP@dea.gov

or

Drug Enforcement Administration
Diversion Control Division
Attn: Policy Section/DPY
8701 Morrisette Drive
Springfield, VA 22152

Inquiries regarding topics within this document may be addressed to [your local DEA Diversion Field Office](#) or the address above.

Printed copies of the complete regulations implementing the CSA can be obtained from:

Superintendent of Documents
U.S. Government Publishing Office
Washington, DC 20402

Both the Code of Federal regulations (CFR) and the Federal Register (which includes DEA's proposed and final rules implementing the CSA) are available on the internet at <https://www.govinfo.gov>.

Unofficial copies of pertinent CFR citations and this Practitioner's Manual may be found on the internet at DEA's Diversion website (Click on "Resources" then "Publications and Manuals"):

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www.DEAdiversion.usdoj.gov

Should any provisions of the CSA or DEA regulations pertinent to this Practitioner's Manual be modified in the future, DEA will issue a revised electronic version of this document, which will be posted on DEA's Diversion website.

Authorized for Public Dissemination

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Message from the Assistant Administrator

DEA is pleased to provide you with the 2023 edition of the Practitioner's Manual to assist you in understanding the provisions of the CSA and its implementing regulations. This Practitioner's Manual will answer questions you may encounter in your practice and provide guidance in complying with the CSA and DEA regulations. This edition has been updated to include information on the provisions of DEA's March 2010 Interim Final Rule authorizing electronic prescriptions for controlled substances, the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, the Secure and Responsible Drug Disposal Act of 2010, the Comprehensive Addiction and Recovery Act of 2016, the SUPPORT for Patients and Communities Act of 2018, and the Consolidated Appropriations Act (CAA) of 2023.¹

There is a legitimate need for controlled substances, and DEA does not want to hinder their legitimate prescribing, administering, and dispensing. However, the diversion and abuse of pharmaceutical controlled substances is a growing public health concern in the United States. Practitioners play an important role in limiting the diversion of controlled substances.

Your role in the proper prescribing, administering, and dispensing of controlled substances is critical to the health of patients and helps protect society against drug abuse and diversion. Your compliance with the CSA and its objectives, and DEA's implementing regulations, is a powerful resource for protecting the public health, assuring patient safety, and preventing the diversion of controlled substances.

Sincerely,

Thomas W. Prevoznik
Acting Assistant Administrator
Diversion Control Division

¹ Pub. L. No. 117-328, 136 Stat. 4459 (2022).

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Preface

DEA was established in 1973 to serve as the primary agency responsible for the enforcement of federal drug laws. The CSA and its implementing regulations establish federal requirements regarding both illicit and licit controlled substances. Subsequent laws added regulated chemicals and certain equipment under the purview of the CSA. With respect to pharmaceutical controlled substances, DEA's responsibility is twofold: 1) prevent diversion and abuse of these substances and 2) ensure an adequate and uninterrupted supply is available to meet the country's legitimate medical, scientific, and research needs. In carrying out this mission, DEA works closely with state and local authorities and other federal agencies.

Under the framework of the CSA, all controlled substance transactions take place within a "closed system" of distribution established by Congress. Within this closed system, all legitimate handlers of controlled substances--manufacturers, distributors, physicians, pharmacies, and others--must be registered with DEA (unless exempt) and maintain strict accounting for all controlled substance transactions.

To carry out this mission effectively, DEA seeks to educate its registrants regarding their legal obligations. It is DEA's goal to maintain a positive working relationship with all of its registrants, including practitioners. DEA understands that it can best serve the public interest by working with the practitioner community to prevent the diversion of pharmaceutical controlled substances and scheduled listed chemical products (SLCPs) into the illicit market.

Federal controlled substance laws are designed to function in tandem with state-controlled substance laws. DEA works in cooperation with state professional licensing boards and state and local law enforcement officials to make certain that pharmaceutical controlled substances are prescribed, administered, and dispensed for a legitimate medical purpose in the usual course of professional practice.

In addition to the diversion of controlled substances, DEA is concerned with the diversion of certain chemicals used in the clandestine manufacture of methamphetamine and amphetamine to include SLCPs. The following SLCPs are contained in certain over-the-counter (OTC) and prescription products: ephedrine, pseudoephedrine, and phenylpropanolamine.

DEA and the practitioner profession have a common interest in the appropriate use of controlled substances. An effective working relationship to ensure compliance with federal requirements will continue to produce lasting benefits on a national scale.

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SECTION II - SCHEDULES OF CONTROLLED SUBSTANCES

Drugs and other substances that are considered controlled substances under the CSA are divided into five schedules. A listing of the substances and their schedules is found in the DEA regulations at [21 CFR 1308.11-15](#). A controlled substance is placed in its respective schedule based on whether it has a currently accepted medical use in treatment in the United States and its relative abuse potential and likelihood of causing dependence when abused. [21 U.S.C. 812\(b\)](#). Some examples of controlled substances in each schedule are listed below.

NOTE: Drugs listed in schedule I have no currently accepted medical use in treatment in the United States and, therefore, may not be prescribed, administered, or dispensed for medical use. [21 U.S.C. 812\(b\)\(1\)](#). In contrast, drugs listed in schedules II-V have an accepted medical use and may be prescribed, administered, or dispensed for medical use. [21 U.S.C. 812\(b\)\(2\)-\(5\)](#).

Schedule I Controlled Substances

Substances in this schedule have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. [21 U.S.C. 812\(b\)\(1\)](#).

Some examples of substances listed in schedule I are heroin, lysergic acid diethylamide (LSD), marijuana (cannabis), peyote, methaqualone, and 3,4-methylenedioxymethamphetamine (MDMA). [21 U.S.C. 812\(c\)](#), schedule I and [21 CFR 1308.11](#).

Schedule II Controlled Substances

Substances in this schedule have a high potential for abuse, a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions, and abuse of the drug may lead to severe psychological or physical dependence. [21 U.S.C. 812\(b\)\(2\)](#).

Examples of schedule II narcotics include morphine and codeine. Other schedule II narcotic substances and their common name brand products include any combination products containing hydrocodone (Maxidone, Zydone, Vicodin, Lortab, Vicoprofen, Replexain) and single entity substances such as hydromorphone (Dilaudid), methadone (Dolophine), meperidine (Demerol), oxycodone (OxyContin), and fentanyl (Sublimaze or Duragesic).

Examples of schedule II stimulants include amphetamine (Dexedrine, Adderall), methamphetamine (Desoxyn), methylphenidate (Ritalin), and lisdexamfetamine (Vyvanse). Other schedule II substances include cocaine, amobarbital, and glutethimide. [21 U.S.C. 812\(c\)](#), [schedule II](#) and [21 CFR 1308.12\(d\)](#).

Schedule III Controlled Substances

Substances in this schedule have a potential for abuse less than substances in schedules I or II, a currently accepted medical use in treatment in the United States, and abuse of the drug may lead to moderate or low physical dependence or high psychological dependence. [21 U.S.C. 812\(b\)\(3\)](#).

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Examples of schedule III narcotics include morphine combination products containing not more than 50 milligrams (mg) of morphine per 100 milliliters (ml) or per 100 grams, with one or more active, non-narcotic ingredients in recognized therapeutic amounts, and codeine combination products containing not more than 90 mg of codeine per dosage unit with an equal or greater quantity of an isoquinoline alkaloid of opium (e.g., Tylenol with codeine). [21 CFR 1308.14\(e\)\(1\)\(vi\)](#) and [\(i\)](#), respectively. Also included are buprenorphine products used to treat opioid addiction.

Examples of schedule III non-narcotics include benzphetamine (Didrex), phendimetrazine, ketamine, and anabolic steroids such as oxandrolone (Oxandrin). [21 U.S.C. 812\(c\), schedule III](#) and [21 CFR 1308.13](#).

Schedule IV Controlled Substances

Substances in this schedule have a low potential for abuse relative to substances in schedule III, a currently accepted medical use in treatment in the United States, and abuse of the drug may lead to limited physical dependence or psychological dependence relative to substances in schedule III. [21 U.S.C. 812\(b\)\(4\)](#).

An example of a schedule IV narcotic is tramadol (Ultram)

Examples of other schedule IV substances include alprazolam (Xanax), carisoprodol (Soma), clonazepam (Klonopin), clorazepate (Tranxene), diazepam (Valium), lorazepam (Ativan), midazolam (Versed), temazepam (Restoril), and triazolam (Halcion). [21 U.S.C. 812\(c\), schedule IV](#) and [21 CFR 1308.14](#).

Schedule V Controlled Substances

Substances in this schedule have a low potential for abuse relative to substances listed in schedule IV, have a currently accepted medical use in treatment in the United States, and abuse of the drug may lead to limited physical dependence or psychological dependence relative to substances in schedule IV.

Schedule V substances consist primarily of preparations containing limited quantities of certain narcotics. [21 U.S.C. 812\(b\)\(5\)](#). These are generally used for antitussive, antidiarrheal, and analgesic purposes. [21 U.S.C. 812\(c\), schedule V](#) and [21 CFR 1308.15](#).

Examples include cough preparations containing not more than 200 mg of codeine per 100 ml or per 100 grams (Robitussin AC, Phenergan with Codeine).

***NOTE:** Certain controlled substances may be classified in a different schedule, either higher or lower, in your state. In this event, as is the case with all controlled substance laws and regulations, when state requirements are more restrictive than federal requirements (or vice versa), registrants must comply with the more restrictive requirements. [21 CFR 1307.02](#).

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SLCP

An SLCP is defined as a product that contains ephedrine, pseudoephedrine, or phenylpropanolamine; and may be marketed or distributed lawfully in the United States under the federal Food, Drug, and Cosmetic Act as a nonprescription drug. [21 U.S.C. 802\(45\)\(A\)](#) and [21 CFR 1300.02\(b\)](#).

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SECTION III - REGISTRATION REQUIREMENTS

Unless otherwise exempted as explained in the subsections below, every practitioner who dispenses, which includes by definition administering and prescribing, controlled substances in schedules II through V, must be registered with DEA. [21 U.S.C. 802\(10\)](#), [21 U.S.C. 822\(a\)\(2\)](#), and [21 CFR 1301.11\(a\)](#). A state license must be obtained. [21 U.S.C. 823\(f\)](#). “The term practitioner means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.” [21 U.S.C. 802\(21\)](#).

To register or reregister as a practitioner, a [DEA Form 224](#) or [Form 224a](#), respectively, must be completed. [21 CFR 1301.13\(e\)\(1\)](#). The cost of the application or renewal fee is indicated on the form.

DEA Forms 224 and 224a must be completed [online](#). [21 CFR 1301.13\(e\)\(2\)](#) and [\(3\)](#).

Paper applications are no longer accepted. On April 11, 2022, DEA published a Final Rule in the *Federal Register*, and now requires all applications for DEA registration, and renewal of those registrations, to be submitted online. ([87 FR 21019](#).)

Under [21 CFR 1301.12\(a\)](#), a practitioner must apply for and obtain a separate registration for each “principal place of business or professional practice at one general physical location where controlled substances are dispensed by a person.”

The CAA² amended the CSA and added an additional condition for qualified practitioners who register with DEA. Section 1263(a) of the CAA defines the term “qualified practitioner” as a practitioner who (i) is licensed under State law to prescribe controlled substances, and (ii) is not solely a veterinarian, under [21 U.S.C. 823\(l\)\(4\)\(B\)](#). [21 U.S.C. 823\(l\)\(1\)](#) provides that, “[a]s a condition on registration under this section to dispense controlled substances in schedule II, III, IV, or V, the Attorney General shall require any qualified practitioner, beginning with the first applicable registration for the practitioner to meet” certain conditions in order to treat patients with Opioid Use Disorder (OUD). The term “first applicable registration” means the first registration or renewal of registration by a qualified practitioner on or after June 27, 2023, under [21 U.S.C. 823\(l\)\(4\)\(A\)](#). Therefore, any qualified practitioner that wants to dispense schedule II, III, IV, or V controlled substances must attest to completing not less than eight hours of training with respect to the treatment and management of patients with opioid or other substance use disorders (SUD). Qualified practitioners will attest to the following:

1. Do you hold a board certification in addiction medicine or addiction psychiatry?
2. Have you graduated in good standing from an accredited medical (allopathic or osteopathic)/dental/nursing school within the United States in the past 5 years and successfully

2 Pub. L. No. 117-328, div. FF, tit. I(B), ch. 6, § 1262(a)(1), 136 Stat. 4459, 5681 (2022).

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completed curriculum that included not less than 8 hours of training on managing patients with opioid or other SUDs, including use of medications to treat SUDs?

3. Have you completed at least 8 hours of training (inclusive or incremental) with respect to the treatment and management of patients with opioid or other SUD by a certified association?

Qualified practitioners are not required to attest to completing this training more than once. [21 U.S.C. 823\(l\)\(2\)\(A\)](#).

There are multiple ways that qualified practitioners can satisfy the new training requirement. Practitioners may have already satisfied the training requirement through past training, credentialing, or educational requirements. If they have not already satisfied the training requirement, practitioners can take training at any time prior to their next renewal of registration, and use this training when completing the attestation on their application. Although Section 1263(a) of the CAA³ requires qualified practitioners to complete training, it does not require a practitioner to provide a record of the training to DEA at the time of registration or renewal of a registration. DEA recommends that qualified practitioners maintain a record of their completed training for subsequent reference or use.

The CAA does not require DEA to provide training, and DEA will not endorse training modules. Practitioners can find additional information on SAMHSA's website at [Recommendations for Curricular Elements in Substance Use Disorders Training | SAMHSA](#).

Qualified Practitioners who attest to completing this training at the time of registration will be able to administer, dispense, or prescribe Food and Drug Administration-approved schedule III, IV, and V controlled substances to patients with OUD.

As part of the application or renewal process, DEA asks the practitioner to provide a business address--the address for the principal place of business--and a mailing address. When DEA issues the practitioner a Certificate of Registration (DEA Form 223), this certificate lists on it the specified business address. The DEA Form 223 shall be maintained at the registered location in a readily retrievable manner and shall be made available for inspection by DEA or any federal, state, or local agency engaged in the enforcement of laws relating to controlled substances. [21 CFR 1301.35\(c\)](#).

The registered location of the principal place of business is considered a "controlled premise" and is a place where original or other records or documents required under the CSA are kept or required to be kept, and where registered practitioners may lawfully administer and dispense controlled substances. [21 U.S.C. 880\(a\)\(1\)-\(2\)](#) and [21 CFR 1316.02\(c\)](#). DEA has the authority to enter a controlled premises to conduct an administrative inspection. [21 U.S.C. 880\(b\)](#) and [21 CFR 1316.03](#). Please note, if a practitioner chooses to register at their residence, it is considered a controlled premise and DEA has the authority to enter and conduct an inspection.

The mailing address is where a practitioner will receive correspondence from DEA. It can be the same as the business address or an alternative address such as a home address or post office box.

3 Pub. L. No. 117-328, 136 Stat. 4459 (2022)

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This address will not be printed on the registration certificate unless the address is the same as the business address printed on the Certificate of Registration.

When issued a Certificate of Registration, a practitioner must take an initial inventory, which is an actual physical count of all controlled substances in their possession (see [Initial Inventory, Section V](#)). [21 CFR 1304.11\(b\)](#).

Certificate of Registration

A practitioner must maintain the Certificate of Registration (DEA Form 223) at the registered location in a readily retrievable manner and available for official inspection. [21 CFR 1301.35\(c\)](#). If a duplicate Certificate of Registration is needed, a practitioner may:

- Download from [DEA website](#) (www.DEADiversion.usdoj.gov).
- Contact DEA Headquarters at 1-800-882-9539.
- E-mail a request to DEA.Registration.Help@dea.gov.
- Contact the local [DEA Registration Specialist](#).

A Certificate of Registration is valid for 36 months. However, a practitioner may receive an initial registration period of a minimum of 28 months or a maximum of 39 months. A detailed explanation for this variation can be found at [21 CFR 1301.13\(d\)](#).

Registration Requirements for Multiple Locations

As stated above, a separate registration must be obtained for each principal place of business or professional practice where controlled substances are stored, administered, or dispensed. [21 U.S.C. 822\(e\)\(1\)](#); [21 CFR 1301.12\(a\)](#). DEA has provided a limited exception to this requirement: If a practitioner is registered at one location, but practices at others within the same state, an additional registration is not required for any other location in that state at which the practitioner only *prescribes* controlled substances. [21 CFR 1301.12\(b\)\(3\)](#). Another exception is allowed for DEA-registered veterinarian practitioners. The Veterinary Medicine Mobility Act of 2014 amended the CSA to address separate registration requirements for veterinarians. [21 U.S.C. 822\(e\)\(2\)](#).

Registration Exemption of Agents and Employees

Individual practitioners who are agents or employees of another practitioner (other than a mid-level practitioner defined under [21 CFR 1300.01](#)), who are registered to dispense controlled substances, may administer or dispense controlled substances under the registration of the employer or principal practitioner in lieu of being registered themselves, and only if authorized or permitted to do so by the jurisdiction where the practice is located. However, this exemption does not extend to prescribing controlled substances. [21 CFR 1301.22 \(b\)](#).

Use of a Hospital's DEA Registration Number

Under [21 CFR 1301.22\(c\)](#), if an individual practitioner is an agent or employee of a DEA-registered hospital or other institution, that practitioner may administer, dispense, or prescribe controlled

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substances under the registration of the hospital or other institution in lieu of being registered, provided that all the following conditions are met:

1. Such dispensing, administering, or prescribing is done in the usual course of professional practice.
2. The practitioner is authorized or permitted to do so by the jurisdiction where practicing.
3. The hospital or other institution where the practitioner is employed has verified the practitioner is permitted to dispense, administer, or prescribe drugs within the jurisdiction.
4. The practitioner is acting only within the scope of employment in the hospital or institution.
5. The hospital or other institution authorizes the practitioner to administer, dispense, or prescribe under the hospital's registration and designates a specific internal code number for each practitioner so authorized. The code number shall consist of numbers, letters, or a combination thereof and shall be a suffix to the institution's DEA registration number, preceded by a hyphen (e.g., AP0123456-10 or AP0123456-A12).
6. The hospital or other institution maintains a current list of internal codes identifying the corresponding practitioner that is made available at all times to other registrants and law enforcement agencies for the purpose of verifying a practitioner's prescribing authority.

Renewal of Registration

A practitioner's registration must be renewed every three years using DEA Form 224a (Renewal Application for DEA Registration). [21 CFR 1301.13\(e\)\(1\)\(iv\)](#). Renewal applications for a DEA registration must be completed online not more than 60 days prior to the current expiration date. [21 CFR 1301.13\(b\)](#). The information from the existing DEA Form 223 is needed to [login to initiate the renewal process](#). The cost of the non-refundable application fee is indicated on the application.

Registrants will begin to receive renewal notifications approximately 60 days prior to the registration expiration date. [21 CFR 1301.13\(e\)\(3\)](#). DEA no longer sends renewal notifications by U.S. Postal Service. Instead, an electronic reminder to renew is sent at 60, 45, 30, 15, and 5 days prior to the expiration date of the registration to the associated email address. All registrants should ensure that the email address listed on their registration is correct and active. See [Registration \(usdoj.gov\)](#) for more information.

The policy and procedures with respect to [renewal and reinstatement of a DEA registration](#) are as follows:

1. Any person who is registered "may apply to be reregistered not more than 60 days before the expiration date of their registration, except that a bulk manufacturer of Schedule I or II controlled substances or an importer of Schedule I or II controlled substances may apply to be reregistered no more than 120 days before the expiration date of their registration." [21 CFR 1301.13\(b\)](#) In the event that an applicant for reregistration (who is doing business under a registration previously granted and not revoked or suspended) has applied for reregistration at

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least 45 days before the date on which the existing registration is due to expire, and the Administrator of DEA (Administrator) has issued no order on the application on the date on which the existing registration is due to expire, the existing registration of the applicant shall automatically be extended and continue in effect until the date on which the Administrator so issues their order. The Administrator may extend any other existing registration under the circumstances contemplated in this section even though the registrant failed to apply for reregistration at least 45 days before expiration of the existing registration, with or without request by the registrant, if the Administrator finds that such extension is not inconsistent with the public health and safety.” [21 CFR 1301.36\(i\)](#).

2. DEA policy allows the reinstatement of an **expired registration** for one calendar month after the expiration date. If the registration is not renewed within that calendar month, an application for a new DEA registration is required. See our [website](#) for more information.
3. Regardless of whether a registration is reinstated within the calendar month after expiration, DEA regulations prohibit the handling of controlled substances for any period of time without a valid registration. [21 CFR 1301.11\(a\)](#). A separate registration shall be required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances or list I chemicals. [21 U.S.C. 822\(e\)\(1\)](#).

For additional information or questions, contact DEA’s Registration Section at 1-800-882-9539 or DEA.Registration.Help@dea.gov.

Modification of Registration

A practitioner may apply to modify a DEA registration at any time. Modifications can include change of business and/or mailing address, name change, or change to handle additional controlled substances. There is no fee for a modification of registration. Modifications are handled in the same manner as applications and must be approved by DEA. [21 CFR 1301.51\(a\)](#). DEA Registrants may request a [modification of registration](#) on the DEA website or contact the local [DEA Registration Specialist](#). If the change in address involves a move to a different state, a practitioner must obtain the proper state-issued license and, if applicable, controlled substances registration from the new state, prior to applying for a modification of registration with DEA. [21 U.S.C. 823\(f\)](#). DEA will not approve the modification until it receives proof of proper state licensure/registration. If the modification is approved, DEA issues a new Certificate of Registration and, if requested, new schedule I & II order forms (DEA Form 222). A practitioner must maintain the certificate until expiration. See [21 CFR 1301.35\(c\)](#).

Opioid (Narcotic) Addiction Treatment Programs

The Narcotic Addict Treatment Act of 1974, the SUPPORT for Patients and Communities Act of 2018 (the SUPPORT Act), and the CAA⁴ amended the CSA with respect to the use of controlled substances in the medical treatment of addiction. These laws established the procedures for

4 Pub. L. No. 117-328, 136 Stat. 4459 (2022).

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approving and licensing practitioners involved in the treatment of opioid addiction as well as improving the quality and delivery of that treatment to the segment of society in need.

Practitioners wishing to administer and dispense a Food and Drug Administration (FDA)-approved schedule II controlled substance (e.g., methadone) for maintenance and detoxification treatment must obtain a separate DEA registration as a narcotic treatment program (NTP)⁵ via a [DEA Form 363](#), [21 CFR 1301.13\(e\)\(1\)](#) and [21 U.S.C. 823\(g\)\(1\)](#). The practitioner must also comply with DEA regulations regarding treatment qualifications, security, records, and unsupervised use of such drugs pursuant to the CSA. [21 CFR 1306.07\(a\)\(2\)](#). In addition to obtaining this separate DEA registration, this type of activity also requires the approval and certification of the Center for Substance Abuse Treatment (CSAT) within the Substance Abuse and Mental Health Services Administration ([SAMHSA](#)) of the U.S. Department of Health and Human Services (HHS), as well as the applicable state methadone authority. [21 U.S.C. 823\(g\)](#).

Qualified Practitioners

On December 29, 2022, President Biden signed into law the Consolidated Appropriations Act of 2023 (CAA),⁶ which expanded access to medications for opioid use disorder (OUD). Specifically, the CAA amended the Controlled Substances Act (CSA) by eliminating the “DATA-Waiver” requirement previously codified in [21 U.S.C. 823\(g\)\(2\)](#).

Historically, DATA-waived practitioners were required by the Substance Abuse and Mental Health Services Administration (SAMHSA) to complete training with regard to treating patients with OUD. By striking [21 U.S.C. 823\(g\)\(2\)](#), section 1262(a)(1) of the CAA⁷ eliminated additional requirements for dispensing narcotic drugs in schedule III, IV, and V for maintenance or detoxification treatment, which required qualifying practitioners to submit a notification of intent of the practitioner to begin dispensing the drugs or combinations to patients for maintenance or detoxification, instead of registering as an NTP. DATA-waived practitioners were assigned a unique identification number, known as the X-number, which was required to be annotated on prescriptions. With the passage of the CAA⁸, practitioners are no longer assigned an X-number and they are no longer required on prescriptions.

Section 1263(a) of the CAA⁹ defines the term “qualified practitioner” as a practitioner who (i) is licensed under state law to prescribe controlled substances; and (ii) is not solely veterinarian. [21 U.S.C.823\(l\)\(4\)\(B\)](#). Additionally, qualified practitioners are registered with DEA to dispense controlled substances, and are qualified through not less than eight (8) hours of specialized training and/or certification to dispense, including prescribing narcotics in schedule III-V, or a combination of such drugs, approved by the FDA specifically for use in narcotic maintenance or detoxification treatment.

5 A narcotic treatment program means a program engaged in maintenance and/or detoxification treatment with narcotic drugs. [21 CFR 1300.01](#). This same section also defines a narcotic drug.

6 Pub. L. No. 117-328, 136 Stat. 4459 (2022).

7 Pub. L. No. 117-328, 136 Stat. 4459 (2022).

8 Pub. L. No. 117-328, 136 Stat. 4459 (2022).

9 Pub. L. No. 117-328, 136 Stat. 4459 (2022).

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Use of DEA Registration Number

DEA strongly opposes the use of a DEA registration number for any purpose other than the one for which it was intended--to provide certification of a DEA registration in transactions involving controlled substances. However, DEA has no regulations that prevent parties from requesting a DEA registration number for identification purposes.

Termination of Registration

A practitioner's registration shall terminate, without any further action by DEA, if and when a practitioner dies, if a business ceases legal existence, or if a practitioner discontinues business or professional practice, or when a practitioner surrenders a DEA registration. [21 CFR 1301.52\(a\)](#).

If a practitioner surrenders their DEA registration, it shall be terminated when a duly executed DEA Form 104, Voluntary Surrender of Controlled Substances Privileges, or any signed writing indicating a desire to surrender a registration is received by any DEA employee. [21 CFR 1301.52\(a\)](#).

If a practitioner discontinues business or professional practice, the practitioner must promptly notify DEA. [21 CFR 1301.52\(a\)](#). DEA also recommends that the practitioner contact the local [Special Agent in Charge](#) and seek authority and instructions to dispose of any controlled substances obtained under the authority of that registration in accordance with [21 CFR part 1317](#).

Denial, Suspension, or Revocation of Registration

Under [21 U.S.C. 824\(a\)](#), DEA has the authority to suspend or revoke a DEA registration upon a finding that a practitioner has:

1. Materially falsified the application.
2. Been convicted of a felony under the CSA or any other law of the United States, or of any state, relating to a controlled substance or a list I chemical.
3. Had a state license or registration suspended, revoked, or denied by a competent state authority and is no longer authorized by state law to engage in the manufacturing, distribution, or dispensing of controlled substances or list I chemicals, or has had a suspension, revocation, or denial of a registration recommended by competent state authority.
4. Committed an act which would render DEA registration inconsistent with the public interest.
5. Been excluded (or directed to be excluded) from participation in a Medicare or state health care program.

Before taking such action, DEA serves upon the registrant an order to show cause why the registration should not be denied, suspended, or revoked. [21 U.S.C. 824\(c\)\(1\)](#). DEA may also simultaneously suspend a registration in cases where there is imminent danger to the public health or safety. [21 U.S.C. 824\(d\)](#). Imminent danger to the public health or safety means that, due to the failure of the registrant to maintain effective controls against diversion or otherwise comply with the obligations of a registration under the CSA, there is a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur in the absence of an immediate suspension of the registration. [21 U.S.C. 824\(d\)\(2\)](#).

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Denial of Registration in the Public Interest

DEA may deny an application for registration if issuing the registration would be inconsistent with public interest. In determining the public interest, [21 U.S.C. 823\(f\)](#) provides that the following factors are to be considered:

1. The recommendation of the appropriate state licensing board or professional disciplinary authority.
2. The applicant's experience in dispensing or conducting research with respect to controlled substances.
3. The applicant's conviction record under federal or state laws relating to the manufacture, distribution, or dispensing of controlled substances.
4. Compliance with applicable state, federal, or local laws relating to controlled substances.
5. Such other conduct which may threaten the public health and safety.

Exemption of Federal Government Practitioners from Registration

"The requirement of registration is waived for any official of the U.S. Army, Navy, Marine Corps, Air Force, Coast Guard, Public Health Service, or Bureau of Prisons who is authorized to prescribe, dispense, or administer, but not to procure or purchase controlled substances in the course of his/her official duties. Such officials shall follow procedures set forth in 21 CFR part 1306 of this chapter regarding prescriptions, but shall state the branch of service or agency (e.g., "U.S. Army" or "Public Health Service") and the service identification number of the issuing official in lieu of the registration number required on prescription forms." [21 CFR 1301.23\(a\)](#).

Exemption of Federal Government Practitioners from Registration Fees

DEA shall exempt from payment of an application fee for registration or reregistration: any individual practitioner who is required to obtain an individual registration in order to carry out his or her duties as an official of an agency of the United States (including the U.S. army, Navy, Marine Corps, Air Force, and Coast Guard), of any state or any political subdivision or agency thereof. 21 CFR 1301.21(a)(2).

If Federal Government practitioners wish to maintain a DEA registration for a private practice, which would include prescribing for private patients, they must be fully licensed to handle controlled substances by the state in which they are located. Under these circumstances, the Federal Government practitioner will not be eligible for the fee exemption and must pay a fee for the registration. [21 CFR 1301.23\(c\)](#).

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SECTION IV - PRESCRIPTIONS FOR CONTROLLED SUBSTANCES

To be valid, a prescription for a controlled substance must be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. The practitioner is responsible for the proper prescribing and dispensing of controlled substances, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription that is not issued for a legitimate medical purpose in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of [21 U.S.C. 829](#). The person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances. [21 U.S.C. 841\(a\)\(1\)](#) and [21 CFR 1306.04\(a\)](#).

Issuance of a Prescription

Under [21 CFR 1306.03](#), a prescription for a controlled substance may only be issued by an individual practitioner who is:

1. Authorized to prescribe controlled substances by the jurisdiction in which they are licensed to practice their profession, and
2. Either registered with DEA or exempted from registration by regulation ([21 CFR 1301.22\(c\)](#) and [21 CFR 1301.23](#)), or
3. An agent or employee of a hospital or other institution acting in the normal course of business or employment under the registration of the hospital or other institution which is registered in lieu of the individual practitioner being registered, provided that additional requirements as set forth in [21 CFR 1301.22\(c\)](#) are met.

Prescription Requirements

A prescription is an order for medication which is dispensed to or for an ultimate user (i.e., patient). A prescription is not an order for medication which is dispensed for immediate administration to the ultimate user (i.e., an order to dispense a drug to an inpatient for immediate administration in a hospital is not a prescription). [21 CFR 1300.01\(b\)](#) (“prescription”).

A prescription for schedule II-controlled substances may be written or electronic, except in certain emergency situations when oral prescriptions may be permissible. [21 CFR 1306.08\(a\), \(b\), 1306.11\(a\), \(d\)](#). A prescription for schedule III-V controlled substances may be written, electronic, or oral. [21 CFR 1306.08\(a\), \(b\), 1306.21\(a\)](#).

A prescription for a controlled substance must be dated and signed on the date when issued. The prescription must include the patient's full name and address, and the practitioner's full name, address, and DEA registration number. [21 CFR 1306.05\(a\)](#).

Under [21 CFR 1306.05\(a\)](#) the prescription must also include:

- Drug Name
- Strength

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- Dosage Form
- Quantity Prescribed
- Directions for Use
- Number of Refills Authorized (if any)

A practitioner or an agent of the practitioner may prepare a written prescription; however, the practitioner is responsible for ensuring that the prescription conforms to all requirements of the law and regulations, both federal and state. [21 CFR 1306.05\(f\)](#). A paper prescription must be written in ink or indelible pencil, typewritten, or printed on a computer, and must be manually signed by the practitioner. [21 CFR 1306.05\(d\)](#).

Be aware that there is a corresponding responsibility with the pharmacist who fills the prescription to ensure that the prescription was issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. [21 CFR 1306.04\(a\)](#). An order purporting to be a prescription issued not in the usual course of professional treatment is an invalid prescription within the meaning and intent of the CSA. The person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances. [21 U.S.C. 841\(a\)\(1\)](#), [21 CFR 1306.04\(a\)](#). In an effort to fulfill their corresponding responsibility, pharmacists may contact the prescribing practitioner.

A practitioner must not issue a prescription to obtain controlled substances for the purpose of general dispensing to patients. [21 CFR 1306.04\(b\)](#).

Electronic Prescriptions for Controlled Substances

DEA regulations give practitioners the option to write prescriptions for controlled substances electronically and permit pharmacies to receive, dispense, and archive electronic prescriptions.¹⁰ An electronic prescription in this context is not an image of a prescription transmitted to the pharmacy as a facsimile. Rather, it is transmitted as an electronic data file to the pharmacy, which imports the data file into its database. [75 FR 16238-39](#).

These regulations do not mandate practitioners to prescribe controlled substances via electronic prescriptions. Practitioners are still able to write, and manually sign, prescriptions for schedule II, III, IV, and V controlled substances and pharmacies are still able to dispense controlled substances based on those written prescriptions. Oral prescriptions can still be issued for schedule III, IV, and V controlled substances.

Electronic prescriptions for controlled substances (EPCS) are only permissible if transmitted using software applications that meet DEA requirements. [21 CFR 1306.08\(a\)\(2\)](#) and [1311.120\(a\)](#). Application service providers are required to obtain a third-party audit or be approved by a DEA-approved certification organization to certify that the application complies with DEA requirements. [21 CFR 1311.300\(a\)](#). The third-party auditor issues a report to the application service provider that indicates whether the application is in compliance. The application service provider must provide a

¹⁰ DEA's March 31, 2010 interim final rule, Electronic Prescriptions for Controlled Substances ([75 FR 16235-16319](#)).

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copy of the report to practitioners who are considering use of the electronic prescription application. [21 CFR 1311.300\(f\)](#).

Under [21 CFR 1311.140\(a\)](#), the following must occur if a practitioner wants to sign an EPCS:

1. The practitioner must access a list of one or more controlled substance prescriptions for a single patient. The list must display the information required by [21 CFR 1311.120\(b\)\(9\)](#).
2. The practitioner must indicate the prescriptions that are ready to be signed.
3. While the prescription information required in [21 CFR 1311.120\(b\)\(9\)](#) is displayed, the following statement or its substantial equivalent is displayed: “By completing the two-factor authentication protocol at this time, you are legally signing the prescription(s) and authorizing the transmission of the above information to the pharmacy for dispensing. The two-factor authentication protocol may only be completed by the practitioner whose name and DEA registration number appear above.”
4. While the prescription information required in [21 CFR 1311.120\(b\)\(9\)](#) and the statement required by [21 CFR 1311.140\(a\)\(3\)](#) of this section remain displayed, the practitioner must be prompted to complete the two-factor authentication protocol.
5. The completion by the practitioner of the two-factor authentication protocol in the manner provided in [21 CFR 1311.140\(a\)\(4\)](#) constitutes the signing of the prescription by the practitioner for purposes of [21 CFR 1306.05\(a\)](#) and [\(e\)](#).
6. Except as provided under [21 CFR 1311.145](#), the practitioner's completion of the two-factor authentication protocol must cause the application to digitally sign and electronically archive the information required under [part 1306](#).
7. Under [21 CFR 1311.140\(b\)](#), the electronic prescription application must clearly label as the signing function the function that prompts the practitioner to execute the two-factor authentication protocol using their credential.
8. Under [21 CFR 1311.140\(c\)](#), any prescription not signed in the manner required by [21 CFR 1311.140](#) shall not be transmitted.

Identity Proofing

Pursuant to [21 CFR 1311.140\(a\)\(5\)](#), and as discussed in the above section, the completion of the two-factor authentication constitutes the signing of an EPCS. DEA regulations require the two-factor authentication for individual practitioners engaged in EPCS including those practitioners working under the registration of a hospital or clinic. [21 CFR 1301.22\(c\)](#) and [1311.110](#).

A hospital, clinic, or other institutional practitioner may obtain the necessary authentication credentials for individual practitioners eligible to use the institution's EPCS application in either of two basic ways. [21 CFR 1311.110](#) and [1311.105](#).

First, the hospital/clinic may elect to conduct its own in-house identity proofing as part of its credentialing process of these individual practitioners and itself authorize the issuance of the authentication credentials. If an institutional practitioner chooses to conduct its own internal identity

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proofing, DEA regulations require that process to meet a number of specific requirements. [21 CFR 1311.110](#).

Second, rather than conducting its own identity proofing, a hospital/clinic may require practitioners to obtain identity proofing and authentication credentials in the same manner as practitioners not operating under an institution's DEA registration, i.e., through a credential service provider (CSP) or certification authority (CA). [21 CFR 1311.105](#). DEA regulations require CSPs to conduct identity proofing at Assurance Level 3 or above of the National Institute of Standards and Technology (NIST) Special Publication (SP) 800-63-1, "Electronic Authentication Guideline." [21 CFR 1311.105\(a\)\(1\)](#). This publication allows either in-person or remote identity proofing.

Since those regulations were published, changes in technology have led to the creation of new, updated NIST guidelines, NIST SP 800-63-3, "Digital Identity Guidelines," published on March 2, 2020. Under NIST SP 800-63-3, the relevant identity proofing assurance level is Identity Assurance Level 2. Due to the nature of technology, Identity Assurance Level 2 of NIST SP 800-63-3 is like DEA's current required standard of Assurance Level 3 of NIST SP 800-63-1. Assurance Level 2 of NIST-SP-800-63-3 allows for either in-person or remote identity proofing. This issue is discussed in DEA's *Federal Register* publication reopening the comment period for the Interim Final Rule. 85 FR 22018. DEA regulations do not require that this process occur in-person. Thus, if the hospital/clinic as well as CSPs and CAs are able to remotely conduct identity proofing in a manner that satisfies these DEA regulatory requirements, they may do so. A DEA registered hospital/clinic may also want to check with their state regulatory boards to maintain compliance with any state rules or regulations regarding this matter.

Practitioner Responsibility for EPCS

EPCS may be subject to state laws and regulations. Regardless of what state law requires, all practitioners who issue EPCS must comply with DEA regulations governing EPCS. If state laws and regulations impose requirements beyond DEA regulations governing EPCS, practitioners must comply with such state requirements in addition to, and not in lieu of, complying with the requirements in DEA regulations. [21 CFR 1307.02](#).

Schedule II Controlled Substances

Schedule II controlled substances require a written prescription which must be signed by the practitioner or an electronic prescription that meets all DEA requirements for electronic prescriptions for controlled substances. [21 CFR 1306.11\(a\)](#), [1306.08](#) and [1311.100\(b\)](#). While some states and insurance carriers may limit the quantity of controlled substances dispensed, there are no express federal limits with respect to the quantities of drugs dispensed via a prescription. However, the amount prescribed must be consistent with the requirement that a prescription for a controlled substance be issued only for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. [21 CFR 1306.04\(a\)](#). For a schedule II controlled substance, an oral prescription is permitted only in an [emergency situation](#). [21 CFR 1306.11\(d\)](#).

Refills for Schedule II Controlled Substances

Refilling a schedule II prescription is prohibited by federal law. [21 U.S.C. 829\(a\)](#).

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Issuance of Multiple Prescriptions for Schedule II Controlled Substances

DEA regulations permit the issuance of multiple prescriptions for schedule II-controlled substances. Under [21 CFR 1306.12\(b\)\(1\)](#), a practitioner may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a schedule II controlled substance provided the following conditions are met:

1. Each prescription must be issued on a separate prescription blank. [72 FR 64921, 64923, \(2007\)](#).
2. Each separate prescription is issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.
3. The individual practitioner provides written instructions on each prescription (other than the first prescription, if the intent is for that prescription to be filled immediately) indicating the earliest date on which a pharmacy may fill each prescription.
4. The individual practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse.
5. The issuance of such multiple prescriptions is permissible under applicable state laws.
6. The individual practitioner complies fully with all other applicable requirements under the CSA and DEA regulations, as well as any additional requirements under state law.

This regulation should not be construed as encouraging practitioners to issue multiple prescriptions or to see patients only once every 90 days when prescribing schedule II-controlled substances. Rather, a practitioner must make a determination, based on sound medical judgment and in accordance with established medical standards, whether it is appropriate to issue multiple prescriptions and how often to see patients when doing so. [21 CFR 1306.12\(b\)\(2\)](#).

Facsimile Prescriptions for Schedule II Controlled Substances

In order to expedite the filling of a prescription, a practitioner may transmit a schedule II prescription to the pharmacy by facsimile. However, the original schedule II prescription must generally be presented to the pharmacist and verified against that facsimile before the controlled substances are dispensed. [21 CFR 1306.11\(a\)](#). The facsimile may be transmitted to the pharmacy by a practitioner or an agent of the practitioner. [21 CFR 1306.03\(b\)](#). All requirements of a valid prescription must be followed. [21 CFR 1306.05\(a\)](#).

There are three exceptions under which a facsimile can serve as the original written prescription. These exceptions apply if the practitioner is:

1. Prescribing a schedule II narcotic controlled substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion. [21 CFR 1306.11\(e\)](#).
2. Prescribing a schedule II-controlled substance for residents of Long Term Care Facilities (LTCFs). [21 CFR 1306.11\(f\)](#).
3. Prescribing a schedule II narcotic controlled substance for a patient enrolled in a hospice care program certified and/or paid for by Medicare under Title XVIII or a hospice program which is licensed by the state. The practitioner or agent must note on the prescription that it is for a hospice patient. [21 CFR 1306.11\(g\)](#).

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Emergency Prescribing for Schedule II Controlled Substances

Under [21 CFR 1306.11\(d\)](#), in the case of an emergency situation (i.e., when the prescribing practitioner has determined that immediate administration of a drug is necessary for proper treatment of the intended ultimate user, no alternative treatment is available (including a drug which is not a schedule II controlled substance), and it is not reasonably possible for the prescribing practitioner to provide a written prescription for the drug at that time), a practitioner may telephone a schedule II prescription to the pharmacist who may then dispense the controlled substance. It is the policy of DEA that the practitioner must personally communicate the emergency oral prescription to the pharmacist, and that a practitioner's agent may **not** call in an oral prescription for a schedule II-controlled substance on behalf of a practitioner even in an emergency situation. See Role of Authorized Agents in Communicating Controlled Substance Prescriptions to Pharmacies. [75 FR 61613](#), October 6, 2010. Furthermore, to be consistent with DEA's policy statement, the following conditions must be met:

1. The quantity prescribed and dispensed must be limited to the amount needed to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a paper or electronic prescription signed by a prescribing practitioner). [21 CFR 1306.11\(d\)\(1\)](#).
2. The prescription must be immediately reduced to writing by the pharmacist and must contain all required information, except for the practitioner's signature. [21 CFR 1306.11\(d\)\(2\)](#).
3. If the pharmacist does not know the prescribing practitioner, the pharmacist must make a reasonable effort to determine that the oral authorization was issued by a DEA-registered individual practitioner. This verification effort may include a call back to the practitioner and/or other good faith efforts to insure their identity. [21 CFR 1306.11\(d\)\(3\)](#).
4. Within seven days after authorizing the emergency oral prescription, the practitioner must furnish to the dispensing pharmacist a paper or electronic prescription for the controlled substance prescribed. The prescription must be annotated with "Authorization for Emergency Dispensing" and the date of the oral prescription. The practitioner may either deliver a paper prescription to the pharmacist in person or by mail, but if delivered by mail, it must be postmarked within the seven-day period. Upon receipt, the dispensing pharmacist must attach this paper prescription to the oral emergency prescription which had earlier been reduced to writing by the pharmacist. For electronic prescriptions, the pharmacist must annotate the record of the electronic prescription with the original authorization and date of the oral order. The pharmacist must notify the local [DEA Diversion Field Office](#) if the practitioner fails to provide the prescription. [21 CFR 1306.11\(d\)\(4\)](#).

Partial Dispensing

A prescription for a schedule II-controlled substance may be partially dispensed if the pharmacist is unable to supply the full quantity of a written or emergency oral (telephone) prescription, provided the pharmacist notes the quantity supplied on the front of the written prescription, on a written record of the emergency oral prescription, or in the electronic prescription record. The remaining portion may be dispensed within 72 hours of the first partial dispensing. However, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist must notify the prescribing practitioner. No

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further quantity may be supplied beyond 72 hours without a new prescription. [21 U.S.C. 829\(f\)\(2\)\(B\)](#) and [21 CFR 1306.13\(a\)](#).

It is DEA's position that the pharmacy must have the balance of the prescription ready for dispensing within the 72-hour limit, but the patient is not required to pick up the balance of the prescription within that 72-hour limit. [21 CFR 1306.13\(a\)](#).

On July 22, 2016, CARA was enacted and provided an addition to the schedule II partial fill allowances under [21 CFR 1306.13](#) (above). CARA Section 702 amended [21 U.S.C. 829](#) by adding subsection (f), which permits a prescription for a controlled substance in schedule II to be partially filled at the request of the patient or the prescribing practitioner if:

1. The partial filling is not prohibited by state law;
2. The prescription is written and filled in accordance with the CSA, DEA regulations, and state law;
3. The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed; and
4. The remaining portions of a partially filled prescription for a controlled substance in schedule II, if filled, shall be filled not later than 30 days after the date on which the prescription was written.

A practitioner must check with their state to determine if its laws or regulations were changed to parallel CARA. If the state regulations have not changed, and they still only allow the partial filling of a schedule II controlled substance under the conditions outlined in [21 CFR 1306.13\(a\)](#) then the stricter state law applies until such time as the state makes a change. [21 CFR 1307.02](#).

Partial Filling of Schedule II Prescriptions for Terminally Ill or LTCF Patients

A prescription for a schedule II-controlled substance written for a patient in an LTCF or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist must contact the practitioner prior to partially filling the prescription. Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient. [21 CFR 1306.13\(b\)](#).

The pharmacist must record on the prescription whether the patient is "terminally ill" or an "LTCF patient." A prescription that is partially filled and does not contain the notation "terminally ill" or "LTCF patient" must be deemed to have been filled in violation of the CSA. For each partial filling, the dispensing pharmacist must record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. The total quantity of schedule II-controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed. Schedule II prescriptions for patients in an LTCF or terminally ill patients are valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of medication. [21 CFR 1306.13\(b\)](#).

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Schedule III-V Controlled Substances

For a pharmacist to dispense a controlled substance in schedules III, IV, or V, a prescription for such substance must be communicated in the following ways: (1) as a paper prescription signed by a practitioner, (2) as a facsimile of that prescription transmitted by the practitioner or their agent to the pharmacy, (3) as an electronic prescription that meets DEA's requirements for such prescriptions, or (4) as an oral prescription made by an individual practitioner to a pharmacist. [21 CFR 1306.21\(a\)](#). In the case of an oral prescription, the pharmacist must promptly reduce it to writing, including all information required in [21 CFR 1306.05](#) except for the signature of the prescribing practitioner.

An individual practitioner may in the course of their professional practice administer or dispense a controlled substance in schedules III, IV, or V without a prescription, subject to [21 CFR 1306.07](#). [21 CFR 1306.21\(b\)](#).

Refills for Schedule III and IV Controlled Substances

Schedules III and IV controlled substances may be refilled if authorized on the original prescription or by oral authorization of the practitioner. The prescription may be refilled only up to five times within six months after the date of issue. A practitioner must issue a new and separate prescription for additional quantities beyond the five-refill, six-month limitation. [21 U.S.C. 829\(b\)](#), [21 CFR 1306.22\(e\)\(4\)](#).

Refills for Schedule V Controlled Substances

The CSA and DEA regulations do not address limits for a schedule V refill. The CSA only provides that a schedule V controlled substance may not be distributed or dispensed other than for a medical purpose. [21 U.S.C. 829\(c\)](#). Consequently, a refill for a schedule V controlled substance is issued by a practitioner for a legitimate medical purpose acting in the usual course of their professional practice.

Facsimile Prescriptions for Schedule III-V Controlled Substances

Prescriptions for schedules III-V controlled substances may be transmitted by facsimile by a practitioner or an agent of the practitioner to the dispensing pharmacy. The facsimile is considered to be equivalent to an original prescription as long as the practitioner manually signed the prescription. [21 CFR 1306.21\(a\)](#) and [21 CFR 1306.21\(c\)](#).

Oral Authorization for Schedule III-V Prescriptions

A practitioner may orally communicate prescriptions for schedule III-V controlled substances to the dispensing pharmacy. The pharmacist must promptly reduce to writing all information required for a valid prescription except for the practitioner's signature. [21 CFR 1306.21\(a\)](#).

Role of Authorized Agents in Prescribing Controlled Substances

DEA published a policy statement on October 6, 2010, regarding the "Role of Authorized Agents in Communicating Controlled Substance Prescriptions to Pharmacies." [75 FR 61613-17](#). This policy statement did not convey any new DEA edicts, but rather it clarified long-standing DEA regulations

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and policies regarding this issue.

The CSA permits a practitioner to use an agent, defined at 21 U.S.C. 802(3), or any other authorized person to act on behalf of or at the direction of a practitioner. Under DEA regulations, an agent could prepare a prescription for signature. [21 CFR 1306.05\(f\)](#). A practitioner acting in the usual course of professional practice must determine that there is a legitimate medical purpose for a controlled substance prescription; an agent may **not** make this determination. [21 CFR 1306.04\(a\)](#).

Below is a summary of the acts, under DEA regulations, that a practitioner's agent may take in connection with controlled substance prescriptions:

1. An authorized agent of an individual practitioner may prepare a written prescription for the signature of the practitioner, provided that the practitioner, in the usual course of professional practice, has determined that there is a legitimate medical purpose for the prescription and has specified to the agent the required elements of the prescription. [21 CFR 1306.03\(b\)](#), [1306.04\(a\)](#).
2. Where a DEA-registered individual practitioner has made a valid oral prescription for a controlled substance in schedules III-V by conveying all the required prescription information to the practitioner's authorized agent, that agent may telephone the pharmacy and convey that prescription information to the pharmacist. [21 CFR 1306.03\(b\)](#), [1306.21\(a\)](#).
3. In those situations in which an individual practitioner has issued a valid written prescription for a controlled substance, and the regulations permit the prescription to be transmitted by facsimile to a pharmacy, the practitioner's agent may transmit the practitioner-signed prescription by facsimile. [21 CFR 1306.11\(a\),\(f\),\(g\)](#), [1306.21\(a\)](#).

Prescription Monitoring Program (PMP)

A PMP (also referred to as a prescription drug monitoring program or PDMP) is a state-administered data collection system used to gather prescription information, primarily for controlled substance prescriptions. PMPs collect, monitor, and analyze electronically transmitted prescribing and dispensing data submitted by pharmacies and, in some states, dispensing practitioners. Access to PMP information is determined by state law. Most states allow practitioners and pharmacists to obtain PMP reports regarding their patients and customers. This is a highly effective tool to aid in proper prescribing and dispensing decisions. The data can be used by practitioners and pharmacists to identify potential "doctor shoppers" and those who attempt to obtain controlled substances by fraud, forgery, or deceit. Many states also provide PMP information to other authorized groups such as law enforcement, licensing and regulatory boards, State Medicaid programs, and state medical examiners.

PMP data is also used to develop medical education programs for practitioners and pharmacists. These programs heighten awareness about diversion, prescription drug abuse, and drug trends. DEA strongly endorses PMPs.

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Treatment of Pediatric Patients with Opiate Dependency

SAMHSA is the agency that has regulatory authority over the administration of methadone to pregnant mothers receiving withdrawal treatment for opioid addiction. SAMHSA, an agency within HHS, leads public health efforts to advance the behavioral health of the nation. SAMHSA's mission is to reduce the impact of substance abuse and mental illness on America's communities. SAMHSA published information to assist practitioners in the treatment of pediatric patients and pregnant or parenting women with opiate dependence, see their [*Clinical Guidance for Treating Pregnant and Parenting Women with Opioid Use Disorder and Their Infants*](#). DEA suggests contacting SAMHSA at (877) 726-4727 or www.SAMHSA.gov for further information.

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SECTION V - RECORDKEEPING REQUIREMENTS

Practitioners must maintain complete and accurate records on a current basis for each controlled substance purchased, received, sold, stored, distributed, dispensed, or otherwise disposed of. [21 CFR 1304.21\(a\)](#). These records are required to provide accountability of all controlled substances from the manufacturing process through the dispensing pharmacy and to the ultimate user. The closed system reduces the potential for diversion of controlled substances.

All required records concerning controlled substances must be maintained for at least two years for inspection and copying by duly authorized DEA officials. [21 U.S.C. 827\(b\)](#) and [21 CFR 1304.04\(a\)](#). Records and inventories of schedule II controlled substances must be maintained separately from all other records of the registrant. [21 CFR 1304.04\(h\)\(1\)](#). All records and inventories of schedules III, IV, and V controlled substances must be maintained either separately from all other records or in such a form that the information required is readily retrievable from the ordinary business records. [21 CFR 1304.04\(h\)\(3\)](#).

Pursuant to [21 CFR 1300.01\(b\)](#), readily retrievable is defined as:

1. Records kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time, and/or
2. Records kept in such a manner that certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records.

Practitioners are not required to keep records of controlled substances that are prescribed in the lawful course of professional practice unless such substances are prescribed for maintenance or detoxification treatment. [21 CFR 1304.03\(c\)](#). Practitioners are also not required to keep records of controlled substances that are administered unless the practitioner regularly engages in the dispensing or administering of controlled substances and charges patients for such dispensing or administering. [21 CFR 1304.03\(d\)](#). Practitioners must keep records of controlled substances administered for [maintenance or detoxification](#) treatment. [21 CFR 1304.03\(d\)](#). Practitioners that dispense controlled substances must maintain records of the quantity dispensed, the name and address of the person to whom it was dispensed, the date dispensed, and the written or typewritten name or initials of the individual who dispensed the controlled substance on behalf of the practitioner. [21 CFR 1304.22\(c\)](#).

Procuring Controlled Substances (All Schedules)

A DEA individual practitioner registration is based on a state license to practice medicine and prescribe controlled substances. [21 U.S.C. 823\(f\)](#) and [21 CFR 1306.03\(a\)\(1\)](#). DEA relies on state licensing boards to determine that a practitioner is qualified to dispense, prescribe, or administer controlled substances and to determine what level of authority a practitioner has, that is, what schedules of controlled substances he/she may dispense, prescribe, or administer. State authority to conduct the above-referenced activities only confers rights and privileges within the issuing state; consequently, the DEA registration based on a state license cannot authorize controlled substance dispensing outside the state.

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Note that a separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, imported, exported, or physically dispensed by a person. [21 CFR 1301.12\(a\)](#). Also, a practitioner may not issue a prescription to a pharmacy to obtain controlled substances for the purpose of general dispensing to patients, such as with an office supply. [21 CFR 1306.04\(b\)](#). With the order of controlled substance by a practitioner from the supplier, the DEA Form 222 documents the transfer of schedules I and II controlled substances. [21 CFR 1305.12](#), and [1305.13\(a\)](#) and [\(e\)](#). An invoice may be used to document the transfer of schedule III-V substances. [21 CFR 1304.22\(c\)](#) and [1304.22\(a\)\(2\)](#). A practitioner may only obtain controlled substances in the schedules included in their registration. [21 U.S.C 822\(b\)](#).

Procuring Schedule II Controlled Substances

If a practitioner is authorized to handle schedule II-controlled substances, a DEA Form 222 or the [electronic equivalent](#) is required for each distribution of a schedule II-controlled substance. [21 CFR 1305.03\(a\)](#), [21 CFR 1305.04](#). This includes distributions or transfers between practitioners. [21 CFR 1307.11\(a\)\(1\)\(iii\)](#).

Requesting DEA Forms 222

DEA Forms 222 are issued in mailing envelopes containing a predetermined number of forms based on the business activity of the registrant, each form consisting of one single-sheet. A limit, which is based on the business activity of the registrant, will be imposed on the number of DEA Forms 222 that will be furnished upon a requisition for order forms unless additional forms are specifically requested and a reasonable need for such additional forms is shown. [21 CFR 1305.11\(a\)](#).

Any practitioner with an active registration that is authorized to order schedule I and II controlled substances is entitled to obtain a DEA Form 222, which will be supplied at any time after a DEA registration is granted. Any practitioner holding a registration authorizing the person to obtain a DEA Form 222 may requisition the forms through a DEA secured network connection or by contacting a local DEA Diversion Field Office or the Registration Section of the Administration through the customer service center. [21 CFR 1305.11\(b\)](#). Each requisition must show the name, address, and registration number of the registrant and the number of DEA Forms 222 desired. [21 CFR 1305.11\(c\)](#).

DEA Forms 222 have an order form number and are issued with the name, address, and registration number of the registrant, the authorized activity, and schedules of the registrant. This information cannot be altered or changed by the registrant; the registrant must report any errors to the local DEA Diversion Field Office or the Registration Section of the Administration to modify the registration. [21 CFR 1305.11\(d\)](#).

Ordering Schedules I and II Controlled Substances

Only schedules I and II controlled substances are ordered with an official paper order form, [DEA Form 222](#), or the electronic equivalent (See below, [Controlled Substance Ordering System \(CSOS\) - Electronic Order Forms](#)). A DEA Form 222 is required for each distribution or transfer of a schedule I

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or schedule II-controlled substance unless exempted. [21 CFR 1305.03](#), [1307.11\(a\)\(1\)\(iii\)](#) and [1301.52\(e\)\(1\)](#).

When a controlled substance has been moved by DEA from schedule I or schedule II to another schedule at the federal level, in many states it may remain a schedule I or schedule II-controlled substance pending any legislative or administrative action that may result from the federal action. States may require transactions that involve substances they classify as schedule I or schedule II to be made via DEA Form 222 or the electronic equivalent.

Completing DEA Forms 222

A purchaser must prepare and execute a DEA Form 222 by use of a typewriter, computer printer, pen, or indelible pencil. [21 CFR 1305.12\(a\)](#). Only one item may be entered on each numbered line. An item must consist of one or more commercial or bulk containers of the same finished or bulk form and quantity of the same substance. The number of lines completed must be noted on that form at the bottom of the form, in the space provided [21 CFR 1305.12\(b\)](#). The purchaser must make a copy of the original DEA Form 222 for its records and then submit the original to the supplier. [21 CFR 1305.13\(a\)](#). The purchaser does not have the option of retaining the original. The copy retained by the purchaser may be in paper or electronic form. [21 CFR 1305.13\(a\)](#). Each DEA Form 222 must be signed and dated by a person authorized to sign a registration application or a person granted power of attorney (See below, [Power of Attorney to Sign an Official Order Form](#)). [21 CFR 1305.12\(d\)](#). When the items are received, the purchaser must document on the purchaser's copy the actual number of commercial or bulk containers received and the date received. [21 CFR 1305.13\(e\)](#). The purchaser must retain a copy of each executed DEA Form 222 and all copies of unaccepted or defective forms with each statement attached. [21 CFR 1305.17\(a\)](#).

DEA Forms 222 must be maintained separately from all other records of the registrant. [21 CFR 1305.17\(c\)](#). DEA Forms 222 are required to be kept available for inspection for a period of two years. [21 CFR 1305.17\(c\)](#). If a purchaser has several registered locations, the purchaser must retain a copy of the executed DEA Form 222 and any attached statements or other related documents (not including unexecuted DEA Forms 222, which may be kept elsewhere under [21 CFR 1305.12\(e\)](#), at the registered location printed on the DEA Form 222. [21 CFR 1305.17\(c\)](#).

Electronic copies of DEA Forms 222 do not need to be stored on a different server or electronic system from a registrant's other records. The requirement to store DEA Forms 222 separately from all other records may be met, for electronic copies, by storing them in such a way that they can be readily retrieved separately from all other records. [21 CFR 1305.17\(e\)](#). Electronic copies of DEA Forms 222 may be stored on a system at a location different from the registered location, provided such copies are readily retrievable at the registered location. [21 CFR 1305.17\(e\)](#). Purchasers must be able, during an inspection or upon other DEA requests, to readily retrieve their electronic copies of DEA Forms 222, with any related statements or other documents, and without any other records. [21 CFR 1304.04\(f\)](#).

Under [21 CFR 1305.15\(a\)\(1\)](#), an order must not be filled if the DEA Form 222 is not complete, legible, or properly prepared, executed, or endorsed, or if the DEA Form 222 shows any alteration, erasure, or change of any description. For a discussion of the circumstances in which an electronic order must not be filled see below, [Controlled Substance Ordering System \(CSOS\) - Electronic Order Forms](#).

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If a DEA Form 222 cannot be filled for any reason, the supplier must return the original DEA Form 222 to the purchaser with a statement explaining the reason the order could not be filled (e.g., illegible or altered). [21 CFR 1305.15\(b\)](#). A supplier may refuse to accept an order for any reason. [21 CFR 1305.15\(c\)](#). If a supplier refuses to accept an order, a statement that the order is not accepted is sufficient. [21 CFR 1305.15\(c\)](#). For electronic orders, if the order cannot be filled, the supplier must notify the purchaser and provide a statement as to the reason; if the order is refused, a statement that the order is not accepted is sufficient (See below, [Controlled Substance Ordering System \(CSOS\) - Electronic Order Forms](#)). [21 CFR 1305.25\(b\)](#).

When a purchaser receives an unaccepted or defective order form, the original DEA Form 222 and the statement must be retained in the files of the purchaser. [21 CFR 1305.17\(a\)](#). When a purchaser receives an unaccepted electronic order from a supplier, the purchaser must electronically link the statement of non-acceptance to the original order, and retain the original order and the statement in accordance with [21 CFR 1305.27](#). [21 CFR 1305.25\(c\)](#). A defective DEA Form 222 may not be corrected; it must be replaced by a new DEA Form 222 for the order to be filled. [21 CFR 1305.15\(d\)](#).

Power of Attorney to Sign DEA Forms 222

Any registrant may authorize one or more individuals, whether or not they are located at the registered location, to obtain and execute DEA Forms 222 for schedule I and II controlled substances by granting a power of attorney to each such individual. [21 CFR 1305.05\(a\)](#). Pursuant to [21 CFR 1305.05\(d\)](#), the power of attorney must be signed by:

- The registrant, if an individual; a partner of the registrant, if a partnership; or an officer of the registrant, if a corporation, corporate division, association, trust or other entity;
- The person to whom the power of attorney is being granted; and
- Two witnesses.

A power of attorney executed under this section may be signed electronically, by any or all of the persons required to sign. [21 CFR 1305.05\(f\)](#).

The power of attorney may be revoked at any time by the person who signed the most recent application for DEA registration or reregistration and two witnesses. [21 CFR 1305.05\(e\)](#). Only if the renewal application is signed by a different person is it necessary to grant a new power of attorney when the practitioner completes a renewal registration. [21 CFR 1305.05\(e\)](#). The power of attorney should be filed with executed DEA Forms 222 if applicable, and must be available for inspection. [21 CFR 1305.05\(a\)](#). The power of attorney is not submitted to DEA.

Suggested formats for granting and revoking a power of attorney follow:

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Power of Attorney for DEA Forms 222 and Electronic Orders

(Name of registrant)

(Address of registrant)

(DEA registration number)

I, _____ (name of person granting power), the undersigned, who am authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act or Controlled Substances Import and Export Act, have made, constituted, and appointed, and by these presents, do make, constitute, and appoint _____ (name of attorney-in-fact), my true and lawful attorney for me in my name, place, and stead, to execute applications for Forms 222 and to sign orders for schedule I and II controlled substances, whether these orders be on Form 222 or electronic, in accordance with [21 U.S.C. 828](#) and [Part 1305](#) of Title 21 of the Code of Federal Regulations. I hereby ratify and confirm all that said attorney must lawfully do or cause to be done by virtue hereof.

(Signature of person granting power)

I, _____ (name of attorney-in-fact), hereby affirm that I am the person named herein as attorney-in-fact and that the signature affixed hereto is my signature.

(Signature of attorney-in-fact)

Witnesses:

1. _____
2. _____

Signed and dated on the ____ day of _____ (year), at _____.

Notice of Revocation

The foregoing power of attorney is hereby revoked by the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act or the Controlled Substances Import and Export Act. Written notice of this revocation has been given to the attorney-in-fact _____ this same day.

(Signature of person revoking power)

Witnesses:

1. _____
2. _____

Signed and dated on the ____ day of _____ (year), at _____.

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Cancellation and Voiding DEA Forms 222

A purchaser may cancel part or all of an order on a DEA Form 222 by notifying the supplier in writing of the cancellation. [21 CFR 1305.19\(a\)](#). The supplier must indicate the cancellation on the original DEA Form 222 sent by the purchaser by drawing a line through the canceled items and printing “canceled” in the space provided for the number of items shipped. [21 CFR 1305.19\(a\)](#).

For information regarding canceled electronic orders, see below, [Controlled Substance Ordering System \(CSOS\) - Electronic Order Forms](#).

Lost or Stolen DEA Forms 222

If a purchaser ascertains that an unfilled DEA Form 222 has been lost, the purchaser must execute another and attach a statement containing the order form number and date of the lost form, and stating that the goods covered by the first DEA Form 222 were not received through loss of that DEA Form 222. [21 CFR 1305.16\(a\)](#). A copy of the second form and a copy of the statement must be retained with a copy of the DEA Form 222 first executed. [21 CFR 1305.16\(a\)](#). A copy of the statement must be attached to a copy of the second DEA Form 222 sent to the supplier. [21 CFR 1305.16\(a\)](#). If the first DEA Form 222 is subsequently received by the supplier to whom it was directed, the supplier must mark upon the face “Not accepted” and return the original DEA Form 222 to the purchaser, who must attach it to the statement. [21 CFR 1305.16\(a\)](#).

A purchaser or supplier, upon discovery of the loss or theft of used or unused order forms, must immediately report the loss or theft to the local [DEA Diversion Field Office](#) and provide the serial numbers of each lost or stolen order form. [21 CFR 1305.16\(b\)](#).

If any DEA Forms 222 are lost or stolen, and the purchaser is unable to state the order form numbers of DEA Forms 222, the purchaser must report, in lieu of numbers of the forms, the date or approximate date of issuance. [21 CFR 1305.16\(d\)](#).

If an unused order form reported stolen or lost is later recovered or found, the local [DEA Diversion Field Office](#) must immediately be notified. [21 CFR 1305.16\(e\)](#).

Return of Unused DEA Forms 222

If the registration of any purchaser terminates (because the purchaser dies, ceases legal existence, discontinues business or professional practice, or changes the name or address as shown on the purchaser's registration) or is suspended or revoked under [21 CFR 1301.36](#) for all schedule I and II controlled substances for which the purchaser is registered, the purchaser must return all unused DEA Forms 222 to the Registration Section. [21 CFR 1305.18](#).

Controlled Substance Ordering System (CSOS) - Electronic Order Forms

If a registrant's DEA registration authorizes that registrant to order schedule II-controlled substances, the registrant may do so electronically via the DEA CSOS. [21 CFR 1311.05\(a\)](#). A supplier or purchaser must maintain records of CSOS electronic orders and any linked records for two years. [21](#)

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[CFR 1311.60\(a\)](#). CSOS allows for the secure electronic transmission of controlled substance orders without the supporting paper DEA Form 222. The use of electronic orders is optional; a registrant may continue to submit orders on paper DEA Forms 222. [Click here](#) for more CSOS information.

Clinical Studies Involving Schedules I-II Controlled Substances

Due to the unique nature of double-blind clinical studies, including the impact on required recordkeeping and DEA's desire to avoid any confusion on behalf of the manufacturer or DEA registrants participating in these studies, DEA would like to reiterate the proper procedure for the use of DEA Form 222 in double-blind clinical studies where schedule I or II controlled substances may be involved. This manual is not an exception to DEA regulations, but an application of DEA's [existing policy](#) regarding double-blind clinical studies. Below is guidance for completing the DEA Form 222 in a double-blind clinical study:

1. Each DEA registrant participating in this study should submit the original paper copy of their DEA Form 222 to the controlled substance supplier and retain a copy (paper or electronic) for the registrant's records. The DEA Form 222 should indicate the total quantity of each test material requested. Test materials may consist of active ingredient dosage units, placebo, or some combination thereof. The registrant will not know if the test materials received actually contain a controlled substance until the end of the study.
2. The controlled substance supplier should record its DEA registration number and the actual quantity of controlled substance(s) (active dosage units) distributed and the date on which the containers are shipped on each original DEA Form 222. [21 CFR 1305.13\(b\)](#). The supplier should retain each original DEA Form 222 separately from all other records in accordance with [21 CFR 1305.17\(c\)](#). ARCOS reporting suppliers are not required to provide DEA a copy of each filled original DEA Form 222. [21 CFR 1305.13\(d\)](#)
3. The DEA registrant participating in this study will physically receive their shipment and record the date of receipt, but they should not fill in the true name of the controlled substance received, or the amount of controlled substance received, on the retained copy of the original DEA Form 222 until after the completion of the double-blind clinical study. Upon completion of the study, the supplier should notify the registrant of the actual name and quantity of the controlled substance(s) involved, if any, that the supplier provided. The registrant should then attach documentation denoting the actual amount of each test material received to their retained copy of the original DEA Form 222, and record the name and quantity of each controlled substance received on their retained copy of the original DEA Form 222. The purchaser should record on its copy of DEA Form 222 the actual amount of each test material received.

Procuring Schedule III-V Controlled Substances

No official government order form is required for ordering schedule III-V controlled substances. A practitioner must record the date the drugs were received. [21 CFR 1304.21\(d\)](#). The record must also contain the name of each controlled substance, the finished form, the number of dosage units of finished form in each commercial container, and the number of commercial containers received. [21 CFR 1304.22\(a\)\(2\)\(iv\)](#) and [1304.22\(c\)](#).

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Procuring Controlled Substance Samples

If a practitioner wishes to procure complimentary controlled substance samples, a written request must be submitted to a DEA-registered supplier (e.g., DEA-registered manufacturer or distributor). The DEA-registered supplier must not distribute complimentary controlled substance samples unless they received a prior written request from a customer; they ascertained that the samples will satisfy the legitimate medical needs of the patients of the customer; and the samples are ordered only in reasonable quantities. [21 CFR 1301.74\(d\)](#). This written request must contain the practitioner's name, address, and DEA registration number, and the name and quantity of the specific controlled substance desired. [21 CFR 1304.22\(a\)\(2\)\(ix\)](#). Schedule II controlled substance samples must be ordered with a DEA Form 222 order form. [21 CFR 1305.04\(a\)](#).

Dispensing Controlled Substances

If authorized by state law, a practitioner may dispense controlled substances to patients. Practitioners must maintain records of the quantity dispensed, the name and address of the person to whom it was dispensed, the date dispensed, and the written or typewritten name or initials of the individual who dispensed the controlled substance on behalf of the practitioner. [21 CFR 1304.22\(c\)](#).

Dispensing Controlled Substances for the Treatment of Pain

On September 6, 2006, DEA published a Policy Statement in the Federal Register, *Dispensing Controlled Substances for the Treatment of Pain*, [71 FR 52716](#), to make clear the longstanding requirement under [21 CFR 1306.04\(a\)](#) that physicians may prescribe controlled substances only for a legitimate medical purpose in the usual course of professional practice. [21 CFR 1306.04](#). Part of the [mission](#) of DEA's Diversion Control Division is to ensure an adequate and uninterrupted supply of controlled substances for legitimate medical, commercial, and scientific needs.

Controlled Substance Distribution by a Practitioner

Pursuant to [21 CFR 1307.11\(a\)\(1\)](#), a DEA-registered practitioner that is allowed to dispense may, without being registered as a distributor, distribute a controlled substance to another DEA-registered practitioner for the purpose of general dispensing of that controlled substance by that practitioner to patients, provided that the following conditions are met:

1. The practitioner who will receive the controlled substance is registered with DEA to dispense that controlled substance;
2. The distributing practitioner records the distribution and the receiving practitioner records the receipt in accordance with [21 CFR 1304.22\(c\)](#);
3. A DEA Form 222 is used for the distribution of schedule I and II controlled substances; and
4. The total number of dosage units of all controlled substances distributed by the distributing practitioner during each calendar year may not exceed five percent of the total number of dosage units of all controlled substances distributed and dispensed by that practitioner during that calendar year. If at any time during the calendar year the controlled substances distributed exceeds five percent, the distributing practitioner must register as a distributor, pursuant to [21 CFR 1307.11\(b\)](#).

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Inventory Requirements

An inventory is a complete and accurate list of all stocks and forms of controlled substances in the possession of the registrant as determined by an actual physical count for schedule I and II controlled substances ([21 CFR 1304.11\(e\)\(6\)\(i\)](#)) and an estimated count or measure of schedule III-V controlled substances, unless the container holds more than 1,000 tablets or capsules (in which case an exact count must be made) ([21 CFR 1304.11\(e\)\(6\)\(ii\)](#)). [21 CFR 1300.01\(b\)](#) and [1304.11\(a\), \(e\)](#). A registrant must maintain all inventories for at least two years at the registered location in a readily retrievable manner for copying and inspection. [21 CFR 1304.04\(a\)](#) and [21 U.S.C. 827\(b\)](#). Inventory records of schedule II-controlled substances must be kept separate from all other records. [21 CFR 1304.04\(f\)\(1\)](#). Inventory records of schedules III-V must be maintained separate from all other records or in such a manner that the required information is [readily retrievable](#). [21 U.S.C. 827\(b\)](#), [21 CFR 1304.04\(f\)\(2\)](#). There is no requirement to submit a copy of the inventory to DEA.

DEA recommends, but does not require, that inventory records include the practitioner's name, address, DEA registration number, and the signature of the person(s) responsible for taking the inventory.

Initial Inventory

A practitioner must take an initial inventory, which is an actual physical count of all controlled substances in a practitioner's possession, on the date the practitioner first engages in the dispensing of controlled substances. [21 CFR 1304.11\(b\)](#), [21 U.S.C. 827\(a\)\(1\)](#). If there are no stocks of controlled substances on hand, a practitioner can make a record showing zero inventory. Pursuant to [21 CFR 1304.11\(a\), \(b\), and \(e\)\(6\)](#), and [21 U.S.C. 827\(a\)\(1\)](#) the inventory must include:

1. The date of the inventory;
2. Whether the inventory was taken at the opening or close of business;
3. The name of each controlled substance inventoried;
4. The finished form of each of the substances (e.g., 10 milligram tablet);
5. The number of dosage units or volume of each finished form in each commercial container (e.g., 100 tablet bottle or 3 milliliter vial);
6. The number of commercial containers of each finished form (e.g., four 100-tablet bottles); and
7. A count of the substance. In determining the number of units of each finished form of a controlled substance in a commercial container that has been opened, the practitioner shall do as follows: If the substance is listed in schedule II, an exact count or measure of the contents is required. If the substance is listed in schedule III, IV, or V, an estimated count or measure of the contents is sufficient unless the container holds more than 1,000 tablets or capsules, in which case an exact count of the contents is required.

Although it is not required by law, DEA recommends that registrants keep an inventory record that includes the name, address, and DEA registration number of the registrant, and the signature of the person or persons responsible for taking the inventory.

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Biennial Inventory

After the initial inventory is taken, the registrant must take a new inventory of all stocks of controlled substances on hand at least every two years. A practitioner must record the same information as the [initial inventory](#) of all controlled substances on hand. [21 CFR 1304.11\(c\)](#). The biennial inventory may be taken on any date which is within two years of the previous inventory date. [21 CFR 1304.11\(c\)](#).

Inventory Date for Newly Controlled Substances

When a drug not previously listed as a controlled substance is scheduled, the drug must be inventoried as of the effective date of scheduling, if possessed by the registrant. [21 CFR 1304.11\(d\)](#).

Disposal of Controlled Substances

DEA-registered practitioners may dispose of out-of-date, damaged, or otherwise unusable or unwanted controlled substances from office stock by transferring them to a DEA registrant known as a reverse distributor. [21 CFR 1317.05\(a\)\(2\)](#). A reverse distributor is authorized to receive controlled substances for destruction or return to the manufacturer. [21 CFR 1300.01](#). When a practitioner distributes schedule II-controlled substances to a reverse distributor, the reverse distributor must issue an official order form (DEA Form 222) to the practitioner. [21 CFR 1305.03\(f\)](#). When a practitioner delivers schedule III-V controlled substances to a reverse distributor for purposes of disposal, the practitioner must maintain a record that lists the date and manner of disposal, name, address, and registration number of the person to whom it was distributed and quantity disposed of. [21 CFR 1304.22\(a\)\(1\)\(ix\)](#). The reverse distributor is responsible for completing a DEA Form 41 (Registrants Inventory of Drugs Surrendered) to record the destruction. [21 CFR 1304.21\(e\)](#). A practitioner must maintain copies of the records documenting the disposal of the controlled substances for a period of two years. [21 U.S.C. 827\(b\)](#) and [21 CFR 1304.04\(a\)](#).

Use of a reverse distributor to dispose of unwanted controlled substances is not required. [21 CFR 1317.05\(a\)](#). If a practitioner desires to dispose of controlled substances in their inventory by means other than delivering the drugs for destruction to a reverse distributor by common or contract carrier pick-up or by reverse distributor pick-up at the registrant's registered location, the registrant must list the controlled substances being disposed of on a [DEA Form 41](#). [21 CFR 1304.21\(e\)](#). This record must be kept for at least two years. [21 CFR 1304.04\(a\)](#).

A paper version of the DEA Form 41 may be requested by writing to:

Drug Enforcement Administration
Diversion Control Division
Attn: Registration Section/DRR
P.O. Box 2639
Springfield, VA 22152-2639

Do not send the drugs to DEA unless you have received prior approval from DEA. The disposal of controlled substances must be in compliance with all federal, state, local, and tribal environmental laws and regulations.

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As a DEA registrant, you are **not** eligible to dispose of controlled substances from your office stock using drop boxes designated for disposal of controlled substances by the general public, or during prescription drug take-back events. [21 CFR 1317.05\(a\)](#).

The following categories of registrants may modify their registration to become collectors, manufacturers, distributors, reverse distributors, narcotic treatment programs, hospital clinics with an on-site pharmacy, and retail pharmacies. [21 CFR 1317.40\(a\)](#). Individual practitioners, such as medical doctors, dentists, or veterinarians are not included in the aforementioned regulation and are not authorized to be collectors. Authorized collectors may maintain collection receptacles at their registered locations. They may also operate a mail-back program as long as they have an on-site means of destruction for the mail-back packages. [21 CFR 1317.70](#). Authorized retail pharmacies and hospital/clinics with an on-site pharmacy may manage collection receptacles at long-term care facilities. [21 CFR 1317.80\(b\)](#). Practitioners can partner with a collector or law enforcement to make mail-back packages available. [21 CFR 1317.70\(c\)](#).

Pharmaceutical Wastage

Pharmaceutical wastage, i.e., controlled substances remaining in a vial, tube, transdermal patch, or syringe after administration to a patient, shall not be placed in a collection receptacle as a means of disposal. Rather, practitioners shall continue to record the destruction of pharmaceutical wastage in accordance with [21 CFR 1304.21\(e\)](#). The disposal regulations contained in [21 CFR Part 1317](#) do not alter a practitioner's existing obligation to destroy pharmaceutical wastage in accordance with federal, state, tribal, and local laws and regulations (e.g., environmental, hazardous/biohazard, and other safety-related laws and regulations). Practitioners must also not dispose of any controlled substances in inventory or stock in a collection receptacle. [21 CFR 1317.75\(b\)](#). The disposal of practitioner inventory (as opposed to pharmaceutical wastage) shall be accomplished in accordance with the disposal requirements of [21 CFR 1317.05\(a\)](#).

DEA understands that there may be some circumstances where there is no authorized person to dispose of the controlled substances, such as when controlled substances are abandoned at a school or summer camp, and return to the ultimate user is not feasible. In such instances, the affected entities should contact local law enforcement or their local DEA office for guidance on proper disposal procedures.

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SECTION VI - SECURITY

All registrants, including practitioners, shall provide effective controls and procedures to guard against theft and diversion of controlled substances. [21 CFR 1301.71\(a\)](#). If a practitioner maintains a stock of controlled substances at their DEA registered office, the controlled substances must be stored in a securely locked, substantially constructed cabinet. [21 CFR 1301.75\(b\)](#).

Requests for Employment Waivers for Certain Employees

A practitioner must not employ, as an agent or employee who has access to controlled substances, any person who has been convicted of a felony relating to controlled substances, or who, at any time, has had an application for a DEA registration denied, had a DEA registration revoked, or has surrendered a DEA registration for cause. "For cause" means surrendering a registration in lieu of, or as a consequence of, any federal or state administrative, civil, or criminal action resulting from an investigation of the individual's handling of controlled substances. [21 CFR 1301.76\(a\)](#).

However, [21 CFR 1307.03](#) does permit registrants desiring to employ an individual who meets this definition to request an exception to this requirement. The employer must have a waiver approved before allowing such an employee or prospective employee to have access to controlled substances. A waiver request should be sent by the employer to the following address:

Drug Enforcement Administration
Diversion Control Division
Attn: Assistant Administrator
8701 Morrisette Drive
Springfield, VA 22152

A waiver will not be considered unless there are valid reasons to believe that diversion is unlikely to occur. In determining whether there is a valid reason to believe that diversion is unlikely to occur, DEA will consider, among other things:

1. A detailed description of the nature and extent of the individual's past controlled substances violations, including all pertinent documentation;
2. Current status of the individual's state licensure;
3. Extent of individual's proposed access to controlled substances. "Access" is not limited to only physical access to controlled substances, but includes any influence over the handling of controlled substances;
4. Registrant's proposed physical and professional safeguards to prevent diversion by the individual;
5. Status of employing registrant regarding handling of controlled substances;
6. Other pertinent information uncovered by DEA in its investigation of the individual's or registrant's handling of controlled substances; and
7. All other relevant factors or materials.

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Theft or Significant Loss of Controlled Substances

A practitioner must notify the local [DEA Diversion Field Office](#) in writing, within one business day of discovery of a theft or significant loss of a controlled substance. [21 CFR 1301.76\(b\)](#). Although not specifically required by the CSA or DEA regulations, a practitioner should also notify local law enforcement and state regulatory agencies. If there is a question as to whether a theft has occurred or a loss is significant, practitioners should err on the side of caution and report it to DEA and local law enforcement authorities.

When determining whether a loss is significant, under [21 CFR 1301.76\(b\)](#) some factors to consider are:

1. The actual quantity of controlled substances lost in relation to the type of business;
2. The specific controlled substances;
3. Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;
4. A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known
5. Whether the specific controlled substances are likely candidates for diversion; and
6. Local trends and other indicators of the diversion potential of the missing controlled substances.

Practitioners must **also** complete a [DEA Form 106](#) (Report of Theft or Loss of Controlled Substances) which is used to document the actual circumstances of the theft or significant loss and the quantities of controlled substances involved. [21 CFR 1301.76\(b\)](#). The [online version](#) can be amended by the reporter at any time to reflect complete and accurate information.

A paper version of the form can be obtained by writing to:

Drug Enforcement Administration
Diversion Control Division
Attn: Registration Section/DRR
8701 Morrisette Drive
Springfield, VA 22152

If completing the paper version, a practitioner must send the original DEA Form 106 to the local [DEA Diversion Field Office](#) and keep a copy for their records. Please see the *Guidelines for Completing the DEA Form 106* ([Appendix C](#)) for additional guidance, or email DEA's regulatory section at DRG@dea.gov. If the theft or loss involves listed chemicals, please see page 53 for information on how to complete a DEA Form 107 (Theft or Loss of Listed Chemicals).

The DEA Form 106 must include the following information:

1. Name and address of the firm (practitioner),
2. DEA registration number,
3. Date of theft or loss (or when discovered if not known),

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4. Name and telephone number of local police department (if notified),
5. Type of theft (e.g., night break-in, armed robbery),
6. List of identifying marks, symbols, or price codes (if any) used by the pharmacy on the labels of the containers, and
7. A listing of controlled substances missing, including the strength, dosage form, and size of container (in milliliters if liquid form) or corresponding National Drug Code numbers.

If Investigation Finds No Theft or Loss

If, after the initial notification to DEA, the investigation of the theft or loss determines no such theft or loss of controlled substances occurred, a DEA Form 106 does not need to be filed. However, for complete and accurate records, it is strongly recommended that the registrant notify DEA in writing of this fact in order to resolve the initial report and explain why no DEA Form 106 was filed regarding the incident. [21 CFR 1301.76](#), [1304.21\(a\)](#), [21 U.S.C. 827\(a\)\(3\)](#).

Improper Use of DEA Form 106, Theft or Loss of Controlled Substances

The DEA Form 106 should not be used to document or explain minor inventory discrepancies, thereby “[balancing the books.](#)” [68 FR 40576](#) (Jul. 8, 2003). The DEA Form 106 should be used only to document thefts or significant losses of controlled substances. Minor inventory discrepancies, not attributable to theft, should not be reported to DEA or recorded on a DEA Form 106. If a practitioner is unsure of the significance of a loss after considering the factors described above, they should file a DEA Form 106. Any continuing pattern of loss of seemingly insignificant quantities should always be considered significant.

Breakage and Spillage of Controlled Substances

While neither the CSA nor DEA's regulations specifically address the breakage and/or spillage of a controlled substance, DEA offers the following guidance, which was also published in the 2003 Notice of Proposed Rulemaking and guidance document, *Reports by Registrants of Theft or Significant Loss of Controlled Substances*, [68 FR 40576, 40578 \(Jul. 8, 2003\)](#). The witnessed breakage or spillage of a controlled substance does not constitute a loss of controlled substances because the registrant can account for the controlled substances. These types of incidents do not require notification to DEA. If there is breakage, spillage, or other damage to controlled substances, but the controlled substances are still recoverable, options one and two for disposing are pursuant to the guidance document. Option three is pursuant to the 2014 Final Rule, Disposal of Controlled Substances, [79 FR 53520](#), (Sept. 9, 2014).

1. Send those controlled substances to a reverse distributor. [21 CFR 1317.05\(a\)\(2\)](#).
2. Contact the local DEA Diversion Field Office to request assistance to dispose of the controlled substances pursuant to [21 CFR 1317.05\(a\)\(4\)](#) and [1304.21\(e\)](#).
3. Promptly destroy that controlled substance in accordance with [21 CFR 1317.90](#) using an on-site method of destruction. [21 CFR 1317.05](#).

DEA provided additional guidance on reporting theft/loss in its July 8, 2003 notice of proposed rulemaking. [68 FR 40576, 40578](#). If the breakage or spillage is clearly observed, but the controlled

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substances are [not recoverable](#), then the practitioner should document the circumstances of the breakage in their inventory records. Two individuals who witnessed the breakage should sign the inventory records, indicating what they witnessed. These records should be maintained in the registrant's files. Under [21 CFR 1304.21\(a\)](#), a registrant must keep complete and accurate inventory records.

In-Transit Loss of Controlled Substances

When all or part of an in-transit shipment of controlled substances fails to reach its intended destination, the supplier is responsible for reporting the in-transit loss of controlled substances to DEA. [21 CFR 1301.74\(c\)](#). The purchaser is responsible for reporting any loss of controlled substances after they have signed for or taken custody of a shipment. The purchaser must then submit a DEA Form 106. [21 CFR 1301.76\(b\)](#).

Robberies and Burglaries Involving Controlled Substances

The Controlled Substance Registrant Protection Act of 1984 (CSRPA) was enacted to protect DEA registrants against certain crimes. (See [18 U.S.C. 2118](#) for a complete text of CSRPA). The CSRPA provides for the federal investigation of controlled substance robberies and burglaries (or attempts) if any of the following conditions are met as noted in [18 U.S.C. 2118\(a\)](#):

- The replacement cost of the controlled substances taken or attempted to be taken is \$500 or more.
- Interstate or foreign commerce was involved in the execution of the crime.
- A person was killed or suffered significant bodily injury as a result of the crime.

The perpetrator(s) convicted of violating CSRPA's provisions may be subject to fines and/or imprisonment. [18 U.S.C. 2118 \(c\)](#).

Recommended Safeguards for Prescribers

Additional measures to ensure security include:

- Keeping all unused prescription pads in a safe place where they cannot be stolen.
- Minimizing the number of prescription pads in use.
- Writing out the quantity prescribed in addition to writing the number prescribed to discourage alterations to the prescription, e.g., forty (40).
- Not preprinting your DEA registration number on your prescription pads.
- Cooperating with any pharmacist who contacts you to verify information about a prescription order; a corresponding responsibility rests with the pharmacist who dispenses the prescription. [21 CFR 1306.04\(a\)](#).
- Using tamper-resistant prescription pads.
- Using Prescription Monitoring Program reports if available.

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SECTION VII - TELEMEDICINE

The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (hereafter referred to as the “Ryan Haight Act” or the “Act”) amended the CSA by adding several new provisions to prevent the illegal distribution and dispensing of controlled substances by means of the internet. Until the Ryan Haight Act, the CSA did not address telemedicine. Practitioners need to know several definitions, as defined in the CSA, to understand the implications of the Ryan Haight Act with regard to the practice of telemedicine.

- **Practice of Telemedicine** - the practice of medicine in accordance with applicable federal and state laws by a practitioner (other than a pharmacist) who is at a location remote from the patient and is communicating with the patient, or health care professional who is treating the patient, using a telecommunications system referred to in section 1834(m) of the Social Security Act ([42 U.S.C. 1395m\(m\)](#)). [21 U.S.C. 802\(54\)](#).
- **In-Person Medical Evaluation** - a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals. [21 U.S.C. 829\(e\)\(2\)\(B\)\(i\)](#). It is a violation of the CSA for a controlled substance that is a prescription drug to be dispensed by means of the Internet without a valid prescription, which as discussed below necessitates a practitioner conducting at least one in-person medical evaluation, except in [specified circumstances](#), and the prescription being issued for a legitimate medical purpose while acting in the usual course of professional practice (hereafter referred to as legitimate medical purpose). [21 U.S.C. 829\(e\)\(1\)](#) and [\(2\)](#). However, the Act also expressly provides that a prescribing practitioner does not automatically meet the requirement of issuing a prescription for a legitimate medical purpose merely by having conducted a single in-person medical evaluation of the patient. A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of their professional practice. [21 CFR 1306.04\(a\)](#).
- **Valid Prescription** - means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by (1) A practitioner who has conducted at least one in-person medical evaluation of the patient or (2) a “covering practitioner.” [21 U.S.C. 829\(e\)\(2\)\(A\)](#), [21 CFR 1306.04\(a\)](#).
- **Covering Practitioner** - means, with respect to a patient, a practitioner who conducts a medical evaluation (other than an in-person medical evaluation) at the request of a practitioner who (1) has conducted at least one in-person medical evaluation of the patient or an evaluation of the patient through the practice of telemedicine, within the previous 24 months; and (2) is temporarily unavailable to conduct the evaluation of the patient. [21 U.S.C. 829\(e\)\(2\)\(C\)](#).

Exceptions to In-person Medical Evaluation Requirement

A DEA-registered practitioner acting within the United States is exempt from the requirement under [21 U.S.C. 829\(e\)](#) of an in-person medical evaluation as a prerequisite to prescribing or otherwise dispensing controlled substances by means of the Internet if the practitioner is engaged in the practice of telemedicine and is acting in accordance with the requirements of [21 U.S.C. 802\(54\)](#).

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There are seven distinct categories included in the definition of the “practice of telemedicine” under [21 U.S.C. 802\(54\)](#).

These categories are:

- (1) Treatment in a hospital or clinic.** The patient is being treated by, and physically located in, a DEA-registered hospital or clinic under [21 U.S.C. 823\(f\)](#) by a practitioner acting in the usual course of professional practice, who is acting in accordance with applicable State law. The practitioner must be registered under [21 U.S.C. 823\(f\)](#) in the State in which the patient is located, unless the practitioner:

 - (i) Is exempted from such registration in all States under section [21 U.S.C. 822\(d\)](#); or
 - (ii) Is an employee or contractor of the Department of Veterans Affairs (VA) who is acting in the scope of such employment or contract, and is registered under section [21 U.S.C. 823\(f\)](#) in any State or is using the registration of a hospital or clinic operated by the VA registered under [21 U.S.C. 823\(f\)](#).
- (2) Treatment in the physical presence of a practitioner.** The patient is being treated by, and in the physical presence of, a practitioner who is acting in the usual course of professional practice and in accordance with applicable State law. The practitioner must be registered under [21 U.S.C. 823\(f\)](#) in the state in which the patient is located, unless the practitioner:

 - (i) Is exempted from such registration in all states under section [21 U.S.C. 822\(d\)](#); or
 - (ii) Is an employee or contractor of the VA who is acting in the scope of such employment or contract, and is registered under [21 U.S.C. 823\(f\)](#) in any state or is using the registration of a hospital or clinic operated by the VA registered under [21 U.S.C. 823\(f\)](#).
- (3) Indian Health Service of tribal organization.** The practitioner is an employee or contractor of the Indian Health Service (IHS) or is working for an Indian tribe or tribal organization under its contract or compact with IHS under the Indian Self-Determination and Education Assistance Act; acting within the scope of such employment, contract, or compact; and is designated as an Internet Eligible Controlled Substances Provider by the Secretary under [21 U.S.C. 831\(g\)\(2\)](#).
- (4) Public health emergency declared by the Secretary of Health and Human Services.** The Secretary has declared a public health emergency under [42 U.S.C. 247d](#), and the practice of telemedicine involves patients located in such areas, and such controlled substances, as the Secretary, with the concurrence of the Administrator, designates, provided that such designation shall not be subject to the procedures prescribed by the Administrative Procedure Act ([5 U.S.C. 551-559 and 701-706](#)).
- (5) Special Registration.** A practitioner has obtained a special registration under [21 U.S.C. 831\(h\)](#) from the Administrator. ([21 U.S.C. 831\(h\)](#));
- (6) Department of VA medical emergency.**

 - (i) There is a medical emergency situation:

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- (A) That prevents the patient from being in the physical presence of a practitioner registered under [21 U.S.C. 823\(f\)](#) who is an VA employee or contractor acting in the usual course of business and employment and within the scope of the official duties or contract of that employee or contractor;
 - (B) That prevents the patient from being physically present at a hospital or clinic operated by VA registered under [21 U.S.C. 823\(f\)](#);
 - (C) During which the primary care practitioner of the patient or a practitioner otherwise practicing telemedicine is unable to provide care or consultation; and
 - (D) That requires immediate intervention by a health care practitioner using controlled substances to prevent what the practitioner reasonably believes in good faith will be imminent and serious clinical consequences, such as further injury or death; and
- (ii) The practitioner:
- (A) Is an VA employee or contractor acting within the scope of that employment or contract;
 - (B) Is registered under [21 U.S.C. 823\(f\)](#) in any state or is utilizing the registration of a hospital or clinic operated by VA registered under [21 U.S.C. 823\(f\)](#); and
 - (C) Issues a controlled substance prescription in this emergency context that is limited to a maximum of a five-day supply which may not be extended or refilled.
- (7) Other circumstances specified by regulation.** There are other circumstances that the Administrator, as delegated by the Attorney General, and Secretary have jointly, by regulation, determined to be consistent with effective controls against diversion and otherwise consistent with the public health and safety.

You are advised to visit our [website](#) where any changes or new regulations will be posted.

Appendices

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APPENDIX A - Definitions Based on the Controlled Substances Act and DEA's Regulations

The following definitions may be found in [21 CFR Part 1300](#) and/or [21 U.S.C. 802](#) and [823](#) except as otherwise noted.

Administer

The direct application of a controlled substance to the body of a patient or research subject by 1) a practitioner (or in their presence by their authorized agent), or 2) the patient or research subject at the direction and in the presence of the practitioner, whether such application is by injection, inhalation, ingestion, or any other means. [21 U.S.C. 802\(2\)](#).

Controlled Substance

A drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V. [21 U.S.C. 802\(6\)](#); [21 CFR 1300.01\(b\)](#).

Detoxification Treatment

The dispensing for a certain defined time period (i.e., short-term and long-term detoxification treatment) of a narcotic drug(s) in decreasing doses to an individual to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such time period. [21 CFR 1300.01\(b\)](#). This regulation contains additional information related to the time periods for short-term and long-term detoxification treatment.

Dispense

To deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling, or compounding necessary to prepare the substance for such delivery. [21 U.S.C. 802\(10\)](#).

Distribute

To deliver (other than by administering or dispensing) a controlled substance or a listed chemical. The term "distributor" means a person who so delivers a controlled substance or a listed chemical. [21 U.S.C. 802\(11\)](#).

Electronic Prescription

A prescription that is generated on an electronic application that meets the requirements of [21 CFR 1311.120\(b\)](#) and transmitted through the application for practitioner's review and approval with all of the data as noted under [21 CFR 1311.120\(b\)\(9\)](#).

Individual Practitioner

A physician, dentist, veterinarian, or other individual licensed, registered or otherwise permitted, by the United States or the jurisdiction in which they practice, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner. [21 CFR 1300.01\(b\)](#).

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Institutional Practitioner

A hospital or other person (other than an individual) licensed, registered or otherwise permitted, by the United States or the jurisdiction in which it practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacy. [21 CFR 1300.01\(b\)](#).

Inventory

All factory and branch stocks in finished form of a basic class of controlled substance manufactured or otherwise acquired by a registrant, whether in bulk, commercial containers, or contained in pharmaceutical preparations in the possession of the registrant (including stocks held by the registrant under separate registration as a manufacturer, importer, exporter, or distributor). [21 CFR 1300.01\(b\)](#).

(Jurisdiction of the) United States

When used in a geographic sense, means all places and waters, continental or insular, subject to the jurisdiction of the United States, which, in addition to the customs territory of the United States, include but are not limited to the U.S. Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands. [21 CFR 1300.01\(b\)](#).

Long Term Care Facility (LTCF)

A nursing home, retirement care, mental care, or other facility or institution which provides extended health care to resident patients. [21 CFR 1300.01\(b\)](#).

Maintenance Treatment

The dispensing for a period in excess of twenty-one days, of a narcotic drug or narcotic drugs in the treatment of an individual for dependence upon heroin or other morphine-like drug. [21 CFR 1300.01\(b\)](#).

Mid-level Practitioner (MLP)

An individual practitioner, other than a physician, dentist, veterinarian, or podiatrist, who is licensed, registered, or otherwise permitted by the United States or the jurisdiction in which they practice, to dispense a controlled substance in the course of professional practice. [21 CFR 1300.01\(b\)](#). This regulatory definition also lists some examples of MLPs.

Paper Prescription

A prescription created on paper or computer generated to be printed or transmitted via facsimile and includes a manual signature. [21 CFR 1300.03](#).

Person

Includes any individual, corporation, government or governmental subdivision or agency, business trust, partnership, association, or other legal entity. [21 CFR 1300.01\(b\)](#).

Prescription

An order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user (e.g., an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription). [21 CFR 1300.01\(b\)](#).

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Qualified Practitioner

A practitioner who (i) is licensed under state law to prescribe controlled substances; and (ii) is not solely a veterinarian. [21 U.S.C. 823\(l\)\(4\)\(B\)](#).

Readily Retrievable

Certain records are kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time, and/or records that are kept on which certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records. [21 CFR 1300.01\(b\)](#).

Reverse Distributor

A person registered with DEA as a reverse distributor who acquires controlled substances from another DEA registrant or law enforcement for the purpose of:

- Returning unwanted, unusable, or outdated controlled substances to the manufacturer or another registrant authorized by the manufacturer to accept returns on the manufacturer's behalf; or
- Destruction.

[21 CFR 1300.01\(b\)](#).

Scheduled Listed Chemical Product

Scheduled listed chemical product is a product that contains ephedrine, pseudoephedrine, or phenylpropanolamine and may be marketed or distributed lawfully in the United States under the federal Food, Drug, and Cosmetic Act as a nonprescription drug. Ephedrine, pseudoephedrine, and phenylpropanolamine include their salts, optical isomers, and salts of optical isomers. Scheduled listed chemical products do not include any products that are controlled substances under 21 CFR Part 1308. [21 U.S.C. 802\(45\)\(A\)](#).

Ultimate User

A person who has lawfully obtained, and who possesses, a controlled substance for their own use or for the use of a member of their household or for an animal owned by them or by a member of their household. [21 U.S.C. 802\(27\)](#); [21 CFR 1300.01\(b\)](#).

Valid Prescription

A prescription that is issued for a legitimate medical purpose in the usual course of professional practice by (1) A practitioner who has conducted at least one in-person medical evaluation of the patient or (2) a "covering practitioner." [21 U.S.C. 829\(e\)\(2\)\(A\)](#), [21 CFR 1306.04\(a\)](#).

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APPENDIX B - List of Abbreviations

CAA	Consolidated Appropriations Act of 2023
CARA	Comprehensive Addiction and Recovery Act of 2016
CFR	Code of Federal Regulations
CSA	Controlled Substances Act
CSAT	Center for Substance Abuse Treatment
CSOS	Controlled Substances Ordering System
CSRPA	Controlled Substance Registrant Protection Act of 1984
DATA	Drug Addiction Treatment Act of 2000
DEA	Drug Enforcement Administration
EPCS	Electronic Prescription for Controlled Substances
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
PMP or PDMP	Prescription Monitoring Program or Prescription Drug Monitoring Program
SAMHSA	Substance Abuse and Mental Health Services Administration
U.S.C.	United States Code

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APPENDIX C - Guidelines for Completing DEA Form 106 - Report of Theft or Loss of Controlled Substances, or DEA Form 107 - Report of Theft or Loss of Listed Chemicals

Instructions for completing the Online [DEA Form 106](#), or the paper [DEA Form 107](#) are provided when filling out either of these forms. Listed below are additional guidelines:

- Do not use DEA Form 106/107 to report miscounts or adjustments to inventory involving clerical errors. You may keep a separate log documenting the discrepancies at your discretion.

The following guidelines apply only if you are using the hard copy version of DEA Form 106:

- If thefts have occurred due to employee pilferage over a period of time, document on the DEA Form 106 the date of the theft or loss (or first discovery of theft or loss). Provide estimated beginning and ending dates of the thefts in the comment section with an explanation.
- On the next line, enter the number of thefts or losses experienced in the last 24 months, but do not include the current theft or loss being reported. If the current theft or loss was the only theft or loss in the last 24 months, enter "0" (zero).
- In section five, enter the amount you paid for the controlled substances.
- In section three, if you accepted receipt of the controlled substance(s) before discovering a loss in transit, identify the supplier and its DEA registration number.
- When explaining how many losses occurred from the same carrier, do not include the current loss.
- The date next to the signature and title on page 4 should be the date the form was completed and transmitted to DEA.
- If amending a paper version of a prior DEA Form 106, print **Amended** in the upper front-page margin, with the date of the theft.

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APPENDIX D - Internet Resources

DEA E-Commerce Program (CSOS) website - <https://www.deaecom.gov/>

DEA's Diversion Control Program Website - www.DEAdiversion.usdoj.gov

DEA Homepage - www.dea.gov

Federation of State Medical Boards - www.FSMB.org

Food and Drug Administration - www.FDA.gov

HHS & SAMHSA's National Clearinghouse for Alcohol and Drug Information -
<https://www.drugabuse.gov/>

National Association of State Controlled Substances Authorities - www.nascsa.org

Office of National Drug Control Policy (ONDCP) - <https://www.whitehouse.gov/ondcp/>

SAMHSA/CSAT Buprenorphine Website - <https://www.samhsa.gov/medication-assisted-treatment/become-buprenorphine-waivered-practitioner>

U.S. Government Printing Office/Code of Federal Regulations - www.govinfo.gov

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APPENDIX E - Small Business and Agriculture Regulatory Enforcement Ombudsman

The Small Business and Agriculture Regulatory Enforcement Ombudsman and 10 Regional Fairness Boards were established to receive comments from small businesses about federal agency enforcement actions. The Ombudsman annually evaluates the enforcement activities and rates each agency's responsiveness to small business. If you wish to comment on DEA enforcement actions, you may contact the Ombudsman at 888-REG-FAIR (888-734-3247).

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APPENDIX F - Additional Assistance and Plain Language

Additional Assistance

This publication is intended to provide guidance and information on the requirements of the Controlled Substances Act and its implementing regulations. If you require additional clarification or assistance, or wish to comment on any matter regarding DEA's requirements or regulatory activities, please contact your local [DEA Diversion Field Office](#). Every effort will be made to respond promptly to your inquiry.

Plain Language

DEA has made every effort to write this Practitioner's Manual in clear, plain language. If you have suggestions as to how to improve the clarity of this Practitioner's Manual, please contact us at:

Drug Enforcement Administration
Attn: Policy Section/DPY
8701 Morrissette Drive
Springfield, VA 22152
Telephone: (571) 362-3260