



Pharmacist's Manual

An Informational Outline of the Controlled Substances Act

Revised 2020

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Drug Enforcement Administration
Pharmacist's Manual

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This Pharmacist's Manual has been prepared by the Drug Enforcement Administration, Diversion Control Division, as a guide to assist pharmacists in their understanding of the Federal Controlled Substances Act and its implementing regulations as they pertain to the pharmacy profession.

The 2020 edition replaces all previous editions of the Pharmacist's Manual issued by the Drug Enforcement Administration, both hard copy and electronic.

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SECTION I - INTRODUCTION

Disclaimer

This Pharmacist's Manual is intended to summarize and explain the basic requirements for prescribing, administering, and dispensing controlled substances under the Controlled Substances Act (CSA), Title 21, United States Code (21 U.S.C.) 801-971 and DEA regulations, Title 21, Code of Federal Regulations (21 CFR), Parts 1300 to End. This Pharmacist's Manual is not a legal document. It 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" and will include statutory and/or regulatory citation(s). Recommended practices in this Pharmacist's Manual are voluntary and use language such as "should" or "recommend" to identify these suggestions. Readers should refer to the most current copy of the CSA, the Drug Addiction Treatment Act of 2000 (DATA), the Combat Methamphetamine Epidemic Act of 2005, 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 (CARA), the SUPPORT for Patients and Communities Act of 2018 (the SUPPORT Act), the CFR, 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 website at www.DEAdiversion.usdoj.gov.

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

ODLP@usdoj.gov

or

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

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

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Printed copies of the complete regulations implementing the CSA (21 CFR Part 1300 to End) may be obtained from:

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

Both the CFR and the Federal Register (which includes proposed and final rules implementing the CSA) are available on the Internet through the U.S. Government Publishing Office website. This website, which provides information by section, citation, and keywords, can be accessed at:

<https://www.govinfo.gov>

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

www.DEAdiversion.usdoj.gov

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

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

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Message from the Assistant Administrator

The Drug Enforcement Administration is pleased to provide you with the 2020 edition of the Pharmacist's Manual to assist you in understanding the provisions of the Controlled Substances Act (CSA) and its implementing regulations. This Pharmacist's Manual will answer questions you may encounter in the practice of pharmacy and provide guidance in complying with CSA regulations. This edition has been updated to include information on the Secure and Responsible Drug Disposal Act of 2010, the Comprehensive Addiction and Recovery Act of 2016, and the SUPPORT for Patients and Communities Act of 2018.

Your role in the proper 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 is a powerful resource for protecting the public health, assuring patient safety, and preventing the diversion of controlled substances and drug products containing listed chemicals.

Sincerely,

William T. McDermott
Assistant Administrator
Diversion Control Division

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Preface

The Drug Enforcement Administration (DEA) was established in 1973 to serve as the primary agency responsible for the enforcement of federal drug laws. The Controlled Substances Act (CSA) and its implementing regulations establish federal requirements regarding both illicit and licit controlled substances. With respect to pharmaceutical controlled substances, DEA's responsibility is twofold: to prevent diversion and abuse of these substances while ensuring 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 pharmacies. DEA understands that it can best serve the public interest by working with the pharmacy 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. Within this framework, the majority of investigations into possible violations of controlled substance laws are carried out by state authorities. DEA focuses its investigations on cases involving violators of the highest level or most significant impact.

In the event a state board revokes the license of a pharmacy, DEA will request a voluntary surrender of the pharmacy's DEA registration. If the pharmacy refuses to surrender its registration, DEA will seek administrative action to revoke its DEA registration based on lack of state authorization. Additional administrative remedies that may be utilized to correct a lack of compliance include a letter of admonition or an administrative hearing. DEA may also pursue civil or criminal sanctions if there is sufficient evidence to justify a prosecution. All such actions are designed to protect the public health and safety.

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In addition to the diversion of controlled substances, DEA is concerned with the diversion of certain chemicals used in the clandestine manufacture of controlled substances. Chemicals such as ephedrine and pseudoephedrine contained in over-the-counter and prescription substances are immediate precursors used in the illicit manufacture of methamphetamine and amphetamine. These products may be purchased or stolen from retail outlets, including pharmacies, for use in clandestine laboratories.

Pharmacies that sell over-the-counter products containing ephedrine and pseudoephedrine must be "self-certified" as required by the Combat Methamphetamine Epidemic Act of 2005 (CMEA). The CMEA created a new category of products designated as SLCPs. SLCPs are products containing ephedrine, pseudoephedrine, or phenylpropanolamine that may be marketed or distributed lawfully in the United States as a non-prescription drug under the Food, Drug, and Cosmetic Act. The retail provisions of the CMEA went into effect on September 30, 2006 and require, among other things, employee training, self-certification, placement of SLCPs out of customer reach, required identification, sales logbooks, and the use of sales and purchase limits.

DEA and the pharmacy profession have strong common interests in the appropriate use of controlled substances and SLCPs. An effective working relationship to ensure compliance with CSA requirements will continue to produce lasting benefits on a national scale.

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SECTION II - SCHEDULES OF CONTROLLED SUBSTANCES

The 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 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. 21 U.S.C. 812(b). Some examples of controlled substances in each schedule are outlined 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 some 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, have no currently accepted medical use in treatment in the United States, and there is a lack of accepted safety for use of the drug or other substance 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 which may lead to severe psychological or physical dependence, and have a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions. 21 U.S.C. 812(b)(2).

Examples of schedule II narcotics include morphine, codeine, and opium. Other schedule II narcotic substances and their common name brand products include: any combination products containing hydrocodone (Maxidone, Zydone, Vicodin, Lortab, Vicoprofen, Reprexain), 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

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(Vyvanse). Other schedule II substances include: cocaine, amobarbital, and glutethimide. 21 U.S.C. 812(c), schedule II and 21 CFR 1308.12.

Schedule III Controlled Substances

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

Examples of schedule III narcotics include morphine combination products containing not more than 50 milligrams of morphine per 100 milliliters or per 100 grams, with one or more active, non-narcotic ingredients in recognized therapeutic amounts, and products containing not more than 90 milligrams of codeine per dosage unit with an equal or greater quantity of an isoquinoline alkaloid of opium (Tylenol with codeine). 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, have a currently accepted medical use in treatment in the United States, and abuse 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).

Other schedule IV substances include: alprazolam (Xanax), 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 may lead to limited physical dependence or psychological dependence relative to substances in schedule IV. They consist primarily of preparations containing limited quantities of certain narcotics. 21 U.S.C. 812(b)(5). These are generally used

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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 milligrams of codeine per 100 milliliters or per 100 grams (Robitussin AC and Phenergan with Codeine).

Scheduled Listed Chemical Products (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 non-prescription drug. 21 U.S.C. 802(45) and 21 CFR 1300.02(b).

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SECTION III - REGISTRATION REQUIREMENTS

New Pharmacy Registration

Every pharmacy that dispenses a controlled substance must be registered with DEA. 21 U.S.C. 823(f) and 21 CFR 1301.11(a). A state license must be obtained. 21 U.S.C. 823(f). Federal agencies are exempt from the state license requirement.

To register as a new pharmacy, the DEA Form 224 must be completed. 21 CFR 1301.13(e)(1)(iv). The cost of the application fee is indicated on the application form. The Certificate of Registration (DEA Form 223) must be maintained at the registered location and kept available for official inspection. 21 CFR 1301.35(c). If a person owns and operates more than one pharmacy, each place of business must be separately registered with DEA. 21 CFR 1301.12(a).

The DEA Form 224 should be completed online.

A paper version of the DEA Form 224 may be requested by writing to:

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

If a pharmacy needs a duplicate Certificate of Registration, a copy may be requested online, or by contacting DEA Headquarters at 1-800-882-9539, or via e-mail at DEA.Registration.Help@usdoj.gov.

Renewal of Pharmacy Registration

A pharmacy registration must be renewed every three years utilizing a DEA Form 224a. 21 CFR 1301.13(e)(1)(iv). The most expeditious method to renew a DEA registration is online, but it may be completed by paper application no earlier 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.

Pharmacies will receive a renewal notification at the mailing address associated with the current registration approximately 60 days prior to the expiration date in accordance with 21 CFR 1301.13(e)(3). DEA will subsequently send an electronic reminder to the email address associated with DEA registration approximately 20 days prior to the expiration date if the renewal has not been received or completed.

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If a pharmacy wishes to obtain a paper DEA Form 224a, the pharmacy may send a request via email to DEA.Registration.Help@usdoj.gov or call 1-800-882-9539.

The completed renewal application should be mailed to the following address:

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

The following policy and procedures with respect to renewal and reinstatement of a DEA registration are as follows:

1. If a **renewal application** is submitted in a timely manner **prior to expiration**, the practitioner may continue operations, authorized by the registration, beyond the expiration date until final action is taken on the application. 21 CFR 1301.13(b), 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.
3. Regardless of whether a registration is reinstated within the calendar month after expiration, federal law prohibits the handling of controlled substances for any period of time under an expired registration. 21 CFR 1301.13(a),(e).

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

Affidavit for Renewal of Retail Chain Pharmacy Registration

Corporations that own or operate a chain of pharmacies may submit a single DEA Form 224b, Retail Pharmacy Registration Affidavit for Chain Renewal. This affidavit, along with a list of the corporation's registrations, is provided in lieu of a separate registration application for each pharmacy registration. No registration may be issued unless the completed affidavit is received by DEA. The corporation should retain a copy of this affidavit with their readily retrievable records for the duration of the registrations covered by the affidavit. A responsible individual must answer the questions listed on the affidavit on behalf of the corporation as they pertain to each registrant.

DEA requests corporations with 50 or more retail pharmacy registrations to enroll the chain renewal program. The corporation would need to send a spreadsheet with their

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DEA registration information. Then DEA will create the chain indicator number and send them back with the renewal letter and an affidavit. Chain renewal information can be found on the DEA website:

https://www.deadiversion.usdoj.gov/drugreg/chain_renewal.htm

The original affidavit along with the registration application fee and the list of registrations should be mailed to:

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

Change of Business Address

Every registrant under 21 U.S.C. 801-904 shall be required to report any change of professional or business address in accordance with DEA regulations.

21 U.S.C. 827(h). Before moving to a new physical location, a pharmacy should first request a modification of registration. Modifications are handled in the same manner as applications and must be approved by DEA. 21 CFR 1301.51(a). A modification of registration can be requested online at www.DEAdiversion.usdoj.gov or in writing to the local DEA Registration Program Specialist (Appendix K) responsible for the area in which the pharmacy is or will be located. The request must contain the registrant's name, address, and registration number as printed on the Certificate of Registration; the new name or address; and a signature in accordance with 21 CFR 1301.13(j). If the change of address involves a change in state, the proper state issued license and, if applicable, controlled substances registration must be obtained prior to the approval of modification of the federal registration. 21 U.S.C. 823(f). If the modification is approved, DEA will issue an updated Certificate of Registration and, if requested, new schedule II order forms (DEA Form 222). The registrant should maintain the new certificate with the old certificate until expiration. A Renewal Application for Registration (DEA Form 224a) will only be sent to the registrant's mailing address on file with DEA. It will not be forwarded.

Termination of Registration

A pharmacy that discontinues business activities either completely, or only regarding controlled substances, must return its DEA registration certificate and unused official order forms (DEA Form 222) to the local DEA Registration Program Specialist (Appendix K). 21 CFR 1301.52(c). In addition, DEA may ask for the location where

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inventories, prescriptions, and other required controlled substance records will be stored during the requisite two-year retention period.

Unwanted controlled substances in the pharmacy's possession must be disposed of in accordance with DEA regulations (See *Section X, Transfer or Disposal of Controlled Substances.*)

Transfer of Business

Pursuant to 21 CFR 1301.52(d), a pharmacy registrant that desires to transfer its business operations to another pharmacy registrant must submit in person or by registered or certified mail, return receipt requested, to the Special Agent in Charge in his or her area, at least 14 days in advance of the date of the proposed transfer (unless the Special Agent in Charge waives this time limitation in individual instances), the following information:

1. The name, address, registration number, and authorized business activity of the registrant discontinuing the business (registrant-transferor);
2. The name, address, registration number, and authorized business activity of the person acquiring the business (registrant-transferee);
3. Whether the business activities will be continued at the location registered by the person discontinuing business, or moved to another location (if the latter, the address of the new location should be listed); and
4. The date on which the transfer of controlled substances will occur.

On the day the controlled substances are transferred, a complete inventory must be taken in accordance with 21 CFR 1304.11 which documents the drug name, dosage form, drug strength, quantity, and date transferred. 21 CFR 1301.52(e)(1). In addition, DEA Form 222 or the electronic equivalent must be prepared to document the transfer of schedule II controlled substances. 21 CFR 1301.52(e)(1), 1305.03. This inventory serves as the final inventory for the registrant going out of business and transferring the controlled substances. It also serves as the initial inventory for the registrant acquiring the controlled substances. A copy of the inventory must be included in the records of each pharmacy. It is not necessary to send a copy of the inventory to DEA unless requested by the Special Agent in Charge. 21 CFR 1301.52(e)(1). The pharmacy acquiring the controlled substances must maintain all records involved in the transfer of the controlled substances for two years. 21 U.S.C. 827(b) and 21 CFR 1304.04(a).

All controlled substance records required to be kept by the registrant-transferor shall be transferred to the registrant-transferee. Responsibility for the accuracy of records prior

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to the date of transfer remains with the transferor, but responsibility for custody and maintenance is the responsibility of the transferee. 21 CFR 1301.52(e)(2).

If the registrant acquiring the pharmacy owns at least one other pharmacy licensed in the same state as the pharmacy being transferred, the registrant may apply for a new DEA registration prior to the date of transfer. DEA may issue a registration which will authorize the registrant to obtain controlled substances at the time of transfer, but the registrant may not dispense controlled substances until the pharmacy has been issued a valid state pharmacy license. 21 CFR 1301.17(b).

A DEA registration application to transfer ownership of an existing pharmacy can be facilitated if the applicant includes an affidavit verifying that the pharmacy has been registered by the state licensing agency. The affidavit verifying the existence of the state license should be attached to the initial application for registration.

Denial of Registration in the Public Interest

A pharmacy may be denied DEA registration upon a finding that such registration is inconsistent with the public interest. 21 U.S.C. 823(f). In determining the public interest pursuant to 21 U.S.C. 823(f), the CSA 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 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.

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 the registrant:

1. Has materially falsified the application;
2. Has been convicted of a felony relating to a controlled substance or a List I chemical;

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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 the suspension, revocation, or denial of a registration recommended by competent state authority;
4. Has committed such acts as would render its registration inconsistent with the public interest as determined under 21 U.S.C. 823(f); or
5. Has been excluded (or directed to be excluded) from participation in a program pursuant to 42 U.S.C. 1320a-7(a).

Chemical Registration Requirements

Registration is not required for regulated sellers of scheduled listed chemical products (SLCPs). 21 U.S.C. 823(h) and 802(39)(A)(iv-v). However, a regulated seller must self-certify with DEA pursuant to federal law (See *Section XIII, Combat Methamphetamine Epidemic Act of 2005*.) 21 U.S.C. 830(e)(1)(B)(i), 21 CFR 1314.40(a). A regulated seller is a retail distributor (including a pharmacy or a mobile retail vendor) of SLCPs, except that the term does not include an employee or agent of the distributor. 21 CFR 1300.02 ("Regulated seller"). Examples of regulated sellers include grocery stores, general merchandise stores, drug stores, or other entities engaged in over-the-counter sales of ephedrine (both single entity and combination products), pseudoephedrine, or phenylpropanolamine products, directly to walk-in customers or in face-to-face transactions by direct sales.

If a pharmacy desires to engage in the distribution of bulk quantities of SLCPs, the pharmacy is required to register with DEA as a chemical distributor because these activities fall outside the definition of a regulated seller. 21 CFR 1309.21(a)(2). Therefore, the pharmacy would be subject to the registration requirements that apply to chemical distributors for those distribution activities, and subject to the pharmacy requirements for its pharmacy activities. To obtain a DEA chemical distributor registration, a pharmacy may complete the DEA Form 510 online. A paper version may be requested by writing to:

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

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SECTION IV - ORDERING CONTROLLED SUBSTANCES

On September 30, 2019, DEA issued a final rule entitled *New Single-Sheet Format for U.S. Official Order Form for Schedule I and II Controlled Substances (DEA Form 222)*, which implements a new single-sheet format for DEA Form 222, used by DEA registrants to order schedule I and II controlled substances. 84 FR 51368. The rule became effective on October 30, 2019, and provides for a two-year transition period, during which the existing triplicate version of the forms may continue to be used. DEA registrants will be allowed to exhaust their supply of the current forms as part of the transition to using the new single-sheet form. When a registrant's supply of triplicate forms is depleted, DEA will issue new single-sheet forms to the registrant. This rule includes a "sunset date" of October 30, 2021—the date after which use of the triplicate forms will not be allowed.

Ordering Schedules I and II Controlled Substances

Only schedule 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 or schedule II controlled substance unless exempted. 21 CFR 1305.03, 1307.11(a)(1)(iii), 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.

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 person 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 person 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

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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).

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 should record the name and address from whom the controlled substances are being ordered must be entered on the form 21 CFR 1305.12(c). If the purchaser does not have this information then the supplier should ensure it is on the form. 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). The supplier must retain the original DEA Form 222 for the supplier's files in accordance with 21 CFR 1305.17(c). Any supplier who is not required to report acquisition/disposition transactions to the Automation of Reports and Consolidated Orders System (ARCOS) under 1304.33(c) (such as a practitioner) must make and submit a copy of the original DEA Form 222 to DEA, either by mail to the Registration Section, or by email to DEA.Orderforms@usdoj.gov. The copy must be forwarded at the close of the month during which the order is filled. If an order is filled by partial shipments, the copy must be forwarded at the close of the month during which the final shipment is made or the 60-day validity period expires.

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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 Forms 222, with any related statements or other documents, and without any other records.

Under 21 CFR 1305.15(a)(1), an order must not be filled if the Form 222 is not complete, legible, or properly prepared, executed, or endorsed, or if the 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*.

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 order, the original DEA Form 222 and the statement must be retained in the files of the purchaser. 21 CFR 1305.17. 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).

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Power of Attorney to Sign DEA Forms 222

Any registrant (pharmacy) may authorize one or more individuals, whether or not they are located at the registered location, to obtain and execute DEA Forms 222 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:

1. 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;
2. The person to whom the power of attorney is being granted; and
3. 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 pharmacy 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.

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

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 _____ .

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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 pharmacy, 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 (Appendix K) 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 provide 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 pharmacy must immediately notify the local DEA Diversion Field Office (Appendix K). 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

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is registered, the purchaser must return all unused DEA Forms 222 to the Registration Section. 21 CFR 1305.18.

Continued Use of Existing Stocks of Triplicate DEA Forms 222

Registrants may continue to use existing stocks of the triplicate DEA Form 222 until October 30, 2021. In any case, as soon as a registrant's supply of triplicate DEA Forms 222 is exhausted, the registrant must use the new single-sheet DEA Form 222. 21 CFR 1305.20.

Procedure for Obtaining Triplicate DEA Forms 222

DEA no longer issues triplicate forms. Triplicate DEA Forms 222 will not be accepted after October 30, 2021. 21 CFR 1305.20(a).

Completing Triplicate DEA Forms 222

A purchaser must prepare and execute a triplicate DEA Form 222 simultaneously by means of interleaved carbon sheets that are part of the triplicate DEA Form 222. Triplicate DEA Forms 222 must be prepared by use of a typewriter, pen, or indelible pencil. 21 CFR 1305.20(b)(1). 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 1305.20(b)(2). Each triplicate DEA Form 222 must be signed and dated by a person authorized to sign a registration application or a person granted power of attorney. 21 CFR 1305.20(b)(4). When the items are received, the purchaser must document on the purchaser's copy (copy three) the actual number of commercial or bulk containers received and the date received. 21 CFR 1305.20(c)(5).

The executed triplicate DEA Form 222 must be maintained separately from the pharmacy's other business records. 21 CFR 1305.20(g)(3). If a purchaser has several registered locations, the purchaser must retain Copy 3 of the executed triplicate DEA Form 222 and any attached statements or other related documents at the registered location printed on the triplicate DEA Form 222. 21 CFR 1305.20(g)(3).

Unaccepted and Defective Triplicate DEA Forms 222

21 CFR 1305.20(e) requires that, for orders using the triplicate DEA Form 222, an order must not be filled if the order is not complete, legible, or properly prepared, executed, or endorsed, or if the order shows any alteration, erasure, or change of any description. If an order cannot be filled, the supplier must return copies 1 and 2 of the triplicate DEA Form 222 to the purchaser with a statement explaining the reason the order could not be

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filled (e.g., illegible or altered). 21 CFR 1305.20(e)(2). A supplier may refuse to accept an order for any reason. 21 CFR 1305.20(e)(3). If a supplier refuses to accept an order, a statement that the order is not accepted is sufficient. 21 CFR 1305.20(e)(3). When a purchaser receives an unaccepted order, Copies 1 and 2 of the triplicate DEA Form 222 and the statement must be attached to Copy 3 and retained in the files of the purchaser. 21 CFR 1305.20(e)(4). A defective triplicate DEA Form 222 may not be corrected; it must be replaced by a new triplicate DEA Form 222 for the order to be filled. 21 CFR 1305.20(e)(4).

The purchaser must retain Copy 3 of each executed triplicate DEA Form 222 and all copies of unaccepted or defective forms with each statement attached. 21 CFR 1305.20(g)(1).

Cancellation and Voiding a Triplicate DEA Form 222

A purchaser may cancel an order (or part of an order) on a triplicate DEA Form 222 by notifying the supplier in writing. 21 CFR 1305.20(i)(1). The supplier must indicate the cancellation on Copies 1 and 2 of the triplicate DEA Form 222 by drawing a line through the canceled item(s) and printing "canceled" in the space provided for the number of items shipped. 21 CFR 1305.20(i)(1).

A supplier may void part or all of an order on a triplicate DEA Form 222 by notifying the purchaser in writing. 21 CFR 1305.20(i)(1). The supplier must indicate the voiding on Copies 1 and 2 of the triplicate DEA Form 222 by drawing a line through the canceled item(s) and printing "canceled" in the space provided for the number of items shipped. 21 CFR 1305.20(i)(1).

Lost or Stolen Triplicate DEA Forms 222

If a purchaser ascertains that an unfilled triplicate DEA Form 222 has been lost, the purchaser must execute another in triplicate and attach a statement containing the serial number and date of the lost form, and stating that the goods covered by the first triplicate DEA Form 222 were not received through loss of that triplicate DEA Form 222. 21 CFR 1305.20(f)(1). Copy 3 of the second form and a copy of the statement must be retained with Copy 3 of the triplicate DEA Form 222 first executed. 21 CFR 1305.20(f)(1). A copy of the statement must be attached to Copies 1 and 2 of the second triplicate DEA Form 222 sent to the supplier. 21 CFR 1305.20(f)(1). If the first triplicate 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 Copies 1 and 2 to the purchaser, who must attach it to Copy 3 and the statement. 21 CFR 1305.20(f)(1). However, if the registrant no longer can use triplicate forms, then the registrant shall proceed by issuing a new single-sheet form in accordance with 21 CFR 1305.16. 21 CFR 1305.20(f)(1).

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Whenever any used or unused triplicate DEA Forms 222 are stolen or lost (other than in the course of transmission) by any purchaser or supplier, the purchaser or supplier must immediately upon discovery of the theft or loss, report the theft or loss to the Special Agent in Charge of the Drug Enforcement Administration in the local DEA Diversion Field Office. 21 CFR 1305.20(f)(2).

Return of Unused Triplicate 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 of this chapter for all schedule I and II controlled substances for which the purchaser is registered, the purchaser must return all unused triplicate DEA Forms 222 to the Registration Section. 21 CFR 1305.20(h).

Controlled Substance Ordering System (CSOS) - Electronic Order Forms

Any registrant permitted to order schedule II controlled substances may do so electronically via the DEA's Controlled Substance Ordering System (CSOS) and maintain the records of these orders electronically for two years. 21 CFR 1311.60(a). The use of electronic orders is optional; registrants may continue to issue orders on a paper DEA Form 222. CSOS allows for secure electronic transmission of controlled substance orders without the supporting paper DEA Form 222. CSOS is the only electronic means of ordering schedule II controlled substances between controlled substance manufacturers, distributors, pharmacies, and other DEA authorized entities. CSOS uses Public Key Infrastructure (PKI) technology, which requires CSOS users to obtain a CSOS digital certificate for electronic ordering. The electronic orders must be signed using a digital signature issued by the Certification Authority (CA) run by DEA. 21 CFR 1305.21(a).

Digital certificates can be obtained only by the person who signed the most recent DEA registration application or renewal application, a person authorized to sign a registration application, or a person granted power of attorney by a DEA registrant to sign orders for one or more schedules of controlled substances. 21 CFR 1311.10(a) and (b). A registrant must appoint a CSOS coordinator who will serve as that registrant's recognized agent regarding issues pertaining to issuance of, revocation of, and changes to digital certificates issued under that registrant's DEA registration. 21 CFR 1311.20(a). A CSOS digital certificate is valid until the DEA registration under which it is issued expires or until the CSOS CA is notified that the certificate should be revoked. 21 CFR 1311.30(e), 1311.40(a). Certificates will be revoked if the certificate holder is no longer authorized to sign schedule II orders for the registrant, if the information on which the certificate is based changes, or if the digital certificate used to sign electronic

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orders has been compromised, stolen, or lost. 21 CFR 1311.30(e), 1311.40(a). A "Questions and Answers" page about the CSOS certificate is available on DEA's E-Commerce Program website at www.DEAecom.gov. Applicants can download the Diversion PKI CSOS Enrollment document and the CSOS Subscriber's Manual for assistance on the enrollment process. DEA maintains a support line to assist applicants and subscribers with issues pertaining to certificate enrollment, issuance, revocation, and renewal. Staff is available from 8:00 a.m. to 5:50 p.m. (Eastern Time), Monday through Friday at 1-877-332-3266 if further assistance is needed.

Unaccepted and Defective Electronic Orders

Under 21 CFR 1305.25(a), an electronic order for controlled substances may not be filled if any of the following occurs:

1. The required data fields have not been completed.
2. The order is not signed using a digital certificate issued by DEA.
3. The digital certificate used has expired or been revoked prior to signature.
4. The purchaser's public key will not validate the digital certificate.
5. The validation of the order shows that the order is invalid for any reason.

If an order cannot be filled, the supplier must notify the purchaser and provide a statement as to the reason (e.g., improperly prepared or altered). A supplier may, for any reason, refuse to accept any order. If a supplier refuses, a statement that the order is not accepted is sufficient. 21 CFR 1305.25(b).

When a purchaser receives an unaccepted electronic order from the supplier, the purchaser must electronically link the statement of non-acceptance to the original order. The original statement and all linked records for that order must be retained for two years. 21 CFR 1305.25(c), 1305.27(a). Neither a purchaser nor a supplier may correct a defective order. The purchaser must issue a new order for the order to be filled. 21 CFR 1305.25(d).

Cancellation and Voiding of Electronic Orders

A supplier may void all (or part) of an electronic order by notifying the purchaser of the voiding. If the entire order is voided, the supplier must make an electronic copy of the order and indicate "void" on the copy and return it to the purchaser. The supplier is not required to retain a record of orders that are not filled. 21 CFR 1305.28(a). The purchaser must retain an electronic copy of the voided order. 21 CFR 1305.28(b).

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Should a supplier partially void an order, the supplier must indicate in the linked record that nothing was shipped for each item voided. 21 CFR 1305.28(c).

Lost Electronic Orders

If a purchaser determines that an unfilled electronic order has been lost before or after receipt, the purchaser must provide, to the supplier, a signed statement. This statement must include the unique tracking number and date of the lost order and state that the goods covered by the first order were not received through loss of that order. 21 CFR 1305.26(a). If the purchaser executes a new order to replace the lost order, the purchaser must electronically link an electronic record of the second order and a copy of the statement with the record of the first order and retain them both. 21 CFR 1305.26(b). If the supplier to whom the order was directed subsequently receives the first order, the supplier must indicate that it is "Not Accepted" and return it to the purchaser. The purchaser must link the returned order to the record of that order and the statement. 21 CFR 1305.26(c).

Ordering Schedules III-V Controlled Substances

The registrant must keep a receipt (invoice or packing slip) on which it records the date the drugs were received and confirm that the order is accurate. 21 CFR 1304.21(a) and (d). Pursuant to 21 CFR 1304.22(c), 1304.22(a)(2), such receipts must also contain the following information:

1. The name of the substance;
2. Each finished form (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);
3. The number of units of finished forms and/or commercial containers acquired from other persons, including the date of and number of units and/or commercial containers in each acquisition to inventory and the name, address, and registration number of the person from whom the units were acquired;
4. The number of commercial containers distributed to other persons, including the date of and number of containers in each reduction from inventory, and the name, address, and registration number of the person to whom the containers were distributed;
5. The number of units of finished forms and/or commercial containers distributed or disposed of in any other manner by the registrant (e.g., by distribution of complimentary samples or by destruction), including the date and manner of

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distribution or disposal, the name, address, and registration number of the person to whom distributed, and the quantity in finished form distributed or disposed.

In addition, these receipts must be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant. 21 CFR 1304.04(f)(2).

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SECTION V - 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 II controlled substances. 21 CFR 1300.01(b). With respect to inventories of a schedule III, IV, or V controlled substance, the registrant may, with respect to an open bottle which contains no more than 1,000 tablets, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case an exact count of the contents must be made. 21 CFR 1304.11(e)(6)(i) and (ii). The CSA also requires that all inventory records be maintained at the registered location for at least two years for copying and inspection. 21 CFR 1304.04(a) and 21 U.S.C. 827(b). In addition, the inventory records of schedule II controlled substances must be kept separate from all other records of the pharmacy. 21 CFR 1304.04(h)(1). The inventory records of schedules III, IV, and V controlled substances must be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy. 21 CFR 1304.04(h)(3).

Initial Inventory

When issued a DEA registration, a registrant must take an initial inventory, which is an actual physical count of all controlled substances in their possession. 21 U.S.C. 827(a)(1). If there are no stocks of controlled substances on hand, the registrant should make a record showing a zero inventory. 21 CFR 1304.11(b). There is no requirement to submit a copy of the inventory to DEA. Under 21 CFR 1304.11(a), (b) and (e)(6), the inventory shall include:

1. The date of the inventory,
2. Whether the inventory was taken at the beginning 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 the 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. The total count of the substance.

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Although the 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.

Biennial Inventory

After the initial inventory, the registrant is required to take a new inventory at least every two years, which requires the same information as the initial inventory (see list above) of all controlled substances on hand. 21 CFR 1304.11(c). There is no requirement to submit a copy of the inventory to DEA.

Newly Scheduled Controlled Substance Inventory

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).

Inventory for Damaged, Defective, or Impure Substances

For damaged, defective, or impure substances awaiting disposal, substances held for quality control purposes, or substances maintained for extemporaneous compoundings, the inventories, pursuant to 21 CFR 1304.11(e)(1)(iv), must include:

1. The name of the substance;
2. The total quantity of the substance to the nearest metric unit weight or the total number of units of finished form; and
3. The reason for the substance being maintained by the registrant and whether such substance is capable of use in the manufacture of any controlled substance in finished form.

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SECTION VI - RECORDKEEPING REQUIREMENTS

Every pharmacy must maintain complete and accurate records on a current basis for each controlled substance received, sold, delivered, 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). Recordkeeping requirements for prescriptions are detailed in Section VII, *Valid Prescription Requirements*.

Under 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.

Required Records

Pursuant to 21 CFR 1304, the records which must be maintained by a pharmacy are:

1. Executed official order forms (DEA Form 222) or the electronic equivalent.
2. Power of Attorney authorization to sign order forms. 21 CFR 1305.05(a).
3. Receipts and/or invoices for schedules III, IV, and V controlled substances.
4. All inventory records of controlled substances, including the initial and biennial inventories, dated as of beginning or close of business.

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5. Records of controlled substances distributed (i.e., sales to other registrants, returns to vendors, distributions to reverse distributors).
 6. The Suspicious Orders Report System (SORS) should be accessed on-line and only be used by DEA registrants that distribute controlled substances to other DEA registrants. Reporting a suspicious order to SORS Online constitutes compliance with the reporting requirement under 21 U.S.C. 832. Previously, only manufacturers and distributors were required to report suspicious orders. The SUPPORT Act requires that ALL DEA registrants that distribute controlled substances report suspicious orders to DEA. Reverse distributors and exporters are not affected by this SUPPORT Act requirement.
 7. Records of controlled substances dispensed, to include prescriptions or a logbook of controlled substances which may be lawfully dispensed without a prescription.
 8. Reports of Theft or Significant Loss (DEA Form 106), if applicable.
 9. Registrant Record of Controlled Substances Destroyed (DEA Form 41), if applicable.
 10. DEA registration certificate. 21 CFR 1301.35(c).
 11. The self-certification certificate and logbook (or electronic equivalent) as required under the Combat Methamphetamine Epidemic Act of 2005. 21 CFR 1314.30.

Central Recordkeeping

A registrant desiring to maintain shipping and financial records (but not executed official order forms) at a central location rather than the registered location must submit written notification of its intention by registered or certified mail, return receipt requested, in triplicate, to the Special Agent in Charge of the local DEA Diversion Field Office in which the registrant is located (Appendix K). Unless the registrant is informed by DEA that permission to keep central records is denied, the registrant may begin maintaining central records 14 days after DEA receives this notification. Central recordkeeping requirements are described in 21 CFR 1304.04(a)(1). Central recordkeeping permits are no longer issued by DEA.

Prescription Records

Pharmacies have two options for filing paper prescription records and one option for electronic prescription records. Paper prescriptions for schedule II controlled substances shall be maintained at the registered location in a separate prescription file.

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21 CFR 1304.04(h)(2). Prescriptions for schedules III, IV, and V controlled substances shall be maintained at the registered location either in a separate prescription file for schedules III, IV, and V, or in such form that they are readily retrievable from the other prescription records of the pharmacy. 21 CFR 1304.04(h)(4). Pursuant to 21 CFR 1304.04(h), controlled substance prescriptions must be filed in one of the following ways:

Paper Prescriptions Records Option 1:

1. A file for schedule II controlled substances dispensed.
2. A file for schedules III, IV and V controlled substances dispensed.

Paper Prescriptions Records Option 2:

1. A file for all schedule II controlled substances dispensed.
2. A file for all other drugs dispensed (non-controlled and those in schedules III, IV and V). If this method is used, a prescription for a schedule III, IV or V drug must be made readily retrievable by use of a red "C" stamp not less than one inch high. If a pharmacy has an electronic recordkeeping system for prescriptions which permits identification by prescription number and retrieval of original documents by prescriber's name, patient's name, drug dispensed, and date filled, the requirement to mark the hard copy with a red "C" is waived. 21 CFR 1304.04(h)(4).

Federal requirements for filling prescriptions shall not be construed as authorizing or permitting any person to do any act which such person is not authorized or permitted to do under other federal laws or obligations under international treaties, conventions or protocols, or under the law of the state in which he or she desires to do such act nor shall compliance with such parts be construed as compliance with other federal or state laws unless expressly provided in such other laws. 21 CFR 1307.02.

Electronic Prescription Records

1. If a prescription is created, signed, transmitted, and received electronically, all records related to that prescription must be retained electronically. 21 CFR 1311.305(a).
2. Electronic records must be maintained electronically for two years from the date of their creation or receipt. However, this record retention requirement shall not preempt any longer period of retention which may be required now or in the

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future, by any other federal or state law or regulation, applicable to pharmacists or pharmacies. 21 CFR 1311.305(b).

3. Records regarding controlled substances must be readily retrievable from all other records. Electronic records must be easily readable or easily rendered into a format that a person can read. 21 CFR 1311.305(c).

Records of electronic prescriptions for controlled substances shall be maintained in an application that meets the requirements of 21 CFR Part 1311 and 21 CFR 1304.04(h)(5). The computers on which the records are maintained may be located at another location, but the records must be readily retrievable at the registered location if requested by a DEA or other law enforcement agent. The electronic application must be capable of printing out or transferring the records in a format that is readily understandable to a DEA or other law enforcement agent at the registered location. Electronic copies of prescription records must be sortable by prescriber name, patient name, drug dispensed, and date filled. 21 CFR 1304.04(h)(5).

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SECTION VII - VALID PRESCRIPTION REQUIREMENTS

To dispense controlled substances, a pharmacist must know the requirements for a valid prescription which are described in this section. A prescription is an order for medication which is dispensed to or for an ultimate user. 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 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), 1306.22(b), the prescription must also include:

1. Drug name
2. Drug strength
3. Dosage form
4. Quantity prescribed
5. Directions for use
6. Number of refills authorized (if any)

A paper prescription must be written in ink or indelible pencil or typewritten, or printed on a computer printer, and must be manually signed by the practitioner on the date when issued. 21 CFR 1306.05(d). An individual (i.e., secretary or nurse) may prepare prescriptions for the practitioner's signature. 21 CFR 1306.05(f). The practitioner is responsible for ensuring the prescription conforms to all requirements of the law and regulations, both federal and state. 21 CFR 1306.05(f). A corresponding liability rests upon the pharmacist, including a pharmacist employed by a central fill pharmacy, who fills a prescription not prepared in the form prescribed by DEA regulations. 21 CFR 1306.05(f).

Acceptable Changes to a Prescription

[Reserved]

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Who May Issue

Under 21 CFR 1306.03, a prescription for a controlled substance may only be issued by a physician, dentist, podiatrist, veterinarian, mid-level practitioner, or other registered practitioner who is:

1. Authorized to prescribe controlled substances by the jurisdiction in which the practitioner is licensed to practice, and
2. Registered with DEA or exempted from registration (e.g., Public Health Service, Federal Bureau of Prisons, military practitioners), 21 CFR 1301.23(a), 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.

Purpose of Issue

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).

A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients. 21 CFR 1306.04(b).

Authorized Agent

An individual practitioner may authorize an agent to perform a limited role in communicating such prescriptions to a pharmacy in order to make the prescription process more efficient. 21 CFR 1306.03(b), 1306.11(a), 1306.21(a). Even though the CSA established a closed system in which all persons in the distribution chain are required to be registered and are held accountable for every controlled substance transaction, Congress recognized a role for agents under the Act. The CSA exempts agents of registrants, including practitioners, from the requirement of registration.

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21 U.S.C. 822(c)(1). The statute defines an "agent" as "an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser." 21 U.S.C. 802(3). The CSA does not permit a prescribing practitioner, however, to delegate to an agent or any other person the practitioner's authority to issue a prescription for a controlled substance. A practitioner acting in the usual course of his or her 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). The common means to communicate a prescription to a pharmacy include hand delivery, facsimile, phone call, or an electronic transmission. The proper role of an agent is fact specific and depends upon the schedule of the controlled substance prescribed, the circumstances of the ultimate user, and the method of communication, among other things.

Summary of the acts that an agent may execute 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).

DEA believes it is in the best interest of the practitioner, the agent, and the dispensing pharmacist that the designation of those persons authorized to act on behalf of the practitioner and the scope of any such authorization be reduced to writing. A signed copy should also be provided to the practitioner's designated agent, the agent's employer (if other than the practitioner), and any pharmacies that regularly receive communications from the agent pursuant to the agreement. Providing a copy to pharmacies likely to receive prescriptions from the agent on the practitioner's behalf may assist those pharmacists with their corresponding responsibility regarding the dispensing of controlled substances. However, even where the pharmacist has a copy of an agency agreement, the pharmacist may also have a duty to inquire further

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depending upon the particular circumstances. (See Federal Register: October 6, 2010, Volume 75, Number 193, page 61613-61617, for the complete policy statement on the *Role of Authorized Agents in Communicating Controlled Substance Prescriptions to Pharmacies.*)

Corresponding Responsibility

A pharmacist has a corresponding responsibility for the proper dispensing of controlled substances. 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 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 U.S.C. 842(a)(1), and 21 CFR 1306.04(a).

A pharmacist is required to exercise sound professional judgment, and to adhere to professional standards, when making a determination about the legitimacy of a controlled substance prescription. 21 CFR 1306.04(a), 21 CFR 1306.06. Such a determination is made before the prescription is dispensed. The law does not require a pharmacist to dispense a prescription of doubtful, questionable, or suspicious medical legitimacy. To the contrary, the pharmacist who deliberately ignores the high probability that a prescription was not issued for a legitimate medical purpose and fills the prescription, may be prosecuted along with the issuing practitioner, for knowingly and intentionally distributing controlled substances. *United States v. Veal*, 23 F.3d 985 (6th Cir.1994). Such action is a felony offense, which upon conviction, may result in a term of imprisonment and a fine. 21 U.S.C. 841(b). Unlawful dispensing of controlled substances by a pharmacist may also be subject to criminal actions against the pharmacy or pharmacist, and to civil enforcement actions against the pharmacy or pharmacist for money penalties or injunctions. 21 U.S.C. 842, 843. Moreover, DEA may revoke a pharmacy's registration based on a finding that its pharmacists have violated the corresponding responsibility rule and both the pharmacy and pharmacists may be the subject of proceedings against their state licenses. *Jones Total Healthcare, L.L.C., v. DEA*, 881 F.3d 823 (11th Cir. 2018).

Electronic Prescriptions

On March 31, 2010, DEA published in the Federal Register an interim final rule *Electronic Prescriptions for Controlled Substances* which became effective June 1, 2010. 75 FR 16235-16319 (Mar. 31, 2010). The rule revises DEA regulations to provide practitioners with the option of writing prescriptions for controlled substances electronically. The regulations also permit pharmacies to receive, dispense, and archive these electronic prescriptions. These regulations are an addition to, not a replacement of, the existing rules.

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Persons who wish to dispense controlled substances using electronic prescriptions must select software that meets the requirements of this rule. 21 CFR 1311.120(a). As of June 1, 2010, only those electronic pharmacy applications that comply with all of DEA's requirements as set forth in 21 CFR Part 1311 may be used by DEA registered pharmacies to electronically receive and archive controlled substances prescriptions and dispense controlled substances based on those prescriptions.

Pursuant to 21 CFR 1306.08, a registered pharmacy may fill electronic prescriptions for controlled substances only if the following conditions are met:

1. The pharmacy uses a pharmacy application that meets all of the applicable requirements of 21 CFR 1311.205, and
2. The prescription is otherwise in conformity with the requirements of the CSA and 21 CFR Part 1311.

A pharmacy cannot process electronic prescriptions for controlled substances until its pharmacy application provider obtains a third party audit or certification review that determines that the application complies with DEA's requirements and the application provider provides the audit/certification report to the pharmacy. 21 CFR 1311.200(a). The audit report the pharmacy receives from the pharmacy application provider indicates if the application is capable of importing, displaying, and storing DEA-required prescription information accurately and consistently. If the third-party auditor or certification organization finds that a pharmacy application does not accurately and consistently import, store, and display the information related to the name, address, and registration number of the practitioner, patient name and address, and prescription information (drug name, drug strength, quantity, directions for use), the indication of signing, the number of refills, and the practitioner's digital signature, where applicable, the pharmacy must not accept electronic prescriptions for the controlled substance. 21 CFR 1311.200(b) and (c).

If the third-party auditor or certification organization finds that a pharmacy application does not accurately and consistently import, store, and display other information required for prescriptions, the pharmacy must not process electronic prescriptions for controlled substances that are subject to the additional information requirements. 21 CFR 1311.200(b). (For example: 21 CFR 1306.11(d)(4) requires practitioners to submit a prescription with the phrase "Authorization for Emergency Dispensing" written on its face in addition to conforming to the requirements of 21 CFR 1306.05. 21 CFR 1306.11(g) requires the practitioner or the practitioner's agent to note on the prescription that the patient is a hospice patient. 21 CFR 1306.05(c) requires the practitioner to note on the face of the prescription the medical need of the patient for the prescription.)

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The pharmacy must determine which employees are authorized to enter information regarding the dispensing of controlled substance prescriptions and annotate or alter records of these prescriptions (to the extent such alterations are permitted under DEA regulations). The pharmacy must ensure that logical access controls in the pharmacy application are set so that only such employees are granted access to perform these functions. 21 CFR 1311.200(e).

When a pharmacist fills a prescription in a manner that would require, under 21 CFR Part 1306, the pharmacist to make notation on the prescription if the prescription were a paper prescription, the pharmacist must make the same notation electronically when filling an electronic prescription and retain the annotation electronically in the prescription record or linked files. 21 CFR 1306.08(b) and (c) and 21 CFR 1311.200(f). When a prescription is received electronically, the prescription and all required annotations must be stored electronically. 21 CFR 1311.305(a) and 21 CFR 1311.200(f).

When a pharmacist receives a paper or oral prescription that indicates that it was originally transmitted electronically to the pharmacy, the pharmacist must check the pharmacy's records to ensure that the electronic version was not received and the prescription dispensed. 21 CFR 1311.200(g). If both prescriptions were received, the pharmacist must mark one as void. 21 CFR 1311.200(g).

When a pharmacist receives a paper or oral prescription that indicates that it was originally transmitted electronically to another pharmacy, the pharmacist must check with that pharmacy to determine whether the prescription was received and dispensed. 21 CFR 1311.200(h). If the pharmacy that received the original electronic prescription had not dispensed the prescription, the pharmacy must mark the electronic version as void or cancelled. 21 CFR 1311.200(h). If the pharmacy that received the original electronic prescription dispensed the prescription, the pharmacy with the paper version must not dispense the paper prescription and must mark the prescription as void. 21 CFR 1311.200(h).

Construction of a Valid DEA Registration Number for Practitioners

A pharmacist has a responsibility to ensure that a prescription has been issued by an appropriately registered or exempt practitioner (See above, *Who May Issue*.) Knowing how a DEA registration number is constructed can be a useful tool for recognizing a forged prescription (See Appendix D, Pharmacist's Guide to Prescription Fraud). Prior to October 1, 1985, DEA policy provided that DEA registration numbers for physicians, dentists, veterinarians, and other practitioners started with the letter A. New registration numbers issued to practitioners after that date begin with the letter B or F. Registration numbers issued to mid-level practitioners begin with the letter M. The first letter of the registration number is almost always followed by the first letter of the registrant's last name (e.g., J for Jones or S for Smith) and then a computer generated sequence of

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seven numbers (such as MJ3614511). A registrant (pharmacy) may verify a practitioner's DEA number by using the following link:

<https://apps.deadiversion.usdoj.gov/webforms/validateLogin.jsp>.

Practitioner's Use of a Hospital's DEA Registration Number

Pursuant to 21 CFR 1301.22(c), practitioners (e.g., intern, resident, staff physician, mid-level practitioner) who are agents or employees of a hospital or other institution, may, when acting in the usual course of business or employment, administer, dispense, or prescribe controlled substances under the registration of the hospital or other institution in which he or she is employed, in lieu of individual registration, provided that:

1. The dispensing, administering, or prescribing is in the usual course of professional practice.
2. The practitioner is authorized to do so by the state in which he or she is practicing.
3. The hospital or institution has verified that the practitioner is permitted to administer, dispense, or prescribe controlled substances within the state.
4. The practitioner acts only within the scope of employment in the hospital or institution.
5. The hospital or institution authorizes the practitioner to administer, dispense, or prescribe under its registration and assigns a specific internal code number for each practitioner.

A current list of internal codes and the corresponding individual practitioners is to be maintained by the hospital or other institution. This list is to be available at all times to other registrants and law enforcement agencies upon request for the purpose of verifying the authority of the prescribing individual practitioner. 21 CFR 1301.22(c)(6). Pharmacists should contact the hospital or other institution for verification if they have any doubts in filling prescriptions issued under a hospital's DEA registration.

Unique Identification Number

The Unique Identification Number (UIN) or "X" number authorizes a DEA registered, Qualified Practitioner (e.g., a physician) under the Drug Addiction Treatment Act of 2000 or Qualifying Other Practitioner (i.e., nurse practitioner, physician's assistant, clinical nurse specialists, certified registered nurse anesthetists, or certified nurse midwives) under the Comprehensive Addiction and Recovery Act of 2016 and the SUPPORT for

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Patients and Communities Act of 2018, to prescribe schedule III-V narcotic controlled substances approved by the Food and Drug Administration specifically for maintenance and detoxification treatment. The Qualifying Practitioner or the Qualifying Other Practitioner will be issued only one UIN. The UIN can be used with multiple DEA registration numbers in any state as long as the DEA registration number with which it is associated remains valid. Pursuant to DEA policy, the UIN number consists of two letters and seven numbers; the first letter is always an X, and is commonly referred to as the "X" number. For example, AB1234567 would have a UIN of XB1234567. 21 U.S.C. 823(g)(2)(D)(ii). For more information on prescription requirements for UINs please see Section XII, *Prescriptions for Maintenance and Detoxification Treatment*.

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 administer, dispense, or prescribe, but not to procure or purchase controlled substances in the course of his or her official duties. 21 CFR 1301.23(a). Such officials must follow procedures set forth in 21 CFR Part 1306 regarding prescriptions, but must also 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. The service identification number for a Public Health Service employee is his or her Social Security identification number. 21 CFR 1301.23(a).

If Federal Government practitioners wish to maintain a DEA registration for a private practice, which would include prescribing for private patients, these practitioners must obtain a registration for such private activities. 21 CFR 1301.23(c) and 21 U.S.C. 823(f).

Registration Requirements for Mid-Level Practitioners

Mid-level practitioners (MLPs) are registered and authorized by DEA and the state in which they practice to dispense, administer, and prescribe controlled substances in the course of professional practice (See Appendix B, Definitions.) Examples of MLPs include, but are not limited to, nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists, physician assistants, optometrists, ambulance services, animal shelters, euthanasia technicians, nursing homes, and homeopathic physicians. 21 CFR 1300.01(b).

MLPs may apply for an individual DEA registration granting controlled substance privileges. 21 CFR 1301.13(a). However, such registration is contingent upon the authority granted by the state in which they are licensed. 21 CFR 1300.01(b) ("*Mid-level practitioner*"). DEA may register MLPs whose states clearly authorize them to prescribe,

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dispense, and administer controlled substances in one or more schedules. 21 U.S.C. 823(f).

For electronic prescriptions written by mid-level practitioners, if required by state law, it is DEA policy that a supervisor's name and DEA number may be listed on the prescription, provided the prescription clearly indicates which is the supervisor, and which is the prescribing practitioner. 75 FR 16257 (Mar. 31, 2010).

Schedule II Controlled Substances

Schedule II controlled substances require a written prescription which must be manually 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, 1311.100(b). There is no federal time limit within which a schedule II prescription must be filled after being signed by the practitioner. However, the pharmacist must determine that the prescription is still needed by the patient, and the amount dispensed 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). Some states and many insurance carriers limit the quantity of controlled substances dispensed to a 30-day supply. Other states and pharmacies have limited the initial prescribing of opioids. Though there are no express federal limits with respect to the quantities of drugs dispensed via a prescription, to be valid, a prescription for controlled substances must only be 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 order is only permitted in an emergency situation. 21 CFR 1306.11(d). Within 7 days after authorizing an emergency oral prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist.

21 CFR 1306.11(d)(4). The prescribing individual practitioner must personally communicate the emergency oral prescription to the pharmacist. An agent may not call in an oral prescription for a schedule II controlled substance on behalf of a practitioner even in an emergency circumstance. *Role of Authorized Agents in Communicating Controlled Substance Prescriptions to Pharmacies*, 75 FR 61613, 61615 (October 6, 2010). (See Section VIII, *Emergency Dispensing*.)

Refills

The refilling of a prescription for a controlled substance listed in schedule II is prohibited. 21 U.S.C. 829(a).

Issuance of Multiple Prescriptions for Schedule II Controlled Substances

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Under 21 CFR 1306.12(b)(1), an individual 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 separate prescription must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice. 21 CFR 1306.12(b)(1)(i).
2. The individual practitioner must provide written instructions on each prescription (other than the first prescription, if the prescribing practitioner intends for that prescription to be filled immediately) indicating the earliest date on which a pharmacy may fill each prescription. 21 CFR 1306.12(b)(1)(ii).
3. The individual practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse. 21 CFR 1306.12(b)(1)(iii).
4. The issuance of multiple prescriptions is permissible under applicable state laws. 21 CFR 1306.12(b)(1)(iv).
5. The individual practitioner complies fully with all other applicable requirements under the CSA and CFR, as well as any additional requirements under state law. 21 CFR 1306.12(b)(1)(v).

It should be noted that this regulation should not be construed as encouraging individual practitioners to issue multiple prescriptions or to see their patients only once every 90 days when prescribing schedule II controlled substances. Rather, individual practitioners must determine on their own, 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 their 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 prescriber may transmit a schedule II prescription to the pharmacy by facsimile. The original schedule II prescription must be presented to the pharmacist and verified against the facsimile prior to the actual dispensing of the controlled substance. 21 CFR 1306.11(a). The pharmacist must make sure the original document is properly annotated and filed with the records that are required to be kept. 21 CFR 1306.11(a), 1304.04(h).

Exceptions for Schedule II Facsimile Prescriptions

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DEA has granted three exceptions to the facsimile prescription requirements for schedule II controlled substances. The facsimile of a schedule II prescription may serve as the original prescription as follows:

1. A practitioner 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 may transmit the prescription by facsimile. The facsimile serves as the original written prescription and no further documentation is required. All normal requirements of a legal prescription must be followed. 21 CFR 1306.11(e).
2. Practitioners prescribing schedule II controlled substances for residents of Long-Term Care Facilities may transmit, or direct their authorized agent to transmit, a prescription to the dispensing pharmacy by facsimile. The facsimile prescription serves as the original written prescription for the pharmacy. No further documentation is required. 21 CFR 1306.11(f).
3. A practitioner 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, may transmit, or direct his or her authorized agent to transmit, a prescription to the dispensing pharmacy by facsimile. The practitioner will note on the prescription that it is for a hospice patient. The facsimile serves as the original written prescription. No further documentation is required. 21 CFR 1306.11(g).

Schedules III-V Controlled Substances

A pharmacist may dispense directly a controlled substance listed in schedule III, IV, or V only pursuant to either a paper prescription signed by a practitioner, a facsimile of a signed paper prescription transmitted by the practitioner or the practitioner's agent to the pharmacy, an electronic prescription that meets DEA's requirements for such prescriptions, or a call-in prescription which is promptly reduced to writing by the pharmacist. 21 CFR 1306.21(a). (See Section VII, Oral Authorization for Schedules III-V Controlled Substances.)

Refills

Schedules III and IV controlled substances may be refilled if authorized on the prescription. However, the prescription may only be refilled up to five times within six months after the date of issue. After five refills or after six months, whichever occurs first, a new prescription is required. 21 U.S.C. 829(b) and 21 CFR 1306.22(a).

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When a prescription for any controlled substance in schedules III or IV is refilled, the following information must be entered on either the back of the prescription, another appropriate document, or an electronic prescription record: the dispensing pharmacist's initials, the date the prescription was refilled, and the amount of drug dispensed on the refill. 21 CFR 1306.22(b) and (c). If the pharmacist only initials and dates the back of the prescription, the pharmacist will be deemed to have dispensed a refill for the full face amount of the prescription. 21 CFR 1306.22(d).

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Electronic Recordkeeping of Schedules III-IV Refill Information

A pharmacy is permitted to use an electronic recordkeeping system as an alternative to the manual method for the storage and retrieval of refill information for original paper prescription orders for schedules III and IV controlled substances. 21 CFR 1306.22(f).

The electronic system must provide online retrieval of original prescription information for those prescriptions which are currently authorized for refill. The information must include, but is not limited to: the original prescription number; date of issuance; full name and address of the patient; the prescriber's name, address, and DEA registration number; the name, drug strength, dosage form and quantity of the controlled substance prescribed (and quantity dispensed if different from the quantity prescribed); and the total number of refills authorized by the prescriber. 21 CFR 1306.22(f)(1).

In addition, the electronic system must provide online retrieval of the current refill history for schedules III or IV controlled substance prescriptions. This information must include, but is not limited to: the name of the controlled substance, the date of refill, the quantity dispensed, the dispensing pharmacist's identification code or name/initials for each refill, and the total number of refills dispensed to date for that prescription. 21 CFR 1306.22(f)(2).

The pharmacist must verify and document that the refill data entered into the system is correct. 21 CFR 1306.22(f)(3). All computer generated prescription/refill documentation must be stored in a separate file at the pharmacy and must be maintained for a period of two years from the dispensing date. Under 21 CFR 1306.22(f), the pharmacy's electronic system must comply with the following guidelines:

1. If the system provides a hard copy printout of each day's controlled substance prescription refills, each pharmacist who refilled those prescriptions must verify the accuracy of the data by signing and dating the printout as he or she would sign a check or legal document. 21 CFR 1306.22(f)(3).
2. The printout must be provided to each pharmacy that uses the computer system within 72 hours of the date on which the refill was dispensed. The printout must be verified and signed by each pharmacist who dispensed the refills. 21 CFR 1306.22(f)(3).
3. In lieu of such a printout, the pharmacy must maintain a bound logbook or a separate file in which each pharmacist involved in the day's dispensing signs a statement, verifying that the refill information entered into the computer that day has been reviewed by him or her and is correct as shown. 21 CFR 1306.22(f)(3).

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4. A pharmacy's electronic system must have the capability of printing out any refill data which the pharmacy must maintain under the CSA. For example, this would include a refill-by-refill audit trail for any specified strength and dosage form of any controlled substance, by either brand or generic name or both, dispensed by the pharmacy. Such a printout must include:
- Prescribing practitioner's name
 - Patient's name and address
 - Quantity and date dispensed on each refill
 - Name or identification code of the dispensing pharmacist
 - Original prescription number

In any electronic system employed by a user pharmacy, the central recordkeeping location must be capable of providing a printout to a requesting pharmacy of the above information within 48 hours. 21 CFR 1306.22(f)(4).

5. In case a pharmacy's electronic system experiences downtime, the pharmacy must have a back-up procedure to document in writing refills of schedules III or IV controlled substances. This procedure must ensure that refills are authorized by the original prescription, that the maximum number of refills has not been exceeded, and that all required data is retained for online entry as soon as possible. 21 CFR 1306.22(f)(5).

A pharmacy may use only one of the two methods described (i.e., manual or electronic) for storage and retrieval of prescription order refill information of schedules III or IV controlled substances. 21 CFR 1306.22(g).

Facsimile Prescriptions for Schedules III-V Controlled Substances

Prescriptions for schedules III-V controlled substances may be transmitted by facsimile from the practitioner or the practitioner's agent to the dispensing pharmacy. The facsimile is considered to be equivalent to an original prescription as long as the practitioner has manually signed the prescription. 21 CFR 1306.21(a),(c).

Oral Authorization for Schedules III-V Prescriptions

A pharmacist may dispense a controlled substance listed in schedules III, IV, or V pursuant to an oral prescription made by an individual practitioner and communicated by the practitioner or their authorized agent, and promptly reduced to writing by the

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pharmacist containing all information required for a valid prescription except for the signature of the practitioner. 21 CFR 1306.03(b), 1306.21(a). (See Appendix D, Pharmacist's Guide to Prescription Fraud.)

Transfer of Schedules III-V Prescription Information

A DEA registered pharmacy may transfer original prescription information for schedules III, IV, and V controlled substances to another DEA registered pharmacy for the purpose of refill dispensing between pharmacies, on a one-time basis only. 21 CFR 1306.25. Neither the CSA nor DEA's regulations permit the transfer of any original unfilled prescription received in paper (including fax) or oral form to another pharmacy; however, after the original prescription is filled, the refills may be transferred, subject to the conditions placed on prescription transfers in 21 CFR 1306.25.

Transfers are subject to the following requirements:

Under 21 CFR 1306.25(b)(1), the transfer must be communicated directly between two licensed pharmacists and the transferring pharmacist must record the following information:

1. Write the word "VOID" on the face of the invalidated prescription; for electronic prescriptions, information that the prescription has been transferred must be added to the prescription record. 21 CFR 1306.25(b)(2)(i).
2. Record on the reverse of the invalidated prescription the name, address, and DEA registration number of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information; for electronic prescriptions, such information must be added to the prescription record. 21 CFR 1306.25(b)(2)(ii).
3. Record the date of the transfer and the name of the pharmacist transferring the information. 21 CFR 1306.25(b)(2)(iii).

Under 21 CFR 1306.25(b)(3), for paper prescriptions and prescriptions received orally and reduced to writing by the pharmacist, the pharmacist receiving the transferred prescription information must write the word "transfer" on the face of the transferred prescription and reduce to writing all information required to be on a prescription and include:

1. Date of issuance of original prescription.
2. Original number of refills authorized on original prescription.

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3. Date of original dispensing.
 4. Number of valid refills remaining and date(s) and locations of previous refill(s).
 5. Pharmacy's name, address, DEA registration number, and prescription number from which the prescription information was transferred.
 6. Name of pharmacist who transferred the prescription.
 7. Pharmacy's name, address, DEA registration number, and prescription number from which the prescription was originally filled.

Transferring Electronic Prescriptions for Controlled Substances (EPCS)

[Reserved]

Under 21 CFR 1306.25(b)(4), for electronic prescriptions being transferred electronically, the transferring pharmacist must provide the receiving pharmacist with the following information in addition to the original electronic prescription data:

1. The date of the original dispensing.
2. The number of refills remaining and the date(s) and locations of previous refills.
3. The transferring pharmacy's name, address, DEA registration number, and prescription number for each dispensing.
4. The name of the pharmacist transferring the prescription.
5. The name, address, DEA registration number, and prescription number from the pharmacy that originally filled the prescription, if different.

The pharmacist receiving a transferred electronic prescription must create an electronic record for the prescription that includes the receiving pharmacist's name and all of the information transferred with the prescription (listed above). 21 CFR 1306.25(b)(5).

The original and transferred prescription(s) must be maintained for a period of two years from the date of last refill. 21 CFR 1306.25(c).

Pharmacies electronically accessing the same prescription record must satisfy all information requirements of a manual mode for prescription transferal. 21 CFR 1306.25(d).

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The procedure allowing the transfer of prescription information for refill purposes is permissible only if allowable under existing state or other applicable law. 21 CFR 1306.25(e).

Prescription Monitoring Programs

A prescription monitoring program is a state-administered data collection system used to gather prescription information. This information may be made available to state and federal investigators on a need-to-know basis.

Many states have established an electronic prescription drug monitoring program because it has proven to be an effective tool for detecting pharmaceutical diversion and for developing pharmacist and physician medical education programs. These programs heighten awareness about diversion, prescription drug abuse, drug trends, and are useful for tracking prescription medication dispensed within a state. In some states, the data can be used by pharmacists to identify potential "doctor shoppers" and those who attempt to obtain controlled substances by fraud, forgery, or deceit.

In the states that have adopted these programs, a large part of their success has been attributed to the pharmacists' participation. DEA strongly endorses prescription monitoring programs.

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SECTION VIII - DISPENSING REQUIREMENTS

Required Information for Prescription Labels

The pharmacist dispensing a prescription for a controlled substance listed in schedules II, III, IV, or V must affix to the package a label showing date of filling, the pharmacy name and address, the serial (prescription) number, the name of the patient, the name of the prescribing practitioner, and directions for use and cautionary statements, if any, contained in such prescription as required by law. 21 CFR 1306.14(a), 1306.24(a). In addition to this information, if a prescription is filled at a central fill pharmacy, the central fill pharmacy must affix to the package a label showing the retail pharmacy name and address and a unique identifier (i.e., the central fill pharmacy's DEA registration number) indicating that the prescription was filled at the central fill pharmacy. 21 CFR 1306.14(b), 1306.24(b).

Federal Food and Drug Administration (FDA) regulations found in 21 CFR 290.5 require that the label of any drug listed as a "controlled substance" in schedules II, III, or IV of the CSA must, when dispensed to or for a patient, contain the following warning: "*CAUTION: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.*" In addition, a pharmacist who receives a prescription for a controlled substance must dispense that prescription to the patient or a member of the patient's household. 21 U.S.C. 802(10) and (27). To deliver the controlled substance to anyone other than the patient or a member of the patient's household is distributing, not dispensing. 21 U.S.C. 802(10) and (11).

Schedule II Controlled Substance Prescriptions

A pharmacist may dispense a schedule II controlled substance, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, only pursuant to a written prescription signed by the practitioner, except in an emergency situation as defined in the FDA regulations, and as described below. 21 CFR 1306.11(a).

Emergency Oral Schedule II Prescriptions

Under FDA and DEA regulations, an "emergency situation" in this context means that the prescribing practitioner has determined that immediate administration of the drug is necessary for proper treatment of the intended ultimate user, that no appropriate 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. 21 CFR 1306.11(d) and 21 CFR 290.10. In a bona fide emergency, a practitioner may telephone a schedule II prescription to the pharmacist who may then dispense the prescription. Under 21 CFR 1306.11(d), the prescribing practitioner must provide a written and signed prescription to the pharmacy within seven days and meet the below requirements:

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1. The drug prescribed and dispensed must be limited to the amount needed to treat the patient during the emergency period. Prescribing or dispensing beyond the emergency period must be pursuant to a paper or electronic prescription signed by the prescribing individual practitioner. 21 CFR 1306.11(d)(1).
2. The prescription order must be immediately reduced to writing by the pharmacist and must contain all required information, except for the prescribing practitioner's signature. 21 CFR 1306.11(d)(2).
3. If the prescribing individual practitioner is not known to the pharmacist, he or she must make a reasonable effort to determine that the oral authorization came from a registered individual practitioner, which may include a call back to the prescribing individual practitioner using his or her telephone number as listed in the telephone directory and/or other good faith efforts to insure his or her identity. 21 CFR 1306.11(d)(3).
4. Within seven days after authorizing an emergency oral prescription, the prescribing practitioner must furnish the pharmacist a written, signed prescription for the emergency quantity of the controlled substance prescribed. 21 CFR 1306.11(d)(4). The prescription must have written on its face "Authorization for Emergency Dispensing" and the date of the oral order. 21 CFR 1306.11(d)(4). The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail, it must be postmarked within the seven day period. 21 CFR 1306.11(d)(4).
5. Upon receipt, the dispensing pharmacist must attach this written prescription to the oral emergency prescription which had earlier been reduced to writing by the pharmacist. 21 CFR 1306.11(d)(4).
6. By regulation, the pharmacist must notify the local DEA Diversion Field Office (Appendix K) if the prescriber fails to provide a written prescription within seven days. 21 CFR 1306.11(d)(4). Failure of the pharmacist to do so will void the authority conferred on the pharmacy to dispense the controlled substance without a written prescription of a prescribing practitioner.
7. For electronic prescriptions, the pharmacist must annotate the record of the electronic prescription with the original authorization and date of the oral order. 21 CFR 1306.11(d)(4).

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Partial Dispensing of Schedule II Controlled Substances

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 further quantity may be supplied beyond 72 hours without a new prescription. 21 CFR 1306.13(a).

It is the position of DEA that the pharmacy must have the balance of the prescription ready for dispensing prior to the 72-hour limit, but the patient is not required to pick up the balance of the prescription within that 72-hour limit.

On July 22, 2016, the Comprehensive Addiction and Recovery Act of 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 in schedule II, if filled, shall be filled not later than 30 days after the date on which the prescription was written.

DEA views CARA's partial fill exception to be in addition to the exceptions currently listed under 21 CFR 1306.13. A pharmacist needs to check with their state to determine if its laws or regulations have been 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.

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Partial Filling of Schedule II Prescriptions for Terminally Ill or Long-Term Care Facility (LTCF) Patients

An LTCF is defined in the CFR as 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) ("*Long-Term Care Facility (LTCF)*").

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. 21 CFR 1306.13(b). 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. 21 CFR 1306.13(b). 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." 21 CFR 1306.13(b). 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. 21 CFR 1306.13(b). 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. 21 CFR 1306.13(b). The total quantity of schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed. 21 CFR 1306.13(b). 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).

Schedules III-V Controlled Substance Prescriptions

A pharmacist may dispense a controlled substance in schedules III, IV, or V having received either a paper prescription signed by a practitioner, a facsimile of that prescription transmitted by the practitioner or their agent to the pharmacy, an electronic prescription that meets DEA's requirements for such prescriptions, or an oral prescription made by an individual practitioner and communicated by the practitioner or their authorized agent. 21 CFR 1306.21(a). The pharmacist must promptly reduce the oral prescription to writing, including all required information except the signature of the prescribing practitioner. 21 CFR 1306.21(a).

Partial Dispensing Schedule III-V Controlled Substances

A pharmacist may partially dispense a prescription for schedules III-V controlled substances provided that each partial filling is recorded in the same manner as a

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refilling, the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed, and no dispensing occurs beyond six months from the date on which the prescription was issued. 21 CFR 1306.23.

Dispensing Without a Prescription

Dispensing a controlled substance without a prescription is governed by 21 CFR 1306.26. The regulation states that a controlled substance listed in schedules II, III, IV, or V which is not a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed by a pharmacist without a prescription to a purchaser at retail, provided that:

1. Such dispensing is made only by a pharmacist and not by a non-pharmacist employee even if under the supervision of a pharmacist (although after the pharmacist has fulfilled his or her professional and legal responsibilities, the actual cash, credit transaction, or delivery, may be completed by a non-pharmacist). 21 CFR 1306.26(a).
2. Not more than 240 cc. (8 ounces) of any such controlled substance containing opium, nor more than 120 cc. (4 ounces) of any other such controlled substance, nor more than 48 dosage units of any such controlled substance containing opium, nor more than 24 dosage units of any other such controlled substance, may be dispensed at retail to the same purchaser in any given 48-hour period. 21 CFR 1306.26(b).
3. The purchaser is at least 18 years of age. 21 CFR 1306.26(c).
4. The pharmacist requires every purchaser of a controlled substance not known to him to furnish suitable identification (including proof of age where appropriate). 21 CFR 1306.26(d).
5. A bound record book must be maintained in accordance with the recordkeeping requirement of 21 CFR 1304.04. (See *Section VI - Recordkeeping Requirements*.) It is maintained by the pharmacist, and contains the name and address of the purchaser, the name and quantity of the controlled substance purchased, the date of each purchase, and the name or initials of the pharmacist who dispensed the substance to the purchaser. 21 CFR 1306.26(e).
6. A prescription is not required for distribution or dispensing of the substance pursuant to any other federal, state or local law. 21 CFR 1306.26(f).

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7. Central fill pharmacies may not dispense controlled substances at the retail level to a purchaser. 21 CFR 1306.26(g).

Delivery of a Controlled Substance to Persons in Other Countries

Controlled substances that are dispensed pursuant to a legitimate prescription may not be delivered or shipped to individuals in other countries without proper authorization. 21 CFR 1312.21(a). Any such delivery or shipment is an export under the CSA and cannot be conducted unless the person sending the controlled substances:

1. Has registered with DEA as an "exporter" (or is exempt from registration). 21 U.S.C. 957(a) & (b); 21 CFR 1312.21(a), (b), 1301.13(e)(1)(ix).
2. Has obtained the necessary permit(s), or submitted the necessary declaration(s) for export. 21 CFR 1312.21(c), 1312.22(a), 1312.23(a-c), 1312.27(a) & (b).

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SECTION IX - SECURITY REQUIREMENTS

Requests for Employment Waivers for Certain Pharmacy Employees

A registrant must not employ in a position which allows 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. 21 CFR 1301.76(a) "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 Morrissette 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;

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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.

Controlled Substance Theft or Significant Loss

Under 21 CFR 1301.76(b), should a theft or significant loss of any controlled substance occur at a pharmacy, the following procedures must be implemented within one business day of the discovery of the theft or loss.

A. Notify DEA and Local Police

The theft of controlled substances from a registrant is a criminal act and a source of diversion that requires notification to DEA. A pharmacy must notify in writing the local DEA Diversion Field Office (Appendix K) 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 federal law or regulations, the registrant should also notify local law enforcement and state regulatory agencies. Prompt notification to law enforcement agencies will allow them to investigate the incident and prosecute those responsible for the diversion. If there is a question as to whether a theft has occurred or a loss is significant, a registrant should err on the side of caution and report it to DEA and local law enforcement authorities. (See below, D. Registrant's Responsibility for Identifying "Significant Loss".)

DEA must be notified directly. 21 CFR 1301.76(b). This requirement is not satisfied by reporting the theft or significant loss in any other manner. For example, a corporation which owns or operates multiple registered sites and wishes to channel all notifications through corporate management or any other internal department responsible for security must still provide notice directly to their local DEA Diversion Field Office in writing within one business day upon discovery and keep a copy of that notice for its records.

B. Complete a DEA Form 106 (Report of Theft or Loss of Controlled Substances)

The DEA Form 106 is used to document the actual circumstances of the theft or significant loss and the quantities of controlled substances involved. A pharmacy must complete a DEA Form 106 (Report of Theft or Loss of Controlled Substances) (21 CFR 1301.76(b)) which can be found online at www.DEAdiversion.usdoj.gov under the Quick Links section. A pharmacy could download a fillable pdf version from this page.

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

Drug Enforcement Administration
Diversion Control Division
Attn: Registration & Program Support Section/DRR
8701 Morrissette Drive
Springfield, VA 22152

If completing the paper version, the pharmacy should send the original DEA Form 106 to the local DEA Diversion Field Office ([Appendix K](#)) and keep a copy for its records. Please see the *Guidelines for Completing the DEA Form 106* ([Appendix I](#)) for additional guidance, or email DEA's regulatory section at DRG@dea.usdoj.gov. If the theft or loss involves listed chemicals, please see page 91 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 (pharmacy),
2. DEA registration number,
3. Date of theft or loss (or when discovered if not known),
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.

C. 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

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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).

D. Registrant's Responsibility for Identifying "Significant Loss"

Although the CSA and the regulations do not define the term "significant loss," it is the responsibility of the registrant to use his or her best judgment to take appropriate action. Whether a "significant loss" has occurred depends, in large part, on the business of the pharmacy and the likelihood of a rational explanation for a particular occurrence. What would constitute a significant loss for a pharmacy may be viewed as comparatively insignificant for a hospital or manufacturer.

Further, the loss of a small quantity of controlled substances, repeated over a period of time, may indicate a significant problem for a registrant, which must be reported. Pursuant to 21 CFR 1301.76(b), the burden of responsibility is on the registrant to identify what is a significant loss and make the required report to DEA.

When determining whether a loss is significant, a registrant should consider, among others, the following factors:

1. The actual quantity of controlled substances lost in relation to the type of business;
2. The specific controlled substances lost;
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.

If it is determined that the loss is not significant, DEA recommends that the registrant place a record of the occurrence in a theft and loss file for future reference. Miscounts

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or adjustments to inventory involving clerical errors on the part of the pharmacy should not be reported on a DEA Form 106, but rather should be noted in a separate log at the pharmacy management's discretion.

In-Transit Loss

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). Otherwise, if the purchaser does not take custody of the shipment it is the supplier's responsibility for reporting any loss of controlled substances in the original shipment.

In-Transit Loss from Central Fill Pharmacy

Central fill pharmacies must comply with 21 CFR 1301.74(e) when selecting private, common, or contract carriers to transport filled prescriptions to a retail pharmacy for delivery to an ultimate user. 21 CFR 1301.76(d). Pursuant to 21 CFR 1301.76(d), when a central fill pharmacy contracts with private, common or contract carriers to transport filled prescriptions to a retail pharmacy, the central fill pharmacy is responsible for reporting the in-transit loss upon discovery of such loss by use of a DEA Form 106. In addition, when a retail pharmacy contracts with private, common, or contract carriers to retrieve filled prescriptions from a central fill pharmacy, the retail pharmacy is responsible for reporting in-transit losses upon discovery using a DEA Form 106. 21 CFR 1301.76(d).

Breakage and Spillage

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, there are **options** for disposing of them:

1. Promptly destroy that controlled substance in accordance with 21 CFR 1317.90 using an on-site method of destruction. 21 CFR 1317.05.
2. Send those controlled substances to an entity registered with DEA to handle returns/disposals (known as a reverse distributor). 21 CFR 1317.05(a)(2).

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3. Contact the local DEA Diversion Field Office to request assistance to dispose of the controlled substances pursuant to 21 CFR 1317.05(a), 1304.21(e).

If the breakage or spillage is clearly observed, but the controlled substances are not recoverable, the registrant should document the circumstances of the event in his or her records. It is DEA's position that in order to maintain complete and accurate records in accordance with 21 CFR 1304.21(a) that non-recoverable breakage or spillage must be recorded on a DEA Form 41 and, as with any other form of disposal under 21 CFR Part 1317, should be signed by two individuals who can testify that a breakage or spillage occurred. These records must be maintained in the registrant's files and contain such information as required by 21 CFR 1304.22(c).

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 Title 18 U.S.C. 2118 for a complete text of CSRPA.) The CSRPA provides for the federal investigation of controlled substance burglaries and robberies (or attempts) if any of the following conditions are met:

1. The replacement cost of the controlled substances taken or attempted to be taken is \$500 or more.
2. Interstate or foreign commerce was involved in the execution of the crime.
3. 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 under Title 18, United States Code (18 U.S.C.).

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SECTION X - TRANSFER OR DISPOSAL OF CONTROLLED SUBSTANCES

Transfer of Controlled Substances

A pharmacy may hire an outside firm to inventory, package, and arrange for the transfer of its controlled substances to another pharmacy, the original supplier, or the original manufacturer. The pharmacy is responsible for the actual transfer of the controlled substances and for the accuracy of the inventory and records. (See *Section XII, Controlled Substance Distribution by a Pharmacy—“Five Percent Rule.”*) The records involving the transfer of controlled substances must be kept readily available by the pharmacy for two years for inspection by DEA. 21 U.S.C. 827(a) and (b), 21 CFR 1304.04(a), 1307.11(a)(1)(ii),(iii), 1305.17(c).

To transfer schedule II controlled substances, the receiving registrant must issue an official order form (DEA Form 222) or an electronic equivalent to the registrant transferring the drugs. 21 CFR 1307.11(a)(1)(iii), 1305.03. The transfer of schedules III-V controlled substances must be recorded by the distributing practitioner in accordance with 21 CFR 1304.22(c) and must be recorded by the receiving practitioner in accordance with 21 CFR 1304.22(c), 21 CFR 1307.11(a)(1)(ii). The document must include the names, addresses, and DEA registration numbers of the parties involved in the transfer of the controlled substances. 21 CFR 1304.22(c). (See *Section IV, Ordering Schedules III-V Controlled Substances.*)

Transfer to a Pharmacy

If a pharmacy goes out of business or is acquired by a new pharmacy, it may transfer the controlled substances to another pharmacy. On the day the controlled substances are transferred, a complete inventory must be taken in accordance with 21 CFR 1304.11 which documents the drug name, dosage form, drug strength, quantity, and date transferred. 21 CFR 1301.52(e)(1). In addition, DEA Form 222 or the electronic equivalent must be prepared to document the transfer of schedule II controlled substances. 21 CFR 1305.03. This inventory will serve as the final inventory for the registrant going out of business and transferring the controlled substances. It will also serve as the initial inventory for the registrant acquiring the controlled substances. A copy of the inventory must be included in the records of each pharmacy. It is not necessary to send a copy of the inventory to DEA. 21 CFR 1301.52(e)(1). The pharmacy acquiring the controlled substances must maintain all records involved in the transfer of the controlled substances for two years. 21 U.S.C. 827(b), 21 CFR 1304.04(a).

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Transfer to the Original Supplier or Original Manufacturer

Any pharmacy may transfer controlled substances to the original supplier or the original manufacturer that is appropriately registered with DEA. Pursuant to 21 CFR 1317.10, 21 CFR 1304.22(c), the pharmacist must maintain a written record showing:

1. The date of the transaction.
2. The name, strength, dosage form, and quantity of the controlled substance.
3. The supplier or manufacturer's name, address, and registration number.

The DEA Form 222 or the electronic equivalent will be the official record for the transfer of schedule II controlled substances. 21 CFR 1317.10(b).

Disposal of Controlled Substances

All controlled substances to be destroyed by a registrant, or caused to be destroyed by a registrant pursuant to 21 CFR 1317.95(c), shall be destroyed in compliance with applicable federal, state, tribal, and local laws and regulations and shall be rendered non-retrievable. 21 CFR 1317.90(a). A pharmacy registrant may dispose of its controlled substances inventory in the following manner pursuant to 21 CFR 1317.05:

1. Promptly destroy that controlled substance in accordance with 21 CFR 1317.90 and 21 CFR 1317.95 using an on-site method of destruction. 21 CFR 1317.05.
2. Promptly deliver that controlled substance to a reverse distributor's registered location by common or contract carrier pick-up or by reverse distributor pick-up at the registrant's registered location. 21 CFR 1317.05(a)(2).
3. For the purpose of return or recall, promptly deliver that controlled substance by common or contract carrier pick-up or pick-up by other registrants at the registrant's registered location to: The registered person from whom it was obtained, the registered manufacturer of the substance, or another registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf. 21 CFR 1317.05(a)(3).
4. Request assistance from the Special Agent in Charge of the Administration in the area in which the practitioner is located. 21 CFR 1317.05(a)(4).

The pharmacy should contact the local DEA Diversion Field Office (Appendix K) for an updated list of DEA registered reverse distributors. In no case should drugs be forwarded to DEA unless the registrant has received prior approval from DEA.

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Reverse Distributors Authorized to Dispose of Controlled Substances

A pharmacy may transfer controlled substances to a DEA registered reverse distributor who handles the disposal of controlled substances. 21 CFR 1317.05(a)(2). When a pharmacy transfers schedule II controlled substances to a reverse distributor for destruction, the reverse distributor must issue an official order form (DEA Form 222) or the electronic equivalent to the pharmacy. 21 CFR 1305.03, 1317.10(b). When schedules III-V controlled substances are transferred to a reverse distributor for destruction, the pharmacy must maintain a record of distribution that lists the drug name, dosage form, drug strength, quantity, and date transferred. 21 CFR 1317.10(a), 1304.22(a)(2)(iv). The DEA registered reverse distributor who destroys the controlled substances is responsible for submitting a DEA Form 41 (Registrants Inventory of Drugs Surrendered) to DEA when the controlled substances have been destroyed. 21 CFR 1304.21(e). A DEA Form 41 should not be used to record the transfer of controlled substances between the pharmacy and the reverse distributor disposing of the drugs.

An PDF version of the DEA Form 41 may be obtained online at www.DEAdiversion.usdoj.gov under the Reporting tab or by the following link: https://www.deadiversion.usdoj.gov/21cfr_reports/surrend/index.html#privacy.

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

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SECTION XI- AUTHORIZED COLLECTORS

On October 12, 2010, the President signed the "Secure and Responsible Drug Disposal Act of 2010" (the Act). This Act amended the CSA to allow authorized manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies to collect pharmaceutical controlled substances from ultimate users by voluntarily administering mail-back programs and maintaining collection receptacles. 21 U.S.C. 822(g)(1), 21 CFR 1317.30(a), 1317.40(a). In addition, the regulations allow authorized hospitals/clinics and retail pharmacies to voluntarily maintain collection receptacles at LTCFs. 21 CFR 1317.75(d)(2)(iii). Ultimate users are thus able to deliver unused pharmaceutical controlled substances to appropriate entities for disposal in a safe and effective manner consistent with effective controls against diversion.

Authorized Collectors

Authorized collectors may receive a controlled substance for the purpose of destruction from an ultimate user, a person lawfully entitled to dispose of an ultimate user decedent's property, or an LTCF on behalf of an ultimate user who resides or has resided at that facility. 21 CFR 1300.01(b) ("collector," "collection"), 1317.30(a)(1) & (b), 1301.51(b).

Retail pharmacies and hospitals/clinics with on-site pharmacies may modify their registrations to obtain authorization to be a collector. 21 CFR 1301.51(b), 1317.40(a). Once authorized, such entities are "authorized collectors." There is no fee for a modification of registration. 21 CFR 1301.51(b)-(c).

Authorization to be a collector is subject to renewal. (See Section III, *Renewal of Pharmacy Registration*). Pursuant to 21 CFR 1301.52(f), if an authorized retail pharmacy or an authorized hospital/clinic with an on-site pharmacy desires to cease activities as an authorized collector, such pharmacy shall notify DEA of its intent by submitting a written notification to the Registration Unit, Drug Enforcement Administration at:

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

Notice may also be submitted on-line at

<https://www.DEAdiversion.usdoj.gov/drugreg/index.html>.

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Authorized Collection Locations

Under 21 CFR 1317.40(b), 1317.75(d), collection by an authorized retail pharmacy or an authorized hospital/clinic with an on-site pharmacy shall only occur:

1. Inside the registered location of the authorized retail pharmacy or authorized hospital/clinic with an on-site pharmacy; and
2. At long-term care facilities at which authorized hospitals/clinics with on-site pharmacies or retail pharmacies are authorized to maintain collection receptacles.

Authorized Collection Receptacle Locations

A. Authorized Retail Pharmacy

At an authorized retail pharmacy, collection receptacles shall be securely placed and maintained inside the registered location, or at an authorized LTCF. 21 CFR 1317.75(d)(1). If placed at an authorized retail pharmacy's registered location, the collection receptacle shall be located in the immediate proximity of a designated area where controlled substances are stored and at which an employee is present (e.g., can be seen from the pharmacy counter.) 21 CFR 1317.75(d)(2).

B. Authorized Hospital/Clinic

At an authorized hospital/clinic with an on-site pharmacy, collection receptacles shall be located in an area regularly monitored by employees, and shall not be located in the proximity of any area where emergency or urgent care is provided. 21 CFR 1317.75(d)(2)(i).

C. Long-Term Care Facility

At an LTCF, a collection receptacle shall be located in a secured area regularly monitored by LTCF employees. 21 CFR 1317.75(d)(2)(iii).

In the preamble of the final rule titled *Disposal of Controlled Substances* published by DEA in the Federal Register on September 9, 2014, DEA stated that the term "regularly" has its ordinary meaning "to generally be considered as being on a routine basis or at routine intervals." 79 FR 53520, 53528 (Sept. 9, 2014).

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Authorized Collection Activities

Under 21 CFR 1317.40(c), authorized collectors with no on-site method of destruction may conduct the following activities:

1. Install, manage, and maintain collection receptacles located at their authorized collection location(s) pursuant to 21 CFR 1317.75, 1317.80. (See below.)
2. Promptly dispose of sealed inner liners and their contents as provided for in 21 CFR 1317.05(c)(2). (See Section X.)

Collection Receptacles

DEA regulations allow authorized collectors to maintain collection receptacles at their authorized collection location(s). 21 CFR 1317.40(c)(2). Thus, ultimate users are able to carry their unwanted pharmaceutical controlled substances to an authorized retail pharmacy, authorized hospital clinic with an on-site pharmacy, or other authorized collector location and deposit their unwanted or expired controlled substances in a secure container for disposal. Hospitals/clinics with on-site pharmacies and retail pharmacies that are authorized to be collectors may also maintain collection receptacles at LTCFs. 21 CFR 1317.40(b)(2).

Only those controlled substances listed in schedule II, III, IV, or V that are lawfully possessed by an ultimate user or other authorized non-registrant person may be collected. 21 CFR 1317.75(b). Controlled and non-controlled substances may be collected together and be comingled, although comingling is not required. 21 CFR 1317.75(b).

Authorized collectors shall only allow ultimate users and other authorized non-registrant persons in lawful possession of a controlled substance in schedule II, III, IV, or V to deposit such substances in a collection receptacle at a registered location. 21 CFR 1317.75(c). Authorized collectors shall not permit an ultimate user to transfer such substance to any person for any reason. 21 CFR 1317.75(c). Once a substance has been deposited into a collection receptacle, the substances shall not be counted, sorted, inventoried, or otherwise individually handled. 21 CFR 1317.75(c).

Collection Receptacle Design Specifications

Under 21 CFR 1317.75(e), a controlled substance collection receptacle shall meet the following design specifications:

1. Be securely fastened to a permanent structure so that it cannot be removed;

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2. Be a securely locked, substantially constructed container with a permanent outer container and a removable inner liner as specified in 21 CFR 1317.60 (see Inner Liner Requirements, below);
 3. The outer container shall include a small opening that allows contents to be added to the inner liner, but does not allow removal of the inner liner's contents;
 4. The outer container shall prominently display a sign indicating that only schedule II-V controlled and non-controlled substances, if a collector chooses to comingle substances, are acceptable substances (schedule I controlled substances, controlled substances that are not lawfully possessed by the ultimate user, and other illicit or dangerous substances are not permitted); and
 5. A small opening in the outer container of the collection receptacle shall be locked or made otherwise inaccessible to the public when an employee is not present (e.g., when the pharmacy is closed), or when the collection receptacle is not being regularly monitored by LTCF employees. This requirement does not apply to collection receptacles placed at narcotic treatment programs. 21 CFR 1317.75(f). However, at a narcotic treatment program, a collection receptacle shall be located in a room that does not contain any other controlled substances and is securely locked with controlled access. 21 CFR 1317.75(d)(2)(ii).
 6. The installation and removal of the inner liner of the collection receptacle shall be performed by or under the supervision of at least two employees of the authorized collector.
 7. For a collection receptacle at an LTCF: The installation, removal, transfer, and storage of inner liners shall be performed either: By or under the supervision of one employee of the authorized collector and one supervisor-level employee of the LTCF (e.g., a charge nurse or supervisor) designated by the authorized collector; or, by or under the supervision of two employees of the authorized collector. 21 CFR 1317.80(c).

Inner Liner Requirements

Under 21 CFR 1317.60(a)-(c), an inner liner shall meet the following requirements:

1. The inner liner shall be waterproof, tamper-evident, and tear-resistant;
2. The inner liner shall be removable and sealable immediately upon removal without emptying or touching the contents;
3. The contents of the inner liner shall not be viewable from the outside when sealed;

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4. The size of the inner liner shall be clearly marked on the outside of the liner (e.g., 5-gallon, 10-gallon, etc.); and
5. The inner liner shall bear a permanent, unique identification number that enables the inner liner to be tracked.
6. Access to the inner liner shall be restricted to employees of the collector.
7. The inner liner shall be sealed by two employees immediately upon removal from the permanent outer container and the sealed inner liner shall not be opened, x-rayed, analyzed, or otherwise penetrated.

Inner Liner Recordkeeping

Pursuant to 21 CFR 1304.22(f)(2), each authorized hospital/clinic with an on-site pharmacy and each authorized retail pharmacy shall maintain the following records with regards to collection receptacle inner liners:

1. Date each unused inner liner is acquired, unique identification number and size (e.g., 5-gallon, 10-gallon, etc.) of each unused inner liner acquired.
2. Date each inner liner is installed, the address of the location where each inner liner is installed, the unique identification number and size (e.g., 5-gallon, 10-gallon, etc.) of each installed inner liner, the registration number of the collector, and the names and signatures of the two employees that witnessed each installation.
3. Date each inner liner is removed and sealed, the address of the location from which each inner liner is removed, the unique identification number and size (e.g., 5-gallon, 10-gallon, etc.) of each inner liner removed, the registration number of the collector, and the names and signatures of the two employees that witnessed each removal.
4. Date each sealed inner liner is transferred to storage, the unique identification number and size (e.g., 5-gallon, 10-gallon, etc.) of each sealed inner liner stored, and the names and signatures of the two employees that transferred each sealed inner liner to storage.
5. Date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each sealed inner liner was transferred, the unique identification number and the size (e.g., 5-gallon, 10-gallon, etc.) of each sealed inner liner transferred, and the names and

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signatures of the two employees that transferred each sealed inner liner to the reverse distributor or distributor.

Collection Receptacles at Long-Term Care Facilities

An LTCF may dispose of controlled substances in schedules II, III, IV, and V on behalf of an ultimate user who resides, or has resided, at such LTCF by transferring those controlled substances into an authorized collection receptacle located at that LTCF. 21 CFR 1317.80(a). When disposing of such controlled substances by transferring those substances into a collection receptacle, such disposal shall occur immediately, but no longer than three business days after the discontinuation of use by the ultimate user. Discontinuation of use includes a permanent discontinuation of use as directed by the prescriber, as a result of the resident's transfer from the LTCF, or as a result of death. 21 CFR 1317.80(a).

Only authorized retail pharmacies and authorized hospitals/clinics with an on-site pharmacy may install, manage, and maintain collection receptacles at LTCFs and remove, seal, transfer, and store, or supervise the removal, sealing, transfer, and storage of sealed inner liners at LTCFs. 21 CFR 1317.80(b). Such authorized retail pharmacies and authorized hospitals/clinics shall comply with all of the requirements of 21 CFR 1317.60, 1317.75, 1317.80, 21 CFR 1317.80(b).

The installation, removal, transfer, and storage of inner liners shall be performed either: By or under the supervision of one employee of the authorized retail pharmacy or authorized hospital/clinic with an on-site pharmacy, and one supervisor-level employee of the LTCF (e.g., a charge nurse or supervisor) designated by the authorized collector; or, by or under the supervision of two employees of the authorized collector. 21 CFR 1317.80(c).

Upon removal, sealed inner liners may only be stored at the LTCF for up to three business days in a securely locked, substantially constructed cabinet or a securely locked room with controlled access until transfer in accordance with 21 CFR 1317.05(c)(2)(iv), 21 CFR 1317.80(d).

Neither an authorized hospital/clinic with an on-site pharmacy nor an authorized retail pharmacy shall operate a collection receptacle at an LTCF until its registration has been modified in accordance with 21 CFR 1301.51, 21 CFR 1317.80(e).

Mail-Back Packages

A hospital/clinic with an on-site pharmacy or a retail pharmacy can partner with an authorized reverse distributor who conducts a mail-back program by providing empty mail-back packages to patients. 21 CFR 1317.70(c). This does not require modification of a DEA registration, and there are no recordkeeping requirements.

SECTION XII - OTHER PHARMACY OPERATIONS

Central Fill Pharmacy

A “central fill pharmacy” (See Appendix B, Definitions) fills prescriptions for controlled substances on behalf of retail pharmacies with which it has a contractual agreement to provide such services or with pharmacies who share a common owner. When one retail pharmacy receives a prescription and a second pharmacy prepares and subsequently delivers the controlled substance medication to the first retail pharmacy for dispensing to the patient, the second pharmacy is engaging in a “central fill” activity. 21 CFR 1300.01(b). Records must be maintained by both the central fill pharmacy and the retail pharmacy that completely reflect the disposition of all controlled substance prescriptions dispensed. 21 CFR 1306.15, 1306.27. Central fill pharmacies are required to comply with the same security and recordkeeping requirements applicable to retail pharmacies including the general requirement to maintain effective controls and procedures to guard against theft and diversion of controlled substances. 21 CFR 1301.71(a), 1301.75-76, 1304.04(h), and 21 U.S.C. 827(b). Retail pharmacies that also perform central fill activities are allowed to do so without a separate DEA registration. 21 CFR 1301.13(e)(1)(iv)(table).

Central fill pharmacies are permitted to prepare both initial and refill prescriptions, subject to all applicable state and federal regulations. Only a licensed pharmacist may fill the prescription. 21 CFR 1306.06. Both the retail and central fill pharmacists have a corresponding responsibility to ensure that the prescription was issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice and otherwise in the manner specified by DEA regulations. 21 CFR 1306.04(a).

Prescription information may be provided to an authorized central fill pharmacy by a retail pharmacy for dispensing purposes. 21 CFR 1306.15, 1306.27. Prescriptions for controlled substances listed in schedules II, III, IV, or V may be transmitted electronically from a retail pharmacy to a central fill pharmacy including via facsimile. 21 CFR 1306.15(a), 1306.27(a). For electronic prescriptions, the name, address, and the DEA registration number of the central fill pharmacy to which the prescription has been transmitted, the name of the retail pharmacy pharmacist transmitting the prescription, and the date of transmittal must be added to the electronic prescription record. 21 CFR 1306.15(a)(1), 1306.27(a)(1).

Under 21 CFR 1306.15(a), 1306.27(a), the retail pharmacy transmitting the prescription information must:

1. Write the words “CENTRAL FILL” on the face of the original prescription and record the name, address, and DEA registration number of the central fill pharmacy to which the prescription has been transmitted and the name

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of the retail pharmacy pharmacist transmitting the prescription, and the date of transmittal;

2. Ensure that all information required to be on a prescription is transmitted to the central fill pharmacy (either on the face of the prescription or in the electronic transmission of information);
3. Maintain the original prescription for a period of two years from the date the prescription was last filled (for schedule II prescriptions) or refilled (for schedules III-V prescriptions);
4. Keep a record of receipt of the filled prescription, including the date of receipt, the method of delivery (private, common, or contract carrier) and the name of the retail pharmacy employee accepting delivery;
5. For schedules III-V prescriptions, indicate in the information transmitted the number of refills already dispensed and the number of refills remaining (refills for schedule II prescriptions are not permitted).

Under 21 CFR 1306.15(b) and 1306.27(b), the central fill pharmacy receiving the transmitted prescription must:

1. Keep a copy of the prescription (if sent via facsimile) or an electronic record of all the information transmitted by the retail pharmacy, including the name, address, and the DEA registration number of the retail pharmacy transmitting the prescription;
2. Keep a record of the date of receipt of the transmitted prescription, the name of the licensed pharmacist filling the prescription, and dates of filling or refilling of the prescription; and
3. Keep a record of the date the filled prescription was delivered to the retail pharmacy and the method of delivery (i.e., private, common, or contract carrier).

Central fill pharmacies must affix to the package a label showing the date of filling, the serial number of the prescription, the name of the patient, the name of the prescribing practitioner, the retail pharmacy name and address, and a unique identifier (i.e., the central fill pharmacy's DEA registration number) indicating that the prescription was filled at the central fill pharmacy and directions for use and cautionary statements, if any, contained in such prescription or required by law. 21 CFR 1306.14(a),(b), 1306.24(a),(b). Central fill pharmacies must comply with the provisions of 21 CFR 1301.74(e) when selecting private, common, or contract carriers to transport filled prescriptions to a retail pharmacy (and likewise for retail pharmacies retrieving filled

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prescriptions from a central fill pharmacy) for delivery to the ultimate user 21 CFR 1301.76(d).

The requirement under 21 CFR 1306.27, to write "CENTRAL FILL" applies to the retail pharmacy transmitting prescription information to a central fill pharmacy; DEA regulations do not require that a central fill pharmacy write "CENTRAL FILL" on the prescriptions that it fills or refills.

Long-Term Care Facilities

An LTCF is defined in the CFR as 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) ("*Long-Term Care Facility (LTCF)*"). In most cases, these facilities are not registered with DEA, yet these health care facilities routinely maintain controlled substances issued via prescription to their residents. These controlled substances are already outside the CSA's closed drug distribution system since they have been dispensed to the ultimate user.

LTCFs frequently need to dispose of unused medications due to a change in the resident's medication or the resident's death. Accordingly, LTCFs should contact the local DEA Diversion Field Office (Appendix K) for drug disposal instructions. DEA is aware of issues currently facing LTCFs concerning the dispensing and handling of controlled substances, which are affected by a variety of state laws and circumstances. Pharmacists should check with their state agency for guidelines concerning controlled substances at LTCFs.

Regulations concerning LTCFs can also be found under:

1. Section VII, *Exceptions for Schedule II Facsimile Prescriptions*
2. Section VIII, *Partial Filling of Schedule II Prescriptions for Terminally Ill or Long-Term Care Facility Patients*
3. Section XI, *Collection Receptacles at Long-Term Care Facilities*

Use of Automated Dispensing Systems by Retail Pharmacies at Long-Term Care Facilities

Automated dispensing system means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, counting, labeling, and dispensing of medications, and which collects, controls, and maintains all transaction information. 21 CFR 1300.01(b) ("*Automated dispensing system*").

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If state law and regulations permit, DEA will allow a retail pharmacy to register at the site of the LTCF and store controlled substances in an Automated Dispensing System (ADS) as outlined in 21 CFR 1301.27. In an ADS, a pharmacy stores bulk drugs in the machine in separate bins or containers. The pharmacy programs and controls the ADS remotely. Authorized LTCF staff are allowed access to its contents, which are dispensed on a single-dose basis at the time of administration pursuant to a valid prescription. The ADS electronically records each dispensing, thus maintaining dispensing records for the pharmacy. Because the drugs are not considered dispensed until the system provides them, drugs in the ADS are counted as pharmacy stock. 21 CFR 1300.01(b) ("*Inventory*"). A registered retail pharmacy that possesses additional registrations for ADS machines at LTCFs may keep most records required for those additional registered sites at the retail pharmacy or other approved central location. 21 CFR 1304.04(a)(2) and 21 CFR 1304.04(b)(1).

DEA registered pharmacies wishing to operate an ADS at an LTCF must contact the DEA Office of Diversion Control, Registration Section, at 1-800-882-9539 for registration instructions. An affidavit which meets the requirement of 21 CFR 1301.17(c) must also be submitted with DEA. 21 CFR 1301.27(a).

Emergency Kits for Long-Term Care Facilities

DEA has issued a policy statement which provides individual state licensing and regulatory boards with general guidelines for establishing specific rules concerning controlled substances used in emergency kits at LTCFs. 45 FR 24128 (Apr. 9, 1980) (See Appendix H, *Guidelines for Emergency Kits in Long-Term Care Facilities*.)

All emergency kits (whether or not they are electronic) remain subject to the policy statement in Appendix H, provided they satisfy the criteria of that policy statement at all times. 45 FR 24128 (Apr. 9, 1980). Among other things, it is crucial to bear in mind that an emergency kit is for use in emergencies as defined by the state. It also bears emphasis that, in accordance with the CSA and DEA regulations, a controlled substance may only be dispensed for emergency purposes (or otherwise) pursuant to a valid prescription or medical order. 21 U.S.C. 841(a)(1), 21 CFR 1306.04(a), 21 CFR 1300.01(b) ("*prescriptions*"). Thus, where the kit is maintained at the LTCF by a pharmacy, controlled substances may not be dispensed from the kit for emergencies prior to receipt by the pharmacist of a valid prescription in accordance with the requirements of 21 CFR 1306.11, 1306.21. As these sections of the regulations indicate, such prescriptions may, depending on the circumstances, be issued in writing (paper or electronic in accordance with Part 1311), orally, or by fax. In addition, 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 his professional practice, and the pharmacist bears a corresponding responsibility therefor. 21 CFR 1306.04(a). If, at any time, a kit is used to administer or dispense controlled substances for a purpose other

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than in emergencies as defined by the state, the kit thereafter ceases to be an emergency kit and, as a result, the separate registration requirement applies.

Opioid (Narcotic) Addiction Treatment Programs

The Narcotic Addict Treatment Act of 1974, the Drug Addiction Treatment Act (DATA) of 2000, the Comprehensive Addiction and Recovery Act of 2016 (CARA) and the SUPPORT for Patients and Communities Act of 2018 amended the CSA with respect to the use of controlled substances in the medical treatment of opioid addiction. These laws established the procedures for 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 dispense FDA approved schedule II controlled substances (e.g., methadone) for maintenance and detoxification treatment must obtain a separate DEA registration as a Narcotic Treatment Program via a DEA Form 363 which may be completed online. 21 U.S.C. 823(f),(g)(1), and 21 CFR 1306.07(a)(1). In addition to obtaining this separate DEA registration, this type of activity also requires the approval and certification by 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).

Qualifying Practitioners

NOTE: For the purposes of this manual, the term “Qualifying Practitioner” will replace the terms “Qualifying Physician” and “DATA-Waived Physician,” and will not include Qualifying Other Practitioners. Also, the term “Qualifying Other Practitioner” will be used for nurse practitioners and physician assistants, and until October 1, 2023, or until this sunset provision in the 2018 SUPPORT for Patients and Communities Act is removed by law, clinical nurse specialists, certified registered nurse anesthetists, or certified nurse midwives.

A “Qualifying Practitioner” is a practitioner who is licensed under state law; who is registered with DEA under 21 U.S.C. 823(f) to dispense controlled substances as defined under 21 U.S.C. 802(10); and, who is qualified by specified training and/or certification. 21 U.S.C. 823(g)(2)(G)(ii),(iii) and 21 CFR 1301.28(b)(1)(i). In order to obtain a waiver from the requirement of obtaining a separate registration as a Narcotic Treatment Program under 21 U.S.C 823(g)(1), a practitioner must be capable of providing directly, by referral, or in such other manner as determined by the Secretary of HHS, appropriate counseling and other appropriate ancillary services. 21 U.S.C. 823(g)(2)(B)(ii) and 21 CFR 1301.28(b)(1)(ii).

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If a practitioner wishes to become a Qualifying Practitioner, the practitioner must submit notification to the Secretary of HHS stating the individual's intent to prescribe or dispense schedules III, IV, or V narcotic controlled drugs or combinations of narcotic controlled drugs approved by the FDA for maintenance or addiction treatment (i.e., buprenorphine or buprenorphine combination products). 21 CFR 1301.28(b)(1). The notice must contain all of the certification required in 21 CFR 1301.28(b)(1)(i). After receiving the notification submitted under 21 CFR 1301.28(b)(1), the Secretary of HHS will forward a copy of the notification to the Administrator of DEA. 21 CFR 1301.28(d)(1).

Upon notification from SAMHSA that the individual practitioner has been issued a written waiver, qualifies under DATA, and has the appropriate DEA registration, DEA will issue a UIN as well as a new DEA Form 223 bearing their DEA registration number, a UIN, a corresponding business activity, and their authorized patient limit. 21 U.S.C. 823(g)(2)(D)(ii). Pursuant to 21 CFR 1301.28(d)(3), the practitioner is required to include the UIN on all prescriptions when prescribing FDA approved schedules III, IV, or V narcotic controlled drugs for use in maintenance or detoxification treatment. 21 CFR 1306.05(b). The listing of the UIN on a prescription is in addition to all other information required on a valid prescription to include the practitioner's DEA registration number (See Section VII, Valid Prescription Requirements.)

Qualifying Other Practitioners

Under federal law, the term "Qualifying Other Practitioner" means a nurse practitioner, physician assistant, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant who satisfies each of the following criteria:

(1) "is licensed under state law to prescribe schedule III, IV, or V medications for the treatment of pain"; (2) "has completed not fewer than 24 hours of initial training addressing each of the topics listed in" 21 U.S.C. 823(g)(2)(G)(ii)(IV), "or has such other training or experience as the Secretary of HHS determines will demonstrate the ability of the nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant to treat and manage opiate-dependent patients"; and (3) "[t]he nurse practitioner, clinical nurse specialist, certified nurse anesthetist, certified nurse midwife, or physician assistant is supervised by, or works in collaboration with, a qualifying physician, or physician assistant is supervised by, or works in collaboration with, a qualifying physician, if the nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant is required by State law to prescribe medications for the treatment of opioid use disorder in collaboration with or under the supervision of a physician."
21 U.S.C. 823(g)(2)(G)(iv).

The Secretary may, by regulation, revise the requirements for being a Qualifying Other Practitioner. A nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant who meets the requirements

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can now be authorized to prescribe FDA-approved schedule III-V narcotic controlled substances for maintenance and detoxification treatment. 21 U.S.C. 823(g)(2)(A)-(B), (G)(iii)-(iv).

Prescriptions for Maintenance and Detoxification Treatment

A Qualifying Practitioner or Qualifying Other Practitioner needs one DEA registration and a Unique Identification Number (UIN) to prescribe FDA approved schedule III-V narcotics within a state for the purpose of treating opioid addiction. 21 CFR 1301.28(a). The prescription must be issued by the individual practitioner for a legitimate medical purpose in the usual course of their professional practice and be compliant with all associated federal and state laws and regulations. 21 CFR 1306.04(a).

If a Qualifying Practitioner or Qualifying Other Practitioner is practicing at multiple locations within the same state and is only prescribing FDA-approved schedule III-V narcotic controlled drugs for maintenance and detoxification treatment, then they must affix to the prescription the DEA registration number that they has been assigned in that jurisdiction along with the UIN. 21 CFR 1306.05(a) and (b). As mentioned previously, a Qualifying Other Practitioner may be required by state law to be supervised by, or work in collaboration with, a Qualifying Practitioner. 21 U.S.C. 823(g)(2)(G)(iv)(III).

If a Qualifying Practitioner is practicing at multiple locations within the same state and is administering or dispensing FDA-approved schedule III-V narcotic controlled drugs for maintenance or detoxification treatment, then they must affix to the prescription, and on all records when dispensing, the DEA registration number that is assigned to that specific registered location in that state along with the UIN. 21 CFR 1301.28(d)(3), 1301.12(a) & (b)(3), 1306.05(a)-(b).

If a Qualifying Practitioner is prescribing FDA-approved schedule III-V narcotic controlled drugs for maintenance and detoxification treatment in multiple states, then he or she must affix to the prescription the DEA registration number that is assigned to that specific registered location in that state along with the UIN. 21 CFR 1306.05(a)-(b), 1301.12(a), 1301.28(d)(3).

The UIN must be used in each jurisdiction where the Qualifying Practitioner or Qualifying Other Practitioner is registered with DEA, and is administering or dispensing FDA-approved schedule III-V narcotic controlled drugs for maintenance or detoxification treatment. 21 CFR 1301.28(d)(3).

Delivery of a Controlled Substance by a Pharmacy to an Administering Practitioner

The SUPPORT for Patients and Communities Act of 2018 (the SUPPORT Act) amended the CSA to allow a pharmacy to deliver a controlled substance to a practitioner in accordance with a prescription that meets the requirements of 21 U.S.C.

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829 and 21 CFR Part 1306 for the purpose of administering the controlled substance by the practitioner if:

1. The controlled substance is delivered by the pharmacy to the prescribing practitioner or the practitioner administering the controlled substance, as applicable, at the location listed on the practitioner's certificate of registration; 21 U.S.C. 829a(a)(1);
2. The controlled substance is to be administered for the purpose of maintenance or detoxification treatment under 21 U.S.C. 823(g)(2) and
 - a. The practitioner who issued the prescription is a "Qualifying Practitioner" or "Qualifying Other Practitioner" per 21 U.S.C. 823(g)(2)(G); and
 - b. The controlled substance is to be administered by injection or implantation; 21 U.S.C. 829a(a)(2);
3. The pharmacy and the practitioner are authorized to conduct the activities specified in this section under the law of the state in which such activities take place; 21 U.S.C. 829a(a)(3);
4. The prescription is not issued to supply any practitioner with a stock of controlled substances for the purpose of general dispensing to patients; 21 U.S.C. 829a(a)(4);
5. The controlled substance is to be administered only to the patient named on the prescription not later than **14 days*** after the date of receipt of the controlled substance by the practitioner; 21 U.S.C. 829a(a)(5); and
6. Notwithstanding any exceptions under 21 U.S.C. 827, the prescribing practitioner, and the practitioner administering the controlled substance, as applicable, maintain complete and accurate records of all controlled substances delivered, received, administered, or otherwise disposed of under this section, including the persons to whom controlled substances were delivered and such other information as may be required by the CSA and DEA regulations (i.e., 21 CFR Part 1304). 21 U.S.C. 829a(a)(6).

***NOTE:** During a 2-year period which began on the date of enactment of the SUPPORT Act, October 24, 2018, the Attorney General, in coordination with the Secretary for Health and Human Services, may reduce the number of days described in "5" above, if the Attorney General determines that such reduction will reduce the risk of diversion or protect the public health. Any such modification shall be for a period not less than 7 days.

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Prescribing Buprenorphine for Pain

Neither the CSA nor its implementing regulations expressly prohibit the prescribing and dispensing of buprenorphine or other opiate products for the treatment of pain. Federal regulations do require that controlled substances be prescribed for a legitimate medical purpose by a DEA registered practitioner acting in the usual course of his or her professional practice. 21 CFR 1306.04(a). If a DEA registered practitioner issues a prescription for a buprenorphine drug product approved by the FDA for the treatment of pain, or off-label prescribes a buprenorphine drug product approved by the Food and Drug Administration (FDA) for maintenance or detoxification treatment for the treatment of pain, then the UIN or "X" Number is not required. Please note that the specific prescribing or dispensing of certain buprenorphine products for pain may be considered "off-label" use. DEA cannot address any possible consequences under the Food, Drug, and Cosmetic Act (FD&C) for dispensing for unapproved (off-label) uses.

Dispensing Controlled Substances for the Treatment of Pain

On September 6, 2006, DEA published in the Federal Register a Policy Statement, *Dispensing Controlled Substances for the Treatment of Pain*. 71 FR 52716 (Sept. 6, 2006). The purpose of the Policy Statement was to make clear the longstanding requirement under the law that physicians may prescribe controlled substances only for a legitimate medical purpose in the usual course of professional practice. 21 CFR 1306.04. In no way should this interfere with the legitimate practice of medicine or cause any physician to be reluctant to provide legitimate pain treatment. The second purpose of the Policy Statement was for DEA to dispel the mistaken notion among a small number of medical professionals that the agency has embarked on a campaign to "target" physicians who prescribe controlled substances for the treatment of pain or that physicians must curb their legitimate prescribing of pain medications to avoid legal liability.

To achieve these aims, the document summarized the relevant legal principles and provided an explanation of DEA's role with respect to the regulation of controlled substances. The document also addressed specific issues and questions that have been raised on a recurring basis by physicians who seek guidance on the subject of dispensing controlled substances for the treatment of pain.

For additional guidance on the responsibilities of the pharmacist where it pertains to the treatment of pain. (See Section VII, *Corresponding Responsibility*.)

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Compounding and Other Manufacturing Activities Involving Controlled Substances

The term “manufacture” means the production, preparation, propagation, compounding, or processing of a drug or other substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of such substance or labeling or relabeling of its container; except that such term does not include the preparation, compounding, packaging, or labeling of a drug or other substance in conformity with applicable state or local law by a practitioner as an incident to his administration or dispensing of such drug or substance in the course of his professional practice. The term “manufacturer” means a person who manufactures a drug or other substance. 21 U.S.C. 802(15).

Controlled Substance Distribution by a Pharmacy - “Five Percent Rule”

Pursuant to 21 CFR 1307.11(a), a pharmacy registered to dispense controlled substances may distribute such substances (without being registered as a distributor) to another pharmacy or to a registered practitioner for the purpose of general dispensing by the practitioner to patients, provided that the following conditions are met:

1. The pharmacy or practitioner that will receive the controlled substance is registered under the CSA to dispense that controlled substance;
2. The distribution is recorded by the distributing practitioner in accordance with 21 CFR 1304.22(c) and the receipt is recorded by the receiving practitioner in accordance with 21 CFR 1304.22(c);
3. If the pharmacy distributes a schedule II controlled substance in response to an official order form (DEA Form 222) submitted by a practitioner in accordance with 21 CFR 1305.12, it must document the transfer on an official order form (DEA Form 222) or the electronic equivalent. The distributing pharmacy must retain the original copy (if using single sheet DEA Form 222), or Copy 1 (if using the triplicate DEA Form 222). Any supplier who is not required to report acquisition/disposition transactions to the Automation of Reports and Consolidated Orders System (ARCOS) under 1304.33(c) (such as a practitioner) must make and submit a copy of the original DEA Form 222 to DEA, either by mail to the Registration Section, or by email to DEA.Orderforms@usdoj.gov. For instructions on completing this form, see Section IV, Ordering Controlled Substances. In addition, pharmacies must have a system to identify any suspicious orders, which when identified must be reported online to SORS.
4. “Five Percent Rule” - The total number of dosage units of all controlled substances distributed by a pharmacy may not exceed five percent of the total number of dosage units of all controlled substances dispensed by the pharmacy

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during a calendar year. If at any time during the calendar year the total number of dosage units of controlled substances distributed exceed five percent of the total number of dosage units of controlled substances distributed and dispensed, the pharmacy is required to register as a distributor.

United States Postal Service Mailing Requirements for Controlled Substances

United States Postal Services issued guidance permitting the mailing of controlled substances by drug manufacturers or their agents, pharmacies, or other authorized handlers when distribution is lawful under DEA regulations and if the mailer or the addressee meets one of the following conditions:

1. The mailer or the addressee is registered with DEA.
2. The mailer or the addressee is exempt from DEA registration as permissible by law.

United States Postal Service issued guidance permitting the mailing of any controlled substance, provided it is not outwardly dangerous and will not cause injury to a person's life or health, and if the following preparation and packaging standards are met:

1. The inner packaging of any parcel containing controlled substances is marked and sealed as required by the provisions of the CSA and its implementing regulations, and is placed in a plain outer container or securely wrapped in plain paper.
2. If the controlled substance consists of a prescription medicine, the inner container is also labeled to show the name and address of the pharmacy, practitioner, or other person dispensing the prescription.
3. The outside wrapper or packaging is free of markings that would indicate the nature of the contents.

For additional guidance on this issue please see the United States Postal Service's Publication 52, *Hazardous, Restricted, and Perishable Mail*, 453 Controlled Substances and Drugs.

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Patients Bringing Medications from Home to the Hospital

DEA is aware that many pharmacies operate in a hospital setting.

If a patient is admitted to a hospital via ambulance/emergency medical services (EMS), and there is no family present, and the patient has in his or her possession dispensed medications, including controlled substances, it is DEA's position that:

1. If the treating practitioner deems that it is medically appropriate for the patient to continue to take any controlled substance medications brought from the patient's residence to the DEA registered hospital, the hospital could secure the controlled substances with the patient's effects in his or her hospital room (e.g., small safe or secured lock box). Thus, the hospital has not taken possession of the controlled substances and it would not be considered an unlawful distribution by the ultimate user under 21 U.S.C. 841(a).
2. If the treating practitioner deems that it would be medically inappropriate for the patient to continue taking any controlled substance medication(s) brought from the patient's residence to the DEA registered hospital, or it is the hospital's policy not to permit patients to bring already dispensed controlled medications into the hospital, then the hospital has the following options:
 - a. If a member of the patient's household arrives at the hospital, the hospital can turn over the patient's medications, including controlled substances, to him or her. The member of the patient's household can take the controlled medications back to the household and/or dispose of them in a manner that is in accordance with federal, state, local and tribal laws and regulations.
 - b. If a hospital has modified its DEA registration to become an authorized collector and has placed a collection receptacle at its registered location, then a member of the patient's household may dispose of the patient's medications, including controlled substances, in the hospital's collection receptacle.
 - c. If a hospital has empty mail-back packages (no modification of the hospital's DEA registration is required), then the hospital may provide one or more of the mail-back packages to a member of the patient's household to place the medications, including controlled substances, into the mail-back package(s) and seal the package(s) for mailing to the authorized DEA registered reverse distributor for disposal purposes.
 - d. If there is no member of the patient's household present, " DEA understands that there may be circumstances where there is no authorized person to dispose of the controlled substances, such as when controlled substances are

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abandoned ... and return to the ultimate user is not feasible. In such instances, the affected entities should contact local law enforcement or their local DEA Diversion Field Office for guidance on proper disposal procedures." 79 FR 53546.

- e. If your state has passed a law or regulation authorizing a hospital to dispose of controlled substances that have been dispensed to a patient admitted to the hospital and are considered abandoned (e.g., the patient left the controlled substance medications and they cannot be returned; or the patient is deceased and the state has authorized that the hospital can dispose of the decedent's personal property to include controlled substance medications), then a hospital may dispose of the abandoned controlled substance medications in accordance with federal, state, local, tribal laws and regulations.

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SECTION XIII - COMBAT METHAMPHETAMINE EPIDEMIC ACT OF 2005

Summary of the Act's Major Provisions

On March 2006, the President signed the *Combat Methamphetamine Epidemic Act of 2005* (CMEA). As a result of this law, DEA issued an Interim Final Rule in the Federal Register on September 26, 2006, which outlined the retail provisions of the CMEA. 71 FR 56008 (Sept. 26, 2006).

The CMEA includes requirements that regulated sellers must follow for retail sales of over-the-counter products containing the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine (PPA), which can be used to manufacture methamphetamine illegally. The CMEA defined "*regulated seller*" to mean a retail distributor (including a pharmacy and mobile retail vendors) and "*at retail*" to mean sale or purchase for personal use. 21 U.S.C. 802(46) and (48), 21 CFR 1300.02(b) ("*regulated seller*" and "*at retail*").

Scheduled Listed Chemical Products

The CMEA created a new category of products called "scheduled listed chemical products" (SLCPs). It includes any product that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act as a non-prescription drug, and that contains ephedrine, pseudoephedrine, or phenylpropanolamine (PPA) (including salts, optical isomers, and salts of optical isomers). 21 U.S.C. 802(45), 21 CFR 1300.02. This applies to non-prescription drug products only, not prescription drug products. Retail sales of SLCPs are excluded from the definition of a "regulated transaction" and from the registration requirement under 21 U.S.C. 823, but are subject to a separate system of retail sales controls under 21 U.S.C. 830, 21 U.S.C. 802(39)(A)(v).

Other requirements of the CMEA include:

1. Requirement of regulated sellers to place the products behind the counter or in locked cabinets. 21 CFR 1314.25(b).
2. Requirement of regulated sellers to check the identity of purchasers and maintain a log of each sale that includes the purchaser's name and address, signature of the purchaser, product sold, quantity sold, date, and time. 21 CFR 1314.30(a), (b).
3. Requirement of regulated sellers to maintain the logbook for at least two years. 21 CFR 1314.30(e).

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4. Requirement of regulated sellers to train employees in the requirements of the law and certify to DEA that the training has occurred. 21 CFR 1314.35(a).
 5. Places a quantity limit of each of the chemicals that may be sold to an individual in a day to 3.6 grams of the chemical (base) without regard to the number of transactions. 21 CFR 1314.20(a).
 6. For non-liquids, product packaging is limited to blister packs containing no more than 2 dosage units per blister. Where blister packs are not technically feasible, the product must be packaged in unit dose packets or pouches. 21 CFR 1314.05.
 7. For individuals, purchases in a 30-day period are limited to 9 grams, of which not more than 7.5 grams may be imported by means of a private or commercial carrier or the U.S. Postal Service. 21 U.S.C. 844(a).

While many states have enacted their own legislation regarding the regulation of these products, federal law also requires regulated sellers to complete a self-certification process with DEA that includes training their employees on the new regulations and procedures. 21 U.S.C. 830(e)(1)(B). The self-certification process must be completed online at www.DEAdiversion.usdoj.gov. 21 CFR 1314.35, 1314.40. If state law differs from federal law regarding the regulation of these products, retail outlets are to adhere to the stricter provisions of both. 21 CFR 1307.02.

Copies of the Interim Final Rule are available at www.DEAdiversion.usdoj.gov (click on the *Combat Methamphetamine Epidemic Act of 2005*, then *Interim Final Rule - Retail Sales of Scheduled Listed Chemical Products*). 71 FR 56008 (Sept. 26, 2006). Details on specific provisions of the CMEA that may impact a pharmacy that engages in retail sales of SLCPs are outlined below.

Recordkeeping Requirements

Under 21 CFR 1314.30(a), regulated sellers are required to maintain a written (bound logbook) or electronic list of sales that identifies the transactions with the following information:

1. The name of the purchaser;
2. The address of the purchaser;
3. The date and time of the sale;
4. The name and amount of product sold.

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The logbook requirement does not apply to any purchase by an individual of a single sales package that contains not more than 60 milligrams of pseudoephedrine. 21 CFR 1314.30(a).

Concurrently, purchasers, under 21 CFR 1314.30(b)(1) and (2), are required to:

1. Present a photo identification issued by a state or the Federal Government, or other forms of identification deemed acceptable under 8 CFR 274a.2(b)(1)(v)(A)-(B). (See Proof of Identity Requirements below for a complete list of acceptable forms of identification.)
2. Sign a *written* logbook pursuant to 21 CFR 1314.30(b)(2)(i), and enter his or her name, address, date, and time of sale.

OR

3. Sign an *electronic* logbook pursuant to 21 CFR 1314.30(b)(2)(ii).

Once identification of the purchaser is presented to the seller, the seller, under 21 CFR 1314.30(b)(2)(ii)(C)-(3), 1314.30(c)(1) and (2), is required to:

1. Determine that the name in the logbook corresponds to the name on the identification and that the date and time are correct.
2. Enter into the logbook the name of the product and the quantity sold.

The logbook must include a notice to purchasers that entering false statements or misrepresentations in the logbook may subject purchasers to criminal penalties under 18 U.S.C.1001. 21 CFR 1314.30(d). Sellers must maintain each entry in the logbook for not fewer than two years after the date on which the entry is made. 21 CFR 1314.30(e).

Loss or Theft of Scheduled Listed Chemical Products

A report should be made orally to the local DEA Diversion Field Office (Appendix K) in the area where the pharmacy is located at the earliest practicable opportunity after becoming aware of the circumstances involved. 21 CFR 1314.15(b). Per 21 CFR 1314.15(c), a written report of losses must be filed within 15 days after the pharmacist becomes aware of the loss or theft. A written report should include the DEA registration number (if applicable), name, business address, date of loss, type of loss, and a description of the circumstances of the loss (e.g., in-transit, theft from premises). 21 CFR 1314.15(e). The written report must be filed using a DEA Form 107 (Report of Theft or Loss of Listed Chemicals). DEA amended 21 CFR 1310.05 to require reports of unusual or excessive loss or disappearance of a listed chemical to be filed through the

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DEA Diversion control Division secure network application. Data will be entered through a secure connection to the online application system. If you have questions regarding the electronic submission, please call the DEA Call Center at 1-800-882-9539.

Proof of Identity Requirements

The CMEA requires an individual to present an unexpired identification card that includes a photograph and is issued by a state or the Federal Government or a document considered acceptable under 8 CFR 274a.2(b)(1)(v)(A) and (B). Those documents currently include the following:

1. United States passport;
2. Alien Registration Receipt Card or Permanent Resident Card, Form I-551;
3. A foreign passport that contains a temporary I-551 stamp, or temporary I-551 printed notation on a machine-readable immigrant visa;
4. An Employment Authorization Document which contains a photograph (Form I-766);
5. In the case of an individual who is employment-authorized incident to status or parole with a specific employer, a foreign passport with an Arrival/Departure Record, Form I-94 (as defined in 8 CFR 1.4), or Form I-94A, bearing the same name as the passport and containing an endorsement by DHS indicating such employment-authorized status or parole, as long as the period of endorsement has not yet expired and the employment is not in conflict with the individual's employment-authorized status or parole;
6. A passport from the Federated States of Micronesia (FSM) or the Republic of the Marshall Islands (RMI) with Form I-94 or Form I-94A indicating non-immigrant admission under the Compact of Free Association Between the United States and the FSM or RMI;
7. In the case of an individual lawfully enlisted for military service in the Armed Forces under 10 U.S.C. 504, a military identification card issued to such individual may be accepted only by the Armed Forces.

For individuals 16 years of age or older:

1. A driver's license or identification card containing a photograph, issued by a state or an outlying possession of the United States. If the driver's license or identification card does not contain a photograph, identifying information shall

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be included such as: name, date of birth, sex, height, color of eyes, and address;

2. School identification card with a photograph;
3. Voter's registration card;
4. U.S. military card or draft record;
5. Identification card issued by federal, state, or local government agencies or entities. If the identification card does not contain a photograph, identifying information shall be included such as: name, date of birth, sex, height, color of eyes, and address;
6. Military dependent's identification card;
7. Native American tribal documents;
8. United States Coast Guard Merchant Mariner Card;
9. Driver's license issued by a Canadian government authority.

For individuals under age 18 who are unable to produce a document from the list above, the following documents are acceptable to establish identity:

1. School record or report card;
2. Clinic doctor or hospital record;
3. Daycare or nursery school record.

NOTE: The list of acceptable forms of identification, as cited in the CMEA, may change ("in effect on or after the date of enactment"). DEA has no discretion to alter the list.

Product Placement

SLCPs must be stored behind the counter or, if in an area where the public has access, in a locked cabinet. 21 U.S.C. 830(e)(1)(A). Although DEA does not include cabinet specifications in the rule, a locked cabinet should be substantial enough that it cannot be easily picked up and removed. In a store setting, the cabinet should be similar to those used to store items, such as cigarettes, that can be accessed only by sales staff. 21 CFR 1314.25(b).

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Self-Certification

As part of the requirements of CMEA, an annual self-certification is required for all regulated sellers of SLCPs. 21 CFR 1314.40(b). A regulated seller must not sell SLCPs unless it has self-certified with DEA. 21 CFR 1314.40(a). In self-certifying, the regulated seller is confirming:

1. The employees who will be engaged in the sale of SLCPs have undergone training regarding provisions of CMEA. 21 U.S.C. 830(e)(1)(A)(vii).
2. Records of the training are maintained. 21 U.S.C. 830(e)(1)(A)(viii).
3. Sales to individuals do not exceed 3.6 grams of ephedrine, pseudoephedrine, or phenylpropanolamine per day. 21 U.S.C. 830(d)(1).
4. Non-liquid forms are packaged as required. 21 U.S.C. 830(d)(2).
5. SLCPs are stored behind the counter or in a locked cabinet. 21 U.S.C. 830(e)(1)(A)(i).
6. A written or electronic logbook containing the required information on sales of these products is properly maintained. 21 U.S.C. 830(e)(1)(A)(iii)-(iv).
7. The logbook information will be disclosed only to federal, state, or local law enforcement and only to ensure compliance with Title 21 of the United States Code or to facilitate a product recall. 21 U.S.C. 830(c).

Regulated sellers of SLCPs self-certify through DEA's Diversion website at www.DEAdiversion.usdoj.gov. Self-certification can be accomplished on any computer (e.g., at the store, at home, at the library, or at any other location).

A certificate will be generated by DEA upon receipt of the self-certification application. The regulated seller may print this certificate, or if the regulated seller is unable to print it, DEA will print and mail the certificate to the regulated seller. Chain stores wishing to file self-certifications for more than 10 locations should print or copy the form electronically and submit the information to DEA by mail. DEA will work with these persons to facilitate this process. Persons interested in this self-certification option should contact DEA for assistance at 1-800-882-9539. For current DEA registrants, the system will pre-populate the form with basic information if the registrant enters his or her DEA registration number in the field provided.

The regulated seller must self-certify to DEA as described above on an **annual basis**. 21 CFR 1314.40(b). It is the responsibility of the regulated seller to ensure that all employees have been trained prior to self-certifying each time. 21 CFR 1314.35(a).

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It is the regulated seller's responsibility to annually renew before the certificate expires if the regulated seller intends to continue selling SLCPs at retail. 21 CFR 1314.40(b). The certificate contains a self-certification number in the upper right corner. The expiration date of the certificate is listed under the self-certification number. Regulated sellers may verify the expiration date of their certificate at www.DEAdiversion.usdoj.gov.

The self-certification requirement is subject to the provisions of 18 U.S.C. 1001. A regulated seller who knowingly or willfully certifies to facts that are not true is subject to fines and imprisonment.

Required Training

Training materials designed by DEA may be used, although a regulated seller may include information in addition to that provided by DEA. DEA training materials may be found at www.DEAdiversion.usdoj.gov.

Training Records

Each employee of a regulated seller who is responsible for delivering SLCPs to purchasers or who deals directly with purchasers by obtaining payment for the SLCPs must undergo training. The regulated seller must maintain a copy of all records demonstrating that such employees have undergone training. 21 CFR 1314.35(a) & (b).

Self-Certification Fee

On December 29, 2008, DEA published a Final Rule in the Federal Register entitled *Combat Methamphetamine Epidemic Act of 2005: Fee for Self-Certification for Regulated Sellers of Scheduled Listed Chemical Products*. 73 FR 79318. (Dec. 29, 2008). The rule established a self-certification fee for regulated sellers of SLCPs that are not DEA pharmacy registrants. 21 CFR 1314.42.

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SECTION XIV - Ryan Haight Online Pharmacy Consumer Protection Act of 2008

Summary of the Ryan Haight Act's Major Provisions

On October 15, 2008, the President signed into law the *Ryan Haight Online Pharmacy Consumer Protection Act of 2008*, often referred to as the *Ryan Haight Act*. This law amends the CSA by adding a series of new regulatory requirements and criminal provisions designed to combat the proliferation of "rogue Internet sites" that unlawfully dispense controlled substances by means of the Internet. The *Ryan Haight Act* applies to all controlled substances in all schedules.

This law became effective April 13, 2009. As of that date, it is illegal under federal law to deliver, distribute, or dispense a controlled substance by means of the Internet unless the online pharmacy holds a modification of DEA registration authorizing it to operate as an online pharmacy. 21 U.S.C. 822(b), 823(f), and 21 CFR 1306.09(b). Thus, a pharmacy which knowingly or intentionally dispenses a controlled substance by means of the Internet that does not have a modification of the DEA registration allowing such activity is in violation of 21 U.S.C. 841(h)(1) and subject to potential criminal prosecution and (in the case of DEA registrants) loss of DEA registration. 21 U.S.C. 841(h)(1) & (2)(A).

Definition of an Online Pharmacy

An online pharmacy is a person, entity, or Internet site, whether in the United States or abroad, that knowingly or intentionally delivers, distributes, or dispenses, or offers or attempts to deliver, distribute, or dispense, a controlled substance by means of the Internet. 21 U.S.C. 802(52)(A) and (B), 21 CFR 1300.04(h). Examples of an online pharmacy may include (but are not limited to) the following:

1. Any website that sells, or offers to sell, any controlled substance or a prescription therefor to a person in the United States.
2. Any person who operates such a website.
3. Any person who pays a practitioner to issue prescriptions for controlled substances for customers of such a website.
4. Any person who pays a pharmacy to fill prescriptions for controlled substances that were issued to customers of such a website.
5. Any pharmacy that knowingly or intentionally fills prescriptions for controlled substances that were issued to customers of such a website.

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6. Any person who sends an e-mail that:
 - a. Offers to sell a controlled substance or a prescription for a controlled substance in a manner not authorized by the Act;
 - b. Directs buyers to a website operating in violation of the Act;
 - c. Or otherwise causes or facilitates the delivery, distribution, or dispensing of a controlled substance in a manner not authorized by the Act.

Online Pharmacy Registration Exemptions

The following are exempt from the Ryan Haight Act's definition of an "online pharmacy" so long as their activities are limited solely to the exemptions provided:

1. Manufacturers or distributors registered under 21 U.S.C. 823(a),(b),(d), or (e) who do not dispense controlled substances to non-registrants. 21 U.S.C. 802(52)(B)(i) and 21 CFR 1300.04(h)(1).
2. Non-pharmacy practitioners who are registered under 21 U.S.C. 823(f) and whose activities are authorized by that registration, provided that any website operated by such non-pharmacy practitioners complies with 21 CFR 1304.50, which requires the website to post in a visible and clear manner on its homepage, or on a page directly linked thereto in which the hyperlink is also visible and clear on the homepage, a list of the DEA registered non-pharmacy practitioners who are affiliated with the website. 21 U.S.C. 802(52)(B)(ii) and 21 CFR 1300.04(h)(2).
3. Any hospital or other medical facility registered under 21 U.S.C. 823(f) that is operated by an agency of the United States (including the Armed Forces). 21 U.S.C. 802(52)(B)(iii) and 21 CFR 1300.04(h)(3).
4. A health care facility owned or operated by an Indian tribe or tribal organization carrying out a contract or compact under the Indian Self-Determination and Education Assistance Act. 21 U.S.C. 802(52)(B)(iv) and 21 CFR 1300.04(h)(4).
5. Any agent or employee of any hospital or facility that is operated by an agency of the United States, provided that hospital or other facility is registered under 21 U.S.C. 823(f), and any agent or employee of any hospital or facility owned or operated by an Indian tribe or tribal organization carrying out a contract or compact under the Indian Self-Determination and Education Assistance Act, provided such agent or employee is lawfully acting in the

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usual course of business or employment, and within the scope of the official duties of such agent or employee, with such hospital or facility, and, with respect to agents or employees of such health care facilities only to the extent such individuals are furnishing services pursuant to those contracts or compacts. 21 U.S.C. 802(52)(B)(v) and 21 CFR 1300.04(h)(5).

6. Mere advertisements that do not attempt to facilitate an actual transaction involving a controlled substance. 21 U.S.C. 802(52)(B)(vi) and 21 CFR 1300.04(h)(6).
7. A person, entity, or Internet site that is not in the United States and does not facilitate the delivery, distribution, or dispensing of a controlled substance by means of the Internet to any person in the United States. 21 U.S.C. 802(52)(B)(vii) and 21 CFR 1300.04(h)(7).
8. A pharmacy registered under 21 U.S.C. 823(f) whose dispensing of controlled substances via the Internet consists solely of “refilling prescriptions for controlled substances in schedule III, IV, or V,” as that term is defined in 21 U.S.C. 802(55) and 21 CFR 1300.04(k). (This definition is set forth at the end of Section XIV). 21 U.S.C. 802(52)(B)(viii)(I). 21 CFR 1300.04(h)(8)(i).
9. A pharmacy registered under 21 U.S.C. 823(f) whose dispensing of controlled substances via the Internet consists solely of “filling new prescriptions for controlled substances in schedule III, IV, or V,” as that term is defined in 21 CFR 1300.04(d). (This definition is set forth at the end of Section XIV.) 21 U.S.C. 802(52)(B)(viii)(II) and 21 CFR 1300.04(h)(8)(ii).
10. Any registered pharmacy whose delivery, distribution, or dispensing of controlled substances by means of the Internet consists solely of filling prescriptions that were electronically prescribed in a manner authorized by the CSA, and if, in view of all of its activities other than those referred to in this paragraph, it would fall outside the definition of online pharmacy. 21 U.S.C. 802(52)(B)(ix) and 21 CFR 1300.04(h)(9).
11. Any registered pharmacy whose delivery, distribution, or dispensing of controlled substances by means of the Internet consists solely of the transmission of prescription information between a pharmacy and an automated dispensing system located in an LTCF when the registration of the automated dispensing system is held by that pharmacy as described in 21 CFR 1301.17, 1301.27 and the pharmacy is otherwise complying with DEA regulations. 21 U.S.C. 802(52) and 21 CFR 300.04(h)(10).

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Notification Requirements

Thirty days prior to offering a controlled substance for sale, delivery, distribution, or dispensing by means of the Internet, the online pharmacy must notify DEA and the state boards of pharmacy in any states in which the online pharmacy offers to sell, deliver, distribute, or dispense controlled substances. 21 CFR 1304.40(a)(1). Completion of the *Application for Modification of Registration for Online Pharmacies* serves as the notification requirement to DEA.

The online pharmacy must make a separate thirty-day advance notice to the state boards of pharmacy in each state in which it intends to offer to sell, deliver, distribute, or dispense controlled substances. Online pharmacies that apply for the modification of registration are required to certify that the applicable state boards of pharmacy have been notified. 21 CFR 1304.40(a)(2).

How to Register as an Online Pharmacy

To operate legally as an online pharmacy, the online pharmacy must first be registered with DEA as a pharmacy under 21 CFR 1301.13. Once registered with DEA as a pharmacy, the pharmacy may apply for a modification of registration to operate as an online pharmacy. 21 CFR 1301.19. To apply for a modification of registration, complete the *Application for Modification of Registration for Online Pharmacies* online at:

<https://apps.DEAdiversion.usdoj.gov/webforms/jsp/regapps/ipharms/ipharmsLogin.jsp>

There is no fee to apply to modify a DEA registration to an online pharmacy. 21 CFR 1301.51(c).

If the modification of registration is approved, the pharmacy will be issued a modified DEA Certificate of Registration with the new business activity listed as online pharmacy. 21 CFR 1301.51(c). The registrant will keep the same DEA registration number. A pharmacy may perform the activities of a retail pharmacy and an online pharmacy at the same time.

State Licensure Requirements

An online pharmacy must comply with the requirements of all applicable state laws concerning the licensure of pharmacies in each state from which it, and in each state to which it delivers, distributes, or dispenses, or offers to deliver, distribute, or dispense, controlled substances by means of the Internet. 21 U.S.C. 831(b) and 21 CFR 1301.19(b). In addition, online pharmacies must certify they are in compliance with these requirements when completing the *Application for Modification of Registration for Online Pharmacies*. 21 CFR 1304.40(a).

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The requirement that an online pharmacy list the states in which it is licensed to dispense controlled substances is designed to ensure that an online pharmacy only dispenses controlled substances to patients in states in which it is authorized to practice pharmacy. (See 21 CFR 1304.45(b)(4)). Dispensing beyond the scope of state licensure is one of the recurring transgressions of some rogue online pharmacies and generally violates state law. A state may bring civil action in federal court to enjoin any violation of the Ryan Haight Act—not merely those violations of state law—and to obtain other appropriate legal or equitable relief. 21 U.S.C. 882(c).

Online Pharmacy Website Requirements

When a pharmacy applies for a modification of registration to become an online pharmacy, it must display on its homepage a declaration that it has done so. Under 21 CFR 1304.40(d), this declaration must state the following:

“In accordance with the Controlled Substances Act and the DEA regulations, this online pharmacy has made the notifications to the DEA Administrator required by 21 U.S.C. 831 and 21 CFR 1304.40.”

Once approved to operate as an online pharmacy, the online pharmacy must display at all times on the homepage of its Internet site a declaration of compliance with the requirements of 21 U.S.C. 831 with respect to the delivery or sale or offer for sale of controlled substances. 21 CFR 1304.45(a). This statement must include the name of the pharmacy as it appears on the DEA Certificate of Registration. 21 CFR 1304.45(a).

An online pharmacy is required to post Internet Pharmacy Site Disclosure Information on the homepage of each Internet site it operates. 21 U.S.C 831(c) and 21 CFR 1304.45(b). Pursuant to 21 U.S.C. 831(c)(1-7) and 21 CFR 1304.45(b)(1-7), it must be posted in a visible and clear manner and contain the following information:

1. The name and address of the pharmacy as it appears on the pharmacy's DEA Certificate of Registration.
2. The pharmacy's telephone number and e-mail address.
3. Name of pharmacist-in-charge, professional degree, states of licensure, and telephone number.
4. List of state(s) in which the pharmacy is licensed to dispense controlled substances.
5. Certification that the pharmacy is registered to deliver, distribute, or dispense controlled substances by means of the Internet.

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6. The name, address, telephone number, professional degree, and states of licensure of any practitioner who has a contractual relationship to provide medical evaluations or issue prescriptions for controlled substances, through referrals from the website or at the request of the owner or operator of the website, or any employee or agent thereof.
7. The following statement must be visible on the website:

“This online pharmacy is obligated to comply fully with the Controlled Substances Act and DEA regulations. As part of this obligation, this online pharmacy has obtained a modified DEA registration authorizing it to operate as an online pharmacy. In addition, this online pharmacy will only dispense a controlled substance to a person who has a valid prescription issued for a legitimate medical purpose based upon a medical relationship with a prescribing practitioner. This includes at least one prior in-person medical evaluation in accordance with section 309 of the Controlled Substances Act (21 U.S.C. 829), or a medical evaluation via telemedicine in accordance with section 102(54) of the Controlled Substances Act (21 U.S.C. 802(54)).”

If at any time an online pharmacy should change its Internet site web address, the online pharmacy must notify DEA at least thirty days in advance of this change. 21 CFR 1304.40(b)(3).

Reporting Requirements

Each online pharmacy must submit a monthly report to DEA of the total quantity of each controlled substance that the online pharmacy has dispensed the previous calendar month. 21 CFR 1304.55(a). The report is required for every month in which the total amount of dispensing of controlled substances by the pharmacy is either (i) 100 or more prescriptions filled or (ii) 5,000 or more dosage units dispensed of all controlled substances combined. 21 CFR 1304.55(a). Should an online pharmacy's total quantity of dispensed controlled substances fall below both of the thresholds listed above, a report is still required that indicates a negative response for that given month. 21 CFR 1304.55(b).

The report must include the total amount of such dispensing by any means including all controlled substances dispensed via Internet transactions, mail-order transactions, face-to-face transactions, or any other means. It is not required that the online pharmacy identify the means of the dispensing in its report. 21 CFR 1304.55(a). Reporting shall be by National Drug Code (NDC) numbers. 21 CFR 1304.55(f). Report the total number of dosage units dispensed for each NDC number. 21 CFR 1304.55(f).

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This report is due on or before the 15th day of the following month. 21 CFR 1304.55(e). For example, an online pharmacy would submit its report for the month of January no later than February 15th. Reports must be submitted electronically via online reporting, electronic upload, or other means as approved by DEA. 21 CFR 1304.55(d). All reports must be kept for at least two years and be readily retrievable for inspection. 21 CFR 1304.55(g).

The reporting requirements apply to every pharmacy that, at any time during a calendar month, holds a modified registration authorizing it to operate as an online pharmacy, regardless of whether it dispenses any controlled substances by means of the Internet during the month. 21 CFR 1304.55(c).

Prescription Requirements

In order for a prescription to be valid, it must be issued for a legitimate medical purpose in the usual course of professional practice by a practitioner who has conducted at least one in-person medical evaluation of the patient or by a covering practitioner. 21 U.S.C. 829(e)(2)(A), and 21 CFR 1300.04(l)(1). An in-person medical evaluation is 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) and 21 CFR 1300.04(f).

Definition of Prescription Terms

A pharmacy website is exempted from the Ryan Haight Act's definition of an "online pharmacy" if its Internet-facilitated activity relating to controlled substances is limited to filling new and/or refilling prescriptions for controlled substances in schedules III, IV, or V. 21 U.S.C. 802(52)(B)(viii). If the pharmacy is so exempted from the definition of an "online pharmacy," it is not required under the Act to obtain a modification of its DEA registration authorizing it to operate as an online pharmacy. 21 U.S.C. 802(52)(B)(viii). Thus, it is important to understand precisely the definitions of the following terms.

Filling New Prescriptions for Controlled Substances in Schedules III-V

As stated in 21 U.S.C. 802(56) and 21 CFR 1300.04(d), the term "filling new prescriptions for controlled substances in schedule III, IV, or V" means filling a prescription for an individual for a controlled substance in schedule III, IV, or V, if:

1. The pharmacy dispensing that prescription has previously dispensed to the patient a controlled substance other than by means of the Internet and pursuant to the valid prescription of a practitioner that meets the applicable requirements of subsections (b) and (c) of section 309 of the Act (21 U.S.C. 829) and 21 CFR 1306.21, 1306.22 (for purposes of this definition, such a prescription shall be referred to as the "original prescription");

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2. The pharmacy contacts the practitioner who issued the original prescription at the request of that individual to determine whether the practitioner will authorize the issuance of a new prescription for that individual for the controlled substance described in paragraph (1) above (i.e., the same controlled substance as described in paragraph (1)); and
3. The practitioner, acting in the usual course of professional practice, determines there is a legitimate medical purpose for the issuance of the new prescription.

Refilling Prescriptions for Controlled Substances in Schedules III-V

As stated in 21 U.S.C. 802(55) and 21 CFR 1300.04(k), the term “refilling prescriptions for controlled substances in schedule III, IV, or V”:

1. Means the dispensing of a controlled substance in schedule III, IV, or V in accordance with refill instructions issued by a practitioner as part of a valid prescription that meets the requirements of 21 U.S.C. 829 and 21 CFR 1306.21, 1306.22, as appropriate; and
2. Does not include the issuance of a new prescription to an individual for a controlled substance that individual was previously prescribed.

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APPENDIX A

This summary is provided as a quick reference to the provisions of the Controlled Substances Act. It is not intended to replace any statutory or regulatory requirement thereof. For complete guidance as to the provisions of each area indicated below, please check the appropriate section of this Pharmacist's Manual.

Summary of Controlled Substances Act Requirements

	Schedule II	Schedules III & IV	Schedule V
<i>Registration</i>	Required	Required	Required
<i>Receiving Records</i>	DEA Form 222	Invoices, readily retrievable	Invoices, readily retrievable
<i>Prescriptions</i>	Written ¹ prescriptions (oral prescriptions only allowed in emergency situations) ²	Written, oral, or fax	Written, oral, or fax
<i>Refills</i>	No	No more than 5 within 6 months	As authorized when prescription is issued or if renewed by a practitioner
<i>Maintenance of Prescriptions</i> ³	Separate file	Separate file or readily retrievable	Separate file or readily retrievable
<i>Distribution Between Registrants</i>	DEA Form 222	Invoices	Invoices
<i>Security</i>	Locked cabinet or dispersed among non-controlled pharmaceuticals	Locked cabinet or dispersed among non-controlled pharmaceuticals	Locked cabinet or dispersed among non-controlled pharmaceuticals
<i>Theft or Significant Loss</i>	Report to DEA and complete DEA Form 106	Report to DEA and complete DEA Form 106	Report to DEA and complete DEA Form 106

NOTE: **All records** must be maintained for 2 years, unless state law requires a longer period. 21 U.S.C. 827(b).

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¹ Written prescriptions include paper prescriptions and electronic prescriptions that meet DEA's requirements for such prescriptions.

² Emergency oral prescriptions are allowable under schedule II and require a signed follow-up prescription within seven days. 21 CFR 1306.11(d)(4).

Exceptions: A facsimile prescription for a schedule II controlled substance serves as the original prescription when issued to a resident of an LTCF. 21 CFR 1306.11(f). A facsimile prescription for a schedule II narcotic substance serves as the original prescription when issued to hospice patients, or patients with a diagnosed terminal illness, or for direct administration by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion. 21 CFR 1306.11(e), (f) and (g).

³ The record of dispensing can also be a bound record book, if the controlled substance is not a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act. 21 CFR 1306.26(e).

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APPENDIX B

Definitions Based on the Controlled Substances Act
and the Code of Federal Regulations

The following definitions may be found in 21 CFR Part 1300 and/or 21 U.S.C. Parts 802 and 823.

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.

Collector

A hospital/clinic with an on-site pharmacy, or retail pharmacy that is authorized under the CSA and DEA regulations to receive a controlled substance for the purpose of destruction from an ultimate user, a person lawfully entitled to dispose of an ultimate user decedent's property, or an LTCF on behalf of an ultimate user who resides or has resided at that facility.

Central Fill Pharmacy

A pharmacy which is permitted by the state in which it is located to prepare controlled substance orders for dispensing pursuant to a valid prescription transmitted to it by a registered retail pharmacy and to return the labeled and filled prescriptions to the retail pharmacy for delivery to the ultimate user. Such central fill pharmacy shall be deemed "authorized" to fill prescriptions on behalf of a retail pharmacy only if the retail pharmacy and central fill pharmacy have a contractual relationship providing for such activities or share a common owner.

Chemicals

Please see the definitions for List I Chemical, Retail Distributor, and Scheduled Listed Chemical Product.

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.

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.

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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.

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.

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).

List I Chemical

A chemical specifically designated by the DEA Administrator in 21 CFR 1310.02(a) that, in addition to legitimate uses, is used in manufacturing a controlled substance in violation of the Controlled Substances Act and is important to the manufacture of a controlled substance.

Long-Term Care Facility

A nursing home, retirement care, mental care, or other facility or institution that provides extended health care to resident patients.

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 he or she practices, to dispense a controlled substance in the course of professional practice. Examples of MLPs include, but are not limited to, nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists, and physician assistants who are authorized to dispense controlled substances by the state in which they practice. Because this authority varies greatly by state, check with the state licensing authority to determine which MLP disciplines are authorized to dispense controlled substances in a particular state or visit www.DEAdiversion.usdoj.gov. (Click on *Registration Support*, then *Resources*, then *Mid-level Practitioners Authorization by State*.)

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Online Pharmacy

An online pharmacy is a person, entity, or Internet site, whether in the United States or abroad, that knowingly or intentionally delivers, distributes, or dispenses, or offers or attempts to deliver, distribute, or dispense, a controlled substance by means of the Internet.

On-Site

Located on or at the physical premises of the registrant's registered location.

Pharmacist

Any pharmacist licensed by a state to dispense controlled substances, and shall include any other person (e.g., pharmacist intern) authorized by a state to dispense controlled substances under the supervision of a pharmacist licensed by such state.

Practitioner

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 they 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.

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).

Qualifying Practitioner

A physician who is licensed under state law, who is registered with DEA to dispense controlled substances, and who is qualified through at least 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.

Qualifying Other Practitioner

A nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant who satisfies each of the following: (1) "is licensed under state law to prescribe schedule III, IV, or V medications for the treatment of pain"; (2) "has completed not fewer than 24 hours of initial training addressing each of the topics listed in [21 U.S.C. 823(g)(2)(G)(ii)(IV)] ... or has such other training or experience as the Secretary of HHS determines will demonstrate the ability of the nurse practitioner or physician assistant to treat and manage opiate-dependent patients"; and (3) "[t]he nurse practitioner or physician assistant is supervised by, or works in collaboration with, a qualifying physician, if the nurse practitioner or physician assistant

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is required by state law to prescribe medications for the treatment of opioid use disorder in collaboration with or under the supervision of a physician.”

Readily Retrievable

Certain records which 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 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.

Regulated Seller

A retail distributor (including a pharmacy or a mobile retail vendor), except that the term does not include an employee or agent of the distributor.

Retail Distributor

A grocery store, general merchandise store, drug store, or other entity or person whose activities as a distributor relating to drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine are limited almost exclusively to sales for personal use, both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales.

Reverse Distributor

A registrant who receives controlled substances acquired 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 where necessary, processing such substances or arranging for processing such substances for disposal.

Scheduled Listed Chemical Product (SLCP)

A product that contains ephedrine, pseudoephedrine, or phenylpropanolamine which may be marketed or distributed lawfully in the United States under the Federal, Food, Drug, and Cosmetic Act as a non-prescription drug. Ephedrine, pseudoephedrine, and phenylpropanolamine include their salts, optical isomers, and salts of optical isomers.

Ultimate User

A person who has lawfully obtained, and who possesses, a controlled substance for his or her own use or for the use of a member of his or her household or for an animal owned by him or her or by a member of his or her household.

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APPENDIX C

Definitions of Abbreviations

CARA.....	Comprehensive Addiction and Recovery Act of 2016
CFR.....	Code of Federal Regulations
CMEA.....	Combat Methamphetamine Epidemic Act of 2005
CSA.....	Controlled Substances Act
CSAT.....	Center for Substance Abuse Treatment
CSOS.....	Controlled Substance Ordering System
CSRPA.....	Controlled Substance Registrant Protection Act of 1984
DATA.....	Drug Addiction Treatment Act of 2000
DEA.....	Drug Enforcement Administration
FDA.....	Food and Drug Administration
HHS.....	Department of Health and Human Services
LTCF.....	Long-Term Care Facility
NATA.....	Narcotic Addiction Treatment Act of 1974
SAMHSA.....	Substance Abuse and Mental Health Services Administration
UIN.....	Unique Identification Number
U.S.....	United States
U.S.C.....	United States Code

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APPENDIX D

Pharmacist's Guide to Prescription Fraud and Identifying Out of Scope Prescriptions

The purpose of this guide is to ensure that controlled substances continue to be available for legitimate medical and scientific purposes while preventing diversion into the illicit market. It is not the intent of this publication to discourage or prohibit the use of controlled substances where medically indicated. However, nothing in this guide should be construed as authorizing or permitting any person to conduct any act that is not authorized or permitted under federal or state laws.

Pharmacist's Responsibilities

The abuse of prescription drugs—especially controlled substances—is a serious social and health problem in the United States today. As healthcare professionals, pharmacists share responsibility for preventing prescription drug abuse and diversion.

1. Pharmacists have a personal responsibility to protect their practice from becoming an easy target for drug diversion. They need to know of the potential situations where drug diversion can occur, and establish safeguards to prevent drug diversion.
2. The dispensing pharmacist must maintain constant vigilance against forged or altered prescriptions. 21 CFR 1301.71(a) 1306.04(a). The CSA holds the pharmacist responsible for knowingly dispensing a prescription that was not issued in the usual course of professional treatment. 21 CFR 1306.04(a).

Types of Fraudulent Prescriptions

Pharmacists should be aware of the various kinds of forged prescriptions that may be presented for dispensing. Some patients, in an effort to obtain additional amounts of legitimately prescribed drugs, alter the practitioner's prescription. They may have prescription pads printed using a legitimate doctor's name, but with a different call back number that is answered by an accomplice to verify the prescription. Drug seeking individuals may also call in their own prescriptions and give their own telephone number as a call-back for confirmation. Drug abusers sometimes steal legitimate prescription pads from practitioner's offices and/or hospitals and prescriptions are written using fictitious patient names and addresses.

In addition, individuals may go to emergency rooms complaining of pain in the hopes of receiving a controlled substance prescription. The prescription can then be altered or copied to be used again. Computers are often used to create prescriptions for non-existent doctors or to copy legitimate doctors' prescriptions. The quantity of drugs prescribed and frequency of prescriptions filled are not lone indications of fraud or

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improper prescribing, especially if a patient is being treated with opioids for pain management. Pharmacists should also recognize that drug tolerance and physical dependence may develop as a consequence of a patient's sustained use of opioid analgesics for the legitimate treatment of chronic pain.

Identifying Out of Scope Prescriptions

The following criteria may indicate that a prescription was not issued for a legitimate medical purpose:

- The prescriber writes significantly more prescriptions (or in larger quantities) compared to other practitioners in the same specialty in the area.
- The patient appears to be returning too frequently. A prescription which should last for a month in legitimate use is being refilled on a biweekly, weekly, or even a daily basis.
- The prescriber writes prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time. Drug abusers often request prescriptions for "uppers and downers" at the same time.
- The patient presents prescriptions written in the names of other people.
- A number of people appear simultaneously, or within a short time, all bearing similar prescriptions from the same physician.
- People who are not regular patrons or residents of the community show up with prescriptions from the same physician.

Identifying Fraudulent Prescriptions

The following criteria may indicate a forged prescription:

- Prescription looks "too good." The prescriber's handwriting is too legible.
- Quantities, directions, or dosages differ from usual medical usage.
- Prescription does not comply with the acceptable standard abbreviations or appears to be textbook presentations.
- Prescription appears to be photocopied.
- Directions are written in full with no abbreviations.

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- Prescription is written in different color inks or written in different handwriting.

Prevention Techniques:

- Know the prescriber and his or her signature.
- Know the prescriber's DEA registration number.
- Know the prescriber's authorized agents and request a copy of any written agreement between prescriber and their agent.
- Know the patient.
- Check the date on the prescription order to determine if it has been presented in a reasonable length of time since being issued by the prescriber.

When there is a question about any aspect of the prescription order, the pharmacist should contact the prescriber for verification or clarification.

If at any time a pharmacist is in doubt, they should require proper identification. Although this procedure is not foolproof (identification papers can also be stolen/forged), it does increase the drug abuser's risk. If a pharmacist believes the prescription is forged or altered, they should not dispense it and should call the local police. If a pharmacist believes they have discovered a pattern of prescription abuse, they should contact the state Board of Pharmacy or the local DEA Diversion Field Office ([Appendix K](#)). Both DEA and state authorities consider retail-level diversion a priority issue.

Proper Controls

Dispensing procedures without control and professional caution are an invitation to the drug abuser. Proper controls can be accomplished by following common sense, sound professional practice, and proper dispensing procedures. In addition, pharmacy staff should have knowledge of these safeguards, as it will help prevent and protect the pharmacy from becoming a source of diversion.

Most drug abusers seek out areas where communication and cooperation between health care professionals are minimal because it makes the drug abuser's work easier. Thus, a pharmacist should encourage other local pharmacists and physicians to develop a working relationship which will promote teamwork and camaraderie. In addition, the pharmacist should become familiar with those controlled substances that are popular for abuse and resale on the streets in the area and should discuss those findings with other pharmacists and practitioners in the community.

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APPENDIX E

Affidavit for a New Pharmacy¹

I, _____, the _____ (Title of officer, official, partner, or other position) of _____ (Corporation, partnership, or sole proprietor), doing business as _____ (Store name) at _____ (Number and Street), _____ (City) _____ (State) _____ (Zip Code), hereby certify that said store was issued a pharmacy permit No. _____ by the _____ (Board of Pharmacy or Licensing Agency) of the State of _____ on _____ (Date).

This statement is submitted in order to obtain a Drug Enforcement Administration registration number. I understand that if any information is false, the Administration may immediately suspend the registration for this store and commence proceedings to revoke under 21 U.S.C. 824(a) because of the danger to public health and safety. I further understand that any false information contained in this affidavit may subject me personally and the above-named corporation/partnership/business to prosecution under Title 18, United States Code (18 U.S.C.).

Signature (Person who signs Application for Registration)

State of _____ County of _____ Subscribed to and sworn before me this _____ day of _____, 20_____.

Notary Public

¹ 21 CFR 1301.17(a).

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APPENDIX F

Affidavit for Transfer of a Pharmacy¹

I, _____, the _____ (Title of officer, official, partner, or other position) of _____ (Corporation, partnership, or sole proprietor), doing business as _____ (Store name) hereby certify:

(1) That said company was issued a pharmacy permit No. _____ by the _____ (Board of Pharmacy or Licensing Agency) of the State of _____ and a DEA Registration Number _____ for a pharmacy located at _____ (Number and Street), _____ (City) _____ (State) _____ (Zip Code); and

(2) That said company is acquiring the pharmacy business of _____ (Name of Seller) doing business as _____ with DEA Registration Number _____ on or about _____ (Date of Transfer) and that said company has applied (or will apply on _____ (Date)) for a pharmacy permit from the Board of Pharmacy (or Licensing Agency) of the State of _____ to do business as _____ (Store name) at _____ (Number and Street) _____ (City) _____ (State) _____ (Zip Code).

This statement is submitted in order to obtain a Drug Enforcement Administration registration number.

I understand that if a DEA registration number is issued, the pharmacy may acquire controlled substances but may not dispense them until a pharmacy permit or license is issued by the state board of pharmacy or licensing agency.

I understand that if any information is false, the Administration may immediately suspend the registration for this store and commence proceedings to revoke under 21 U.S.C. 824(a) because of the danger to public health and safety. I further understand that any false information contained in this affidavit may subject me personally and the above-named corporation/partnership/business to prosecution under Title 18, United States Code (18 U.S.C.).

Signature (Person who signs Application for Registration)

State of _____ County of _____ Subscribed to and sworn before me this _____ day of _____, 20_____.

Notary Public

¹ 21 CFR 1301.17(b).

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APPENDIX G

**Equivalency Tables for Ephedrine, Pseudoephedrine, and
Phenylpropanolamine Under the Combat Methamphetamine Epidemic Act of
2005**

RETAIL DAILY SALE LIMITS ARE NOT TO EXCEED THE FOLLOWING AMOUNTS PER PURCHASER	
Ingredient	Number of Tablets = 3.6 grams
25 mg Ephedrine HCl	175
25 mg Ephedrine Sulfate	186
30 mg Pseudoephedrine HCl	146
60 mg Pseudoephedrine HCl	73
120 mg Pseudoephedrine HCl	36
30 mg Pseudoephedrine Sulfate	155
60 mg Pseudoephedrine Sulfate	77
120 mg Pseudoephedrine Sulfate	38
Phenylpropanolamine (PPA)	The Food and Drug Administration issued a voluntary recall of this ingredient as being unsafe for human consumption. Veterinary use is by prescription only.

30-DAY SALE LIMITS ARE NOT TO EXCEED THE FOLLOWING AMOUNTS PER PURCHASER		
Ingredient	Number of tablets at retail = 9 grams	Number of tablets for mail orders = 7.5 grams
25 mg Ephedrine HCl	439	366
25 mg Ephedrine Sulfate	466	389
30 mg Pseudoephedrine HCl	366	305
60 mg Pseudoephedrine HCl	183	152
120 mg Pseudoephedrine HCl	91	76
30 mg Pseudoephedrine Sulfate	389	324
60 mg Pseudoephedrine Sulfate	194	162
120 mg Pseudoephedrine Sulfate	97	81
Phenylpropanolamine (PPA)	The Food and Drug Administration issued a voluntary recall of this ingredient as being unsafe for human consumption. Veterinary use is by prescription only.	

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APPENDIX H

Guidelines for Emergency Kits in Long-Term Care Facilities

A pharmacy may place an emergency kit with controlled substances in a non-DEA registered LTCF if the appropriate state agency or regulatory authority specifically approves the placement and promulgates procedures that delineate:

1. The source from which the LTCF may obtain controlled substances for emergency kits and that the source of supply is a DEA registered hospital/clinic, pharmacy, or practitioner.
2. The security safeguards for each emergency kit stored at the LTCF, including who may have access to the emergency kit, and specific limitation of the type and quantity of controlled substances permitted in the kit.
3. The responsibility for proper control and accountability of the emergency kit within the LTCF, including the requirement that the LTCF and the supplying registrant maintain complete and accurate records of the controlled substances placed in the emergency kit, the disposition of the controlled substances, and the requirement to take and maintain periodic physical inventories.
4. The emergency medical conditions under which the controlled substances may be administered to LTCF patients, including the requirement that controlled substances be administered by authorized personnel only as expressly authorized by an individual practitioner and in compliance with the provisions of 21 CFR 1306.11 and 1306.21.
5. The prohibited activities that if violated could result in state revocation, denial, or suspension of the privilege to supply or possess emergency kits containing controlled substances.

The requirements for emergency kits in LTCFs were published in a Federal Register notice on April 9, 1980. 45 FR 24128. Pharmacies and LTCFs may wish to consult the notice to ensure compliance with the requirements.

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APPENDIX I

Guidelines for Completing the DEA Form 106 (Theft or Loss of Controlled Substances)
or the DEA Form 107 (Theft or Loss of Listed Chemicals)

Instructions for completing the DEA Form 106 are provided when filling out either the paper or electronic version of the form. Instructions are provided when filling out the electronic form of the DEA Form 107. Listed below are additional guidelines:

1. Do not use a DEA Form 106 to report an accidental spillage. Save the broken bottles, salvage the product if possible, and contact the local DEA Diversion Field Office (Appendix K) for additional instructions. This type of a loss, if considered significant, should be reported on a DEA Form 41, Registrants Inventory of Drugs Surrendered. 21 CFR 1304.21(e).
2. If thefts have occurred due to employee pilferage over a period of time, document on the DEA Form 106 or DEA Form 107 the date of discovery in block 4. Provide estimated beginning and ending dates of the thefts in box 17 with an explanation.
3. If there are multiple thefts or losses on the same day (e.g., mail-order pharmacy), report each theft or loss on a separate DEA Form 106 or DEA Form 107.
4. Miscounts or adjustments to inventory involving clerical errors on the part of the pharmacy should not be reported on a DEA Form 106 or DEA Form 107.
5. In block 9, 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).
6. In block 12, enter the amount the pharmacy paid for the controlled substances or listed chemical products, not the retail value.
7. In blocks 14 b & c, if the customer accepted the controlled substances or listed chemical products before discovering a loss in transit, identify the supplier and its DEA registration number.
8. In block 14 f, when explaining how many losses occurred from the same carrier, do not include the current loss.
9. The date next to the signature and title on page 2 should be the date the form was completed, signed, and sent to the local DEA Diversion Field Office (Appendix K).

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10. Document the National Drug Code (NDC) number of the controlled substance, and if the loss was a partial container, document the actual amount of theft or loss within the container.
11. For the DEA Form 106, If the controlled substance contains hydrocodone, oxycodone or a similar controlled substance and contains acetaminophen, aspirin, or ibuprofen, indicate the strength of the non-controlled substance as well as the strength of the controlled substance contained in the product.
12. 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 J

DEA Policy Statement on Role of Authorized Agents

On October 6, 2010, DEA published in the Federal Register a statement of policy to provide guidance under existing law regarding the proper role of a duly authorized agent of a DEA registered individual practitioner in connection with the communication of a controlled substance prescription to a pharmacy.

Please refer to DEA's Diversion website, www.DEAdiversion.usdoj.gov, to see the complete policy statement on the *Role of Authorized Agents in Communicating Controlled Substance Prescriptions to Pharmacies* 75 FR 61613 (Oct. 6, 2010).

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APPENDIX K

DEA Registration Program Specialists in Field Divisions

Registration Program Specialists are available during normal business hours to provide information about new applications, renewals, order forms, or changes to a DEA registration. Addresses and telephone numbers are subject to change. The most current listing of Registration Program Specialists is located on DEA's Diversion website, www.DEAdiversion.usdoj.gov. Click on "Registration" and then look for the "Registration Support" subheading near the end of the page, wherein you will find a link to help you locate your local field office registration program specialist.

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APPENDIX L

Drug Enforcement Administration
Diversion Field Office Locations

Visit www.DEAdiversion.usdoj.gov for current addresses and telephone numbers.

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APPENDIX M

Internet Resources

DEA's Diversion Control Division Website

www.DEAdiversion.usdoj.gov

DEA Homepage

www.dea.gov

U.S. Government Publishing Office

<https://www.govinfo.gov>

Provides access to the CFR, Parts 1300 to End, primary source for the Pharmacist's Manual, and the Federal Register which contains proposed and finalized amendments to the CFR.

Office of National Drug Control Policy (ONDCP)

www.whitehouse.gov/ondcp

Food and Drug Administration

www.FDA.gov

SAMHSA

www.samhsa.gov

CSAT

<https://www.samhsa.gov/about-us/who-we-are/offices-centers/csat>

Federation of State Medical Boards

www.FSMB.org

National Association of Boards of Pharmacy

<https://nabp.pharmacy>

National Association of State Controlled Substances Authorities

www.nascsa.org

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APPENDIX N

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 will annually evaluate the enforcement activities and rate each agency's responsiveness to small business. If you wish to comment on DEA enforcement actions, you may contact the Ombudsman at 1-888-REG-FAIR (1-888-734-3247).

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APPENDIX O

Additional Assistance

This publication is intended to provide guidance and information on the requirements of the CSA 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 (Appendix K). Every effort will be made to respond promptly to your inquiry.

Plain Language

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

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

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