



A PHARMACY CONTINUING EDUCATION PROGRAM

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January 2010 "Federal Controlled Substance Dispensing Requirements" 707-000-10-001-H03-P

32nd Year



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"Pharmacy Law 2010"

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**"CONTROLLED SUBSTANCES."** There is a lot of misunderstanding regarding controlled drugs. In this lesson, we provide the language to many of the DEA requirements & follow with explanations. It may be considered to be a didactic exercise, but occasionally, it's a good thing to go over matters using this technique. This lesson provides 3.0 hours (0.3 CEUs) of credit, and is intended for pharmacists in all practice settings. **The program ID # for this lesson is 707-000-10-001-H03-P. Pharmacists completing this lesson by January 31, 2013 may receive full credit. To obtain continuing education credit for this lesson, you must answer the questions on the quiz (70% correct required), and return the quiz. Should you score less than 70%, you will be asked to repeat the quiz. Computerized records are maintained for each participant.**

If you have any comments, suggestions or questions, contact us at the above address, or call toll free 1-800-323-4305. (In Alaska and Hawaii phone 1-847-945-8050). **Please write your ID Number (the number that is on the top of the mailing label) in the indicated space on the quiz page** (for continuous participants only).

**The objectives of this lesson are such that upon completion the participant will be able to:**

1. Describe the framework of the closed system of controlled substance distribution.
2. Discuss general requirements for controlled substance prescriptions.
3. List the requirements for issuing and processing Schedule II prescriptions.
4. List the requirements for issuing and processing Schedule III, IV and V prescriptions.
5. Describe practices that assure access to controlled substances for those who need them but deny access for those who would divert and abuse them.

**All opinions expressed by the author/authors are strictly their own and are not necessarily approved or endorsed by W-F Professional Associates, Inc. Consult full prescribing information on any drugs or devices discussed.**

## I. Introduction

Pharmacists take seriously their responsibility to control access to drugs that are subject to diversion and abuse. While making sure that availability is not unnecessarily denied to patients who legitimately need medications, pharmacists are attentive to the imperative that they reduce the illegal distribution of prescription drugs by those who would profit from the misfortunes of others. Possession and oversight of the drugs is limited to those who are registered with the federal Drug Enforcement Administration (DEA) or who are employed by a DEA registrant.

This lesson quotes extensively from federal DEA rules for controlled substances. These rules are largely self-explanatory, but we include explanations of particular points that can be difficult to interpret.

## II. General Requirements for Controlled Substances

Within DEA regulations, there are a number of provisions that relate to all controlled substances, and then several provisions that relate only to certain schedules of controlled substances. For practical purposes, Schedule I controlled substances are not generally prescribed. Schedule II controlled substances are the most highly regulated of those that are made available for general use. Schedules III, IV and V are regulated essentially the same at the dispenser level. A very few Schedule V controlled substances are subject to special rules that acknowledge their over-the-counter status. The first provisions listed here apply to all controlled substances, and they are followed by the provisions applicable to Schedule II, and those applicable to Schedule III, IV, and V.

### A. Section 1306.03 Persons entitled to issue prescriptions.

(a) A prescription for a controlled substance may be issued only by an individual practitioner who is:

- (1) authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession and
- (2) either registered or exempted from registration.

(b) A prescription issued by an individual practitioner may be communicated to a pharmacist by an employee or agent of the individual practitioner.

When the rules refer to "individual practitioner" the agency is using that term as a synonym with what pharmacists would usually call the "prescriber." Authority to prescribe controlled substances is determined by state law, so if a state authorizes physician assistants, nurse practitioners, or even pharmacists (this is the case in a small number of states) to prescribe controlled substances, the agency will issue a DEA registration to that prescriber. Some prescribers, such as those who work entirely within registered institutions, need not have a personal DEA registration. Note that a controlled substances prescription must be communicated to a pharmacist, but it may be communicated by the prescriber's employee or agent (who need not be an employee).

### B. Section 1306.04 Purpose of issue of prescription.

(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and 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.

(b) 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.

(c) A prescription may not be issued for the dispensing of narcotic drugs listed in any schedule for "detoxification treatment" or "maintenance treatment" unless the prescription is for a Schedule III, IV, or V narcotic drug approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment.

Pharmacists have a corresponding responsibility to not knowingly dispense medications pursuant to a purported prescription. An order is a purported prescription, rather than a prescription, if it has not been issued for a legitimate medical purpose or if it has been issued outside the usual course of professional practice. Prescribers may not issue prescriptions for "office use," for them to dispense to their patients. Instead, prescriptions must be issued for a specific patient. There are special clinics and practices that are allowed to issue prescriptions for patients who are being treated for the disease of addiction, and unless a prescription for a controlled substance is issued consistent with the requirements applicable to these patients, it is not a prescription but a purported prescription.

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**C. Section 1306.05 Manner of issuance of prescriptions.**

(a) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the name, address and registration number of the practitioner. In addition, a prescription for a Schedule III, IV, or V narcotic drug approved by FDA specifically for "detoxification treatment" or "maintenance treatment" must include the identification number issued by the Administrator under §1301.28(d) of this chapter or a written notice stating that the practitioner is acting under the good faith exception of §1301.28(e). Where a prescription is for gamma-hydroxybutyric acid, the practitioner shall note on the face of the prescription the medical need of the patient for the prescription. A practitioner may sign a prescription in the same manner as he would sign a check or legal document (e.g., J.H. Smith or John H. Smith). Where an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typewriter and shall be manually signed by the practitioner. The prescriptions may be prepared by the secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. 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.

(b) An individual practitioner exempted from registration under Sec. 1301.22(c) of this chapter shall include on all prescriptions issued by him or her the registration number of the hospital or other institution and the special internal code number assigned to him or her by the hospital or other institution as provided in Sec. 1301.22(c) of this chapter, in lieu of the registration number of the practitioner required by this section. Each written prescription shall have the name of the physician stamped, typed, or handprinted on it, as well as the signature of the physician.

(c) An official exempted from registration under Sec. 1301.22(c) shall include on all prescriptions issued by him his branch of service or agency (e.g., "U.S. Army" or "Public Health Service") and his service identification number, in lieu of the registration number of the practitioner required by this section. The service identification number for a Public Health Service employee is his Social Security identification number. Each prescription shall have the name of the officer stamped, typed, or handprinted on it, as well as the signature of the officer.

Just as pharmacists have a corresponding responsibility to assure that a prescription has been issued for a legitimate medical purpose and in the usual course of professional practice, they have what is called a professional liability if they dispense controlled substances pursuant to an order that does not meet the mandated formalities of a prescription. These formalities are well known to pharmacists and are outlined in the section above.

**D. Section 1306.06 Persons entitled to fill prescriptions.**

A prescription for controlled substances may only be filled by a pharmacist, acting in the usual course of his professional practice and either registered individually or employed in a registered pharmacy, a registered central fill pharmacy or registered institutional practitioner.

Only a pharmacist may fill a prescription. Under federal law there is no list of tasks that pharmacists must perform, and of those that pharmacists may delegate to a pharmacy technician, while filling a controlled substance prescription. That distinction is made under state laws. In some states, the pharmacist need only perform the final check of a controlled substance prescription that has been prepared by a technician. In other states, the pharmacist must control every aspect of the dispensing of controlled substances.

**E. Section 1306.07 Administering or dispensing of narcotic drugs.**

(a) A practitioner may administer or dispense directly (but not prescribe) a narcotic drug listed in any schedule to a narcotic dependant person for the purpose of maintenance or detoxification treatment if the practitioner meets both of the following conditions:

(1) The practitioner is separately registered with DEA as a narcotic treatment program.

(2) The practitioner is in compliance with DEA regulations regarding treatment qualifications, security, records, and unsupervised use of the drugs pursuant to the Act.

(b) Nothing in this section shall prohibit a physician who is not specifically registered to conduct a narcotic treatment program from administering (but not prescribing) narcotic drugs to a person for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment. Not more than one day's medication may be administered to the person or for the person's use at one time. Such emergency treatment may be carried out for not more than three days and may not be renewed or extended.

(c) This section is not intended to impose any limitations on a physician or authorized hospital staff to administer or dispense narcotic drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction, or to administer or dispense narcotic drugs to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts.

(d) A practitioner may administer or dispense (including prescribe) any Schedule III, IV, or V narcotic drug approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment to a narcotic dependent person if the practitioner complies with the requirements of §1301.28 of this chapter.

When prescribers choose to administer controlled substances themselves, the rules are somewhat relaxed over those that apply to dispensing by a pharmacist. The administration activity is more limited in scope than is the dispensing activity, and it is conducted within a more controlled environment, thus the need for regulatory oversight is less.

**II. Schedule II Prescriptions**

As pharmacists well know, Schedule II controlled substances are the most highly regulated of generally available controlled substances. These drugs have an accepted medical use and they have a higher abuse potential than controlled substances in Schedules III, IV and V. Some examples of single entity Schedule II narcotics include morphine, codeine, hydrocodone, and opium. Other Schedule II narcotic substances and their common name brand products include: hydro-morphone (Dilaudid®), methadone (Dolophine®), meperidine (Demerol®), oxycodone (Percodan®) and fentanyl (Sublimaze®). Some examples of Schedule II stimulants include amphetamine (Dexedrine®), Adderall®, methamphetamine (Desoxyn®) and methylphenidate (Ritalin®).

**A. Section 1306.11 Requirement of prescription.**

(a) A pharmacist may dispense directly a controlled substance listed in Schedule II, 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 as provided in paragraph (d) of this section. A prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy via facsimile equipment, provided that the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except as noted in paragraph (e), (f), or (g) of this section.

(b) An individual practitioner may administer or dispense directly a controlled substance listed in Schedule II in the course of his professional practice without a prescription, subject to Sec. 1306.07.

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule II only pursuant to a written prescription signed by the prescribing individual practitioner or to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user.

(d) In the case of an emergency situation, as defined by the Secretary in Sec. 290.10 of this title, a pharmacist may dispense a controlled substance listed in Schedule II upon receiving oral authorization of a prescribing individual practitioner, provided that:

(1) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a written prescription signed by the prescribing individual practitioner);

(2) The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required in Sec. 1306.05, except for the signature of the prescribing individual practitioner;

(3) If the prescribing individual practitioner is not known to the pharmacist, he must make a reasonable effort to determine that the oral authorization came from a registered individual practitioner, which may include a callback to the prescribing individual practitioner using his phone number as listed in the telephone directory and/or other good faith efforts to insure his identity; and

(4) 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. In addition to conforming to the requirements of Sec. 1306.05, the prescription shall have written on its face "Authorization for Emergency Dispensing," and the date of the oral order. 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 7 day period. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced to writing. The pharmacist shall notify the nearest office of the Administration if the prescribing individual practitioner fails to deliver a written prescription to him; failure of the pharmacist to do so shall void the authority conferred by this paragraph to dispense without a written prescription of a prescribing individual practitioner.

(5) Central fill pharmacies shall not be authorized under this paragraph to prepare prescriptions for a controlled substance listed in Schedule II upon receiving an oral authorization from a retail pharmacist or an individual practitioner.

(e) A prescription prepared in accordance with Sec. 1306.05 written for a Schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be transmitted by the practitioner or the practitioner's agent to the pharmacy by facsimile. The facsimile serves as the original written prescription for purposes of this paragraph (e) and it shall be maintained in accordance with Sec. 1304.04(h) of this chapter.

(f) A prescription prepared in accordance with Sec. 1306.05 written for Schedule II substance for a resident of a Long Term Care Facility may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The facsimile serves as the original written prescription for purposes of this paragraph (f) and it shall be maintained in accordance with Sec. 1304.04(h).

(g) A prescription prepared in accordance with Sec. 1306.05 written for a Schedule II narcotic 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 be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The practitioner or the practitioner's agent will note on the prescription that the patient is a hospice patient. The facsimile serves as the original written prescription for purposes of this paragraph (g) and it shall be maintained in accordance with § 1304.04(h) of this chapter.

Although Schedule II prescriptions must be issued in writing, there are some exceptions to that requirement. Facsimile transmission is permitted for all Schedule II prescriptions, as long as the pharmacist receives the original prescription prior to delivery of the medication to the patient. In an emergency, Schedule II prescriptions may be issued verbally by the prescriber, and the above conditions must be maintained.

**B. Section 1306.12 Refilling prescriptions; Issuance of multiple prescriptions.**

(a) The refilling of a prescription for a controlled substance listed in Schedule II is prohibited.

(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:

(i) Each separate prescription is issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice;

(ii) The individual practitioner provides 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;

(iii) The individual practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse;

(iv) The issuance of multiple prescriptions as described in this section is permissible under the applicable state laws; and

(v) The individual practitioner complies fully with all other applicable requirements under the Act and these regulations as well as any additional requirements under state law.

(2) Nothing in this paragraph (b) shall be construed as mandating or 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.

After several years of controversy, the DEA now permits prescribers to issue multiple Schedule II prescriptions on the same day, all dated on that day of issue, but some carrying the instruction that they are to be filled at a subsequent time. The limitations on the practice are listed above. The purpose of allowing prescriptions to be issued and dispensed in this way is to avoid interruption in therapy for stabilized patients who do not need to see their physician monthly and who cannot acquire more than a limited supply at one time.

**C. Section 1306.13 Partial filling of prescriptions.**

(a) The partial filling of a prescription for a controlled substance listed in Schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and he makes a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription). The remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.

(b) A prescription for a Schedule II controlled substance written for a patient in a Long Term Care Facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist must contact the practitioner prior to partially filling the prescription. Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient. The pharmacist must record on the prescription whether the patient is "terminally ill" or an "LTCF patient." A prescription that is partially filled and does not contain the notation "terminally ill" or "LTCF patient" shall be deemed to have been filled in violation of the Act. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. The total quantity of Schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed. Schedule II prescriptions for patients in a LTCF or patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of medication.

(c) Information pertaining to current Schedule II prescriptions for patients in a LTCF or for patients with a medical diagnosis documenting a terminal illness may be maintained in a computerized system if this system has the capability to permit:

(1) Output (display or printout) of the original prescription number, date of issue, identification of prescribing individual practitioner, identification of patient, address of the LTCF or address of the hospital or residence of the patient, identification of medication authorized (to include dosage, form, strength and quantity), listing of the partial fillings that have been dispensed under each prescription and the information required in Sec. 1306.13(b).

(2) Immediate (real time) updating of the prescription record each time a partial filling of the prescription is conducted.

(3) Retrieval of partially filled Schedule II prescription information is the same as required by Sec. 1306.22(b)(4) and (5) for Schedule III and IV prescription refill information.

Schedule II prescriptions may be partially filled for any patient, as long as the balance of the prescription is dispensed within 72 hours, or the prescriber is notified that the balance cannot be dispensed. For some patients, a 60-day period of partial dispensing is permitted. These are the "terminally ill" and "LTCF patients" referred to above.

**D. Section 1306.14 Labeling of substances and filing of prescriptions.**

(a) The pharmacist filling a written or emergency oral prescription for a controlled substance listed in Schedule II shall affix to the package a label showing date of filling, the pharmacy name and address, the serial number of the prescription, the name of the patient, the name of the prescribing practitioner, and directions for use and cautionary statements, if any, contained in such prescription or required by law.

(b) If the prescription is filled at a central fill pharmacy, the central fill pharmacy shall 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, in addition to the information required under paragraph (a) of this section.

(c) The requirements of paragraph (a) of this section do not apply when a controlled substance listed in Schedule II is prescribed for administration to an ultimate user who is institutionalized: Provided, That:

(1) Not more than 7-day supply of the controlled substance listed in Schedule II is dispensed at one time;

(2) The controlled substance listed in Schedule II is not in the possession of the ultimate user prior to the administration;

(3) The institution maintains appropriate safeguards and records regarding the proper administration, control, dispensing, and storage of the controlled substance listed in Schedule II; and

(4) The system employed by the pharmacist in filling a prescription is adequate to identify the supplier, the product, and the patient, and to set forth the directions for use and cautionary statements, if any, contained in the prescription or required by law.

(d) All written prescriptions and written records of emergency oral prescriptions shall be kept in accordance with requirements of Sec. 1304.04(h) of this chapter.

(e) Where a prescription that has been prepared in accordance with section 1306.12(b) contains instructions from the prescribing practitioner indicating that the prescription shall not be filled until a certain date, no pharmacist may fill the prescription before that date.

The section above describes specific requirements for the labeling of Schedule II medication when dispensed to a patient, and requirements for filing prescriptions for Schedule II drugs. Regulators want to be able to read a vial of medication possessed by a patient and see that the medication is legitimately possessed. They also want to be able to examine pharmacy records to see patterns of distribution of Schedule II drugs to patients. Within the confines of a highly controlled medical center, the requirements are relaxed for the distribution of limited amounts of Schedule II drugs.

**E. Section 1306.15 Provision of prescription information between retail pharmacies and central fill pharmacies for prescriptions of Schedule II controlled substances.**

Prescription information may be provided to an authorized central fill pharmacy by a retail pharmacy for dispensing purposes. The following requirements shall also apply:

(a) Prescriptions for controlled substances listed in Schedule II may be transmitted electronically from a retail pharmacy to a central fill pharmacy including via facsimile. The retail pharmacy transmitting the prescription information must:

(1) Write the word "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 of the retail pharmacy pharmacist transmitting the prescription, and the date of transmittal;

(2) Ensure that all information required to be on a prescription pursuant to Section 1306.05 of this part 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 filled;

(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.

(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 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 pharmacist filling the prescription, and the date of filling of the prescription;
- (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 dispensing of Schedule II drugs is specifically permitted under DEA regulations. Recordkeeping must thoroughly document a trail of responsibility for the drugs as they are prepared.

### III. Schedule III, IV and V Prescriptions

Schedule III controlled substances have an abuse potential which is less than those in Schedule II, but more than Schedule IV substances.

Schedule IV controlled substances have an abuse potential less than those listed in Schedule III and more than substances in Schedule V.

Schedule V controlled substances have an abuse potential less than those listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotic and stimulant drugs generally for antitussive, antidiarrheal and analgesic purposes.

#### A. Section 1306.21 Requirement of prescription.

(a) A pharmacist may dispense directly a controlled substance listed in Schedule III, IV, or V which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, only pursuant to either a written prescription signed by a practitioner or a facsimile of a written, signed prescription transmitted by the practitioner or the practitioner's agent to the pharmacy or pursuant to an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist containing all information required in Sec. 1306.05, except for the signature of the practitioner.

(b) An individual practitioner may administer or dispense directly a controlled substance listed in Schedule III, IV, or V in the course of his/her professional practice without a prescription, subject to Sec. 1306.07.

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule III, IV, or V only pursuant to a written prescription signed by an individual practitioner, or pursuant to a facsimile of a written prescription or order for medication transmitted by the practitioner or the practitioner's agent to the institutional practitioner-pharmacist, or pursuant to an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist (containing all information required in Section 1306.05 except for the signature of the individual practitioner), or pursuant to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user, subject to Sec. 1306.07.

In stark contrast with Schedule II prescriptions, Schedule III, IV and V prescriptions may be issued verbally. Pharmacists still have a responsibility to assure the validity of a prescription that has not been issued in writing. All of the information that is required in a written prescription must be preserved in the documentary record that supports dispensing of a controlled substance pursuant to verbal authority to dispense.

#### B. Section 1306.22 Refilling of prescriptions.

(a) No prescription for a controlled substance listed in Schedule III or IV shall be filled or refilled more than six months after the date on which such prescription was issued and no such prescription authorized to be refilled may be refilled more than five times. Each refilling of a prescription shall be entered on the back of the prescription or on another appropriate document. If entered on another document, such as a medication record, the document must be uniformly maintained and readily retrievable. The following information must be retrievable by the prescription number consisting of the name and dosage form of the controlled substance, the date filled or refilled, the quantity dispensed, initials of the dispensing pharmacist for each refill, and the total number of refills for that prescription. If the pharmacist merely initials and dates the back of the prescription it shall be deemed that the full face amount of the prescription has been dispensed. The prescribing practitioner may authorize additional refills of Schedule III or IV controlled substances on the original prescription through an oral refill authorization transmitted to the pharmacist provided the following conditions are met:

(1) The total quantity authorized, including the amount of the original prescription, does not exceed five refills nor extend beyond six months from the date of issue of the original prescription.

(2) The pharmacist obtaining the oral authorization records on the reverse of the original prescription the date, quantity of refill, number of additional refills authorized, and initials the prescription showing who received the authorization from the prescribing practitioner who issued the original prescription.

(3) The quantity of each additional refill authorized is equal to or less than the quantity authorized for the initial filling of the original prescription.

(4) The prescribing practitioner must execute a new and separate prescription for any additional quantities beyond the five refill, six-month limitation.

(b) As an alternative to the procedures provided by subsection (a), an automated data processing system may be used for the storage and retrieval of refill information for prescription orders for controlled substances in Schedule III and IV, subject to the following conditions:

(1) Any such proposed computerized system must provide on-line retrieval (via CRT display or hard-copy printout) of original prescription order information for those prescription orders which are currently authorized for refilling. This shall include, but is not limited to, data such as the original prescription number, date of issuance of the original prescription order by the practitioner, full name and address of the patient, name, address, and DEA registration number of the practitioner, and the name, strength, dosage form, quantity of the controlled substance prescribed (and quantity dispensed if different from the quantity prescribed), and the total number of refills authorized by the prescribing practitioner.

(2) Any such proposed computerized system must also provide on-line retrieval (via CRT display or hard-copy printout) of the current refill history for Schedule III or IV controlled substance prescription orders (those authorized for refill during the past six months.) This refill history shall include, but is not limited to, the name of the controlled substance, the date of refill, the quantity dispensed, the identification code, or name or initials of the dispensing pharmacist for each refill and the total number of refills dispensed to date for that prescription order.

(3) Documentation of the fact that the refill information entered into the computer each time a pharmacist refills an original prescription order for a Schedule III or IV controlled substance is correct must be provided by the individual pharmacist who makes use of such a system. If such a system provides a hard-copy printout of each day's controlled substance prescription order refill data, that printout shall be verified, dated, and signed by the individual pharmacist who refilled such a prescription order. The individual pharmacist must verify that the data indicated is correct and then sign this document in the same manner as he would sign a check or legal document (e.g., J. H. Smith, or John H. Smith). This document shall be maintained in a separate file at that

pharmacy for a period of two years from the dispensing date. This printout of the day's controlled substance prescription order refill data must be provided to each pharmacy using such a computerized system within 72 hours of the date on which the refill was dispensed. It must be verified and signed by each pharmacist who is involved with such dispensing. In lieu of such a printout, the pharmacy shall maintain a bound log book, or separate file, in which each individual pharmacist involved in such dispensing shall sign a statement (in the manner previously described) each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by him and is correct as shown. Such a book or file must be maintained at the pharmacy employing such a system for a period of two years after the date of dispensing the appropriately authorized refill.

(4) Any such computerized system shall have the capability of producing a printout of any refill data which the user pharmacy is responsible for maintaining under the Act and its implementing regulations. 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). Such a printout must include name of the prescribing practitioner, name and address of the patient, quantity dispensed on each refill, date of dispensing for each refill, name or identification code of the dispensing pharmacist, and the number of the original prescription order. In any computerized system employed by a user pharmacy the central recordkeeping location must be capable of sending the printout to the pharmacy within 48 hours, and if a DEA Special Agent or Diversion Investigator requests a copy of such printout from the user pharmacy, it must, if requested to do so by the Agent or Investigator, verify the printout transmittal capability of its system by documentation (e.g., postmark).

(5) In the event that a pharmacy which employs such a computerized system experiences system down-time, the pharmacy must have an auxiliary procedure which will be used for documentation of refills of Schedule III and IV controlled substance prescription orders. This auxiliary procedure must insure that refills are authorized by the original prescription order, that the maximum number of refills has not been exceeded, and that all of the appropriate data is retained for on-line data entry as soon as the computer system is available for use again.

(c) When filing refill information for original prescription orders for Schedule III or IV controlled substances, a pharmacy may use only one of the two systems described in paragraphs (a) or (b) of this section.

Pharmacists may refill Schedule III, IV and V prescriptions, for as many times as the prescriber authorizes them to be refilled, up to five times in a six month period. So this equals six dispensings in six months (one original dispensing and five refill dispensing). The key to this provision is that the prescriber must authorize the refills. The DEA requirements specify how pharmacists must document the authority they obtain to refill Schedule III, IV and V prescriptions.

**C. Section 1306.23 Partial filling of prescriptions.**

The partial filling of a prescription for a controlled substance listed in Schedule III, IV, or V is permissible, provided that:

- (a) Each partial filling is recorded in the same manner as a refilling,
- (b) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed, and
- (c) No dispensing occurs after 6 months after the date on which the prescription was issued.

Although some pharmacy computer systems may not permit it, DEA allows for the provision of the entire supply of authorized medication, even if quantities supplied periodically are less than those that are authorized by the prescriber. This is done through the provision of partial fillings.

**D. Section 1306.24 Labeling of substances and filing of prescriptions.**

(a) The pharmacist filling a prescription for a controlled substance listed in Schedule III, IV, or V shall affix to the package a label showing the pharmacy name and address, the serial number and date of initial filling, the name of the patient, the name of the practitioner issuing the prescription, and directions for use and cautionary statements, if any, contained in such prescription as required by law.

(b) If the prescription is filled at a central fill pharmacy, the central fill pharmacy shall 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, in addition to the information required under paragraph (a) of this section.

(c) The requirements of paragraph (a) of this section do not apply when a controlled substance listed in Schedule III, IV, or V is prescribed for administration to an ultimate user who is institutionalized: Provided, That:

- (1) Not more than a 34-day supply or 100 dosage units, whichever is less, of the controlled substance listed in Schedule III, IV, or V is dispensed at one time;
  - (2) The controlled substance listed in Schedule III, IV, or V is not in the possession of the ultimate user prior to administration;
  - (3) The institution maintains appropriate safeguards and records the proper administration, control, dispensing, and storage of the controlled substance listed in Schedule III, IV, or V; and
  - (4) The system employed by the pharmacist in filling a prescription is adequate to identify the supplier, the product and the patient, and to set forth the directions for use and cautionary statements, if any, contained in the prescription or required by law.
- (d) All prescriptions for controlled substances listed in Schedules III, IV, and V shall be kept in accordance with Sec. 1304.04(h) of this chapter.

Schedule III, IV and V prescriptions must be labeled and filed in much the same way as Schedule II prescriptions, although the standard method for filing Schedule II prescriptions is to separate them from the filing system for Schedule III, IV and V prescriptions.

**E. Section 1306.25 Transfer between pharmacies of prescription information for Schedules III, IV, and V controlled substances for refill purposes.**

(a) The transfer of original prescription information for a controlled substance listed in Schedules III, IV or V for the purpose of refill dispensing is permissible between pharmacies on a one time basis only. However, pharmacies electronically sharing a real-time, on-line database may transfer up to the maximum refills permitted by law and the prescriber's authorization. Transfers are subject to the following requirements:

- (1) The transfer is communicated directly between two licensed pharmacists and the transferring pharmacist records the following information:
  - (i) Write the word "VOID" on the face of the invalidated prescription.
  - (ii) 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.
  - (iii) Record the date of the transfer and the name of the pharmacist transferring the information.
- (b) The pharmacist receiving the transferred prescription information shall reduce to writing the following:

- (1) Write the word "transfer" on the face of the transferred prescription.
- (2) Provide all information required to be on a prescription pursuant to 21 CFR 1306.05 and include:
  - (i) Date of issuance of original prescription;
  - (ii) Original number of refills authorized on original prescription;
  - (iii) Date of original dispensing;
  - (iv) Number of valid refills remaining and date(s) and locations of previous refill(s);
  - (v) Pharmacy's name, address, DEA registration number and prescription number from which the prescription information was transferred;
  - (vi) Name of pharmacist who transferred the prescription.
  - (vii) Pharmacy's name, address, DEA registration number and prescription number from which the prescription was originally filled;
- (3) The original and transferred prescription(s) must be maintained for a period of two years from the date of last refill.
- (c) Pharmacies electronically accessing the same prescription record must satisfy all information requirements of a manual mode for prescription transfer.
- (d) The procedure allowing the transfer of prescription information for refill purposes is permissible only if allowable under existing state or other applicable law.

Prescriptions for Schedule III, IV and V controlled substances may be transferred from one pharmacy to another, primarily to allow a second pharmacy to dispense refills of a prescription originally filled elsewhere. It is always the responsibility of the second pharmacist to assure that there is authority from the prescriber to dispense medication pursuant to a transferred prescription.

**F. Section 1306.26 Dispensing without prescription.**

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:

- (a) Such dispensing is made only by a pharmacist (as defined in part 1300 of this chapter), and not by a nonpharmacist employee even if under the supervision of a pharmacist (although after the pharmacist has fulfilled his professional and legal responsibilities set forth in this section, the actual cash, credit transaction, or delivery, may be completed by a nonpharmacist);
- (b) 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;
- (c) The purchaser is at least 18 years of age;
- (d) The pharmacist requires every purchaser of a controlled substance under this section not known to him to furnish suitable identification (including proof of age where appropriate);
- (e) A bound record book for dispensing of controlled substances under this section is maintained by the pharmacist, which book shall contain the name and address of the purchaser, the name and quantity of controlled substance purchased, the date of each purchase, and the name or initials of the pharmacist who dispensed the substance to the purchaser (the book shall be maintained in accordance with the recordkeeping requirement of Sec. 1304.04 of this chapter); and
- (f) A prescription is not required for distribution or dispensing of the substance pursuant to any other Federal, State or local law.
- (g) Central fill pharmacies may not dispense controlled substances to a purchaser at retail pursuant to this section.

This provision is in some ways a quaint vestige of days gone by when pharmacists were primary health care providers to whom patients turned when they needed medications to treat minor illnesses. In states where limited quantities of Schedule V preparations may be sold over-the-counter, the pharmacist is responsible for making sure that such sales comply with state law.

**G. Section 1306.27 Provision of prescription information between retail pharmacies and central fill pharmacies for initial and refill prescriptions of Schedule III, IV, or V controlled substances.**

Prescription information may be provided to an authorized central fill pharmacy by a retail pharmacy for dispensing purposes. The following requirements shall also apply:

- (a) Prescriptions for controlled substances listed in Schedule III, IV or V may be transmitted electronically from a retail pharmacy to a central fill pharmacy including via facsimile. The retail pharmacy transmitting the prescription information must:
  - (1) Write the word "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 of the retail pharmacy pharmacist transmitting the prescription, and the date of transmittal;
  - (2) Ensure that all information required to be on a prescription pursuant to § 1306.05 of this part is transmitted to the central fill pharmacy (either on the face of the prescription or in the electronic transmission of information);
  - (3) Indicate in the information transmitted the number of refills already dispensed and the number of refills remaining;
  - (4) Maintain the original prescription for a period of two years from the date the prescription was last refilled;
  - (5) 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.
- (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 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;
  - (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).

**IV. Conclusion**

Although the DEA requirements for controlled substance prescriptions are extensive and demanding, they are a necessity to reduce the diversion of prescription drugs and the suffering that can result from the abuse of prescription drugs. Pharmacists who familiarize themselves with these requirements need not be daunted by them. They are manageable. Pharmacists who follow the rules can both reduce drug diversion and provide necessary medications to patients who must have them.

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**LESSON EVALUATION**

Please fill out this section as a means of evaluating this lesson. The information will aid us in improving future efforts. Either circle the appropriate evaluation answer, or rate the item from 1 to 7 (1 is the lowest rating; 7 is the highest).

1. Does the program meet the learning objectives?

- |  |     |    |
|--|-----|----|
| Discuss general requirements for controlled substance prescriptions              | Yes | No |
| List requirements for issuing & processing C-II prescriptions                    | Yes | No |
| List requirements for issuing & processing CIII, IV & V prescriptions            | Yes | No |
| Describe the framework of the closed system of controlled substance distribution | Yes | No |

2. Was the program independent & non-commercial Yes No

	Poor		Average		Excellent		
	1	2	3	4	5	6	7

3. Relevance of topic

4. What did you like most about this lesson? \_\_\_\_\_

5. What did you like least about this lesson? \_\_\_\_\_

**Please Select the Most Correct Answer**

- |  |  |
|--|--|
| <p>1. Which of these authorizes prescribing of controlled substances &amp; leads to acquisition of a DEA registration?<br/>                 A. Federal law<br/>                 B. State law<br/>                 C. Eiter State or Federal law<br/>                 D. Neither State or Federal Law</p> <p>2. Under DEA regulations, a prescriber may obtain a supply of medication for dispensing by using a prescription for "office use."<br/>                 A. True<br/>                 B. False</p> <p>3. Under DEA regulations, which of these need not be on the prescription for a controlled substance?<br/>                 A. Address of patient<br/>                 B. Address of pharmacist<br/>                 C. Registration number of practitioner<br/>                 D. Quantity prescribed</p> <p>4. Under DEA regulations, a practitioner may sign a prescription using a nickname or informal personal sign.<br/>                 A. True<br/>                 B. False</p> <p>5. A patient receives a prescription for 100 doses of a C-III drug. There are no refills. The pharmacist dispenses 50 units. Then 25 days later, the patient returns &amp; requests the additional 50 dosage units. Is the second dispensing permitted under Federal law?<br/>                 A. Yes<br/>                 B. No</p> | <p>6. To prescribe controlled substances for withdrawal of maintenance of addiction, a prescriber must have special qualifications &amp; registration with the DEA.<br/>                 A. True<br/>                 B. False</p> <p>7. Oxycodone is in which schedule under Federal law?<br/>                 A. II<br/>                 B. III<br/>                 C. IV<br/>                 D. V</p> <p>8. A pharmacist fills a verbal order for a Schedule II drug in an emergency situation. Within how many days must the prescriber cause a written prescription to be delivered to the pharmacist?<br/>                 A. 3 days<br/>                 B. 5 days<br/>                 C. 7 days<br/>                 D. 14 days</p> <p>9. A prescription for a patient confirmed as "terminally ill" may be partially filled over what period of time?<br/>                 A. 30 days<br/>                 B. 60 days<br/>                 C. 90 days<br/>                 D. 120 days</p> <p>10. In what schedule of controlled substances is pentazocine classified under Federal law?<br/>                 A. II<br/>                 B. III<br/>                 C. IV<br/>                 D. V</p> |
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