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The Federal Controlled Substances Act: A Primer for the Pharmacy Technician

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LEARNING OBJECTIVES

Upon completion of this module, the subscriber will be able to:

1. Explain the various schedules of controlled substances including providing examples of medications within each schedule.
2. Describe the requirements for a valid controlled substance prescription.
3. Outline the procedure for ordering controlled substances.
4. Identify the dispensing requirements for controlled substances.
5. List criteria for identifying possibly fraudulent controlled substance prescriptions.

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The Federal Controlled Substances Act: A Primer for the Pharmacy Technician

INTRODUCTION

On July 22, 2010, David Vogel, the operator and owner of an internet-based pharmacy through which millions of hydrocodone tablets and other controlled substances were sold and distributed without valid prescriptions, was convicted of conspiracy to distribute a controlled substance under the Controlled Substances Act.[1] In addition, Mr. Vogel and his 3 accomplices were found guilty of federal drug and money laundering violations. Mr. Vogel could end up facing 5 years in federal prison on the drug conspiracy charge, up to 20 years for the money laundering conspiracy charge, and up to 10 years for each individual money laundering charge. Criminal activity involving controlled substances, such as Mr. Vogel's case, unfortunately occurs more frequently than should be expected in the U.S. Although pharmacy technicians may never participate in such an extreme case of illegal controlled substances distribution, technicians need to be familiar with important aspects of the Federal Controlled Substances Act.

The Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, more commonly known as the Controlled Substances Act, became effective on May 1, 1971.[2,3] This federal law contains 3 different Titles covering 3 distinct, but related, topics. Title I deals with the establishment of rehabilitation programs for drug abusers, Title II addresses the registration and distribution of controlled substances, and Title III discusses issues related to the importation and exportation of controlled substances.[2] The main segment of interest to pharmacy technicians and pharmacists is Title II.

The goal of the Controlled Substances Act is to improve the manufacturing, importation and exportation, distribution, and dispensing of controlled substances.[3] In order to achieve this goal, manufacturers, distributors, and dispensers of controlled substances must be registered with the Drug Enforcement Administration (DEA), the agency charged with enforcement of the Act on the federal level.[2-5] Registration of these entities with the DEA results in the formation of a "closed system" for

controlled substances distribution.[3] This closed system allows for controlled substances to be traced from initial manufacture to final dispensing to the patient where the pharmacy technician plays an important role. This continuing education module provides pharmacy technicians with an overview of important aspects of the Federal Controlled Substances Act. The bulk of the information within this module is drawn from the Pharmacist's Manual – An Informational Outline of the Controlled Substances Act that is updated and published by the DEA. The pharmacy technician should refer to this manual (see the reference listing at the end of this continuing education program) for information on related topics not covered within this module.

What is a Controlled Substance?

Controlled substances are generally defined as medications that are considered easily abusable.[4,5] Under the Controlled Substances Act, these medications are categorized into 5 Schedules. Definitions of each Schedule with corresponding examples of medications are presented in Table 1. Schedule I medications have the highest abuse potential while medications in Schedule V have a low abuse potential. Beyond the Schedules in Table 1, the Controlled Substances Act also contains information on what are known as "Scheduled Listed Chemical Products" or SLCPs.[3] These listed chemicals are products that contain ephedrine, pseudoephedrine, or phenyl-propanolamine that may be marketed or distributed legally in the U.S. as nonprescription drugs. Scheduled Listed Chemical Products are discussed in more depth within the Combat Methamphetamine Epidemic Act section of this continuing education module.

Table 1. Schedules of Controlled Substances[2,3]

Schedule	Definitions	Examples
Schedule I	High abuse potential with no accepted medical use; medications within this Schedule may not be prescribed, dispensed, or administered	Heroin, marijuana, ecstasy, gamma hydroxybutyric acid (GHB)
Schedule II	High abuse potential with severe psychological or physical dependence; however, these medications have an accepted medical use and may be prescribed, dispensed, or administered	Morphine, codeine, hydrocodone, hydromorphone, methadone, oxycodone, fentanyl, methylphenidate, pentobarbital
Schedule III	Intermediate abuse potential (i.e. less than Schedule II but more than Schedule IV medications)	hydrocodone/acetaminophen 5mg/500mg or 10mg/650mg, codeine in combination with acetaminophen, aspirin, or ibuprofen, anabolic steroids, ketamine
Schedule IV	Abuse potential less than Schedule II but more than Schedule V medications	Propoxyphene, butorphanol, pentazocine, alprazolam, clonazepam, diazepam, midazolam, phenobarbital, pemoline, sibutramine
Schedule V	Medications with the least potential for abuse among the controlled substances	Robitussin AC®, Phenergan® with codeine

Of note, states like California have passed laws allowing for patients with a legitimate medical need, as certified by a physician, to possess or grow marijuana.[2,6] State laws such as these do not alter the fact that marijuana remains a Schedule I medication under federal law.

In addition, medications may be removed or added to a Schedule or be switched from one Schedule to another.[2] The authority to add, remove, or switch lies with the Attorney General of the United States. The Attorney General generally works with the Secretary of the Department of Health and Human Services to determine an ultimate decision on a medication's Schedule.

Pharmacy Registration

Registration with the DEA is required by every pharmacy that dispenses controlled substances.[3] Prior to obtaining a DEA registration, a pharmacy must have a state license for operation. Obtaining a DEA pharmacy registration is done by completing the Application for New Registration (i.e. DEA Form-224). Instructions for completing the form are found on the U.S. Department of Justice DEA Office of Diversion Control website at: http://www.deadiversion.usdoj.gov/drugreg/reg_apps/224/224_instruct.htm.[7] In addition, pharmacies can apply for a new or renewal registration electronically via http://www.deadiversion.usdoj.gov/drugreg/reg_apps/pdf_apps.htm.[8] Once approved, a pharmacy must renew registration every 3 years.

Some drug products such as pseudoephedrine, phenylpropanolamine, and ephedrine-containing medications are classified as "listed chemicals" as described above.[3] These chemicals may be used inappropriately to compound illegal substances such as methamphetamine (i.e. crystal). If a pharmacy were to engage in the wholesale distribution of these chemicals, a DEA chemical registration would also be required in addition to registration for handling controlled substances. This is rarely the case since most pharmacies are retail distributors of these chemicals (i.e. regulated sellers) and not wholesale distributors. A regulated seller legally sells the above mentioned chemicals only for personal use either directly to walk-in customers or via other face-to-face transactions.

Once granted, a DEA registration may be suspended or revoked by the U.S. Attorney General.[3] Reasons for suspending or revoking a registration include:

- Falsifying the application for the registration
- Prior conviction of a felony related to a controlled substance or a List I chemical (i.e. phenylpropanolamine or pseudoephedrine)
- Suspension, revocation, or denial of a state license
- Committing an act that "renders registration inconsistent with the public interest"
- Exclusion from Medicare or Medicaid programs

The Attorney General may also deny registration or renewal.[3] In so doing, he or she determines if issuing the registration or renewal would be inconsistent with the public interest. This is done by weighing the factors summarized in Table 2.

Table 2. Factors for Denying Registration or Renewal[3]

1. State licensing board or professional disciplinary authority recommendations
2. Experience of the applicant with regard to dispensing or conducting research with controlled substances
3. Prior conviction record related to any aspect of controlled substances (i.e. manufacture, distribution, or dispensing)
4. Compliance with laws regarding controlled substances
5. Any other conduct that may contribute negatively to public health or safety

Controlled Substance Prescriptions

In order for a prescription for a controlled substance to be considered valid, it must be "issued for a legitimate medical purpose by a registered practitioner acting in the usual course of sound professional practice."[9] Registered practitioner refers to any healthcare professional that is authorized to prescribe controlled substances within the area in which he or she is licensed to practice and is registered with the DEA or is exempt from registration (i.e. physicians employed by the Public Health Service or Bureau of Prisons).[3]

All of the following must be included in a prescription for a controlled substance:[9]

- Issue date
- Name and address of patient
- Name, address, and DEA registration number of practitioner
- Drug name
- Strength of drug
- Dosage form (i.e. tablet, suspension, etc.)
- Quantity prescribed
- Directions for use
- Refills (if authorized)
- Manual signature of the prescriber

Schedule II prescriptions must be presented to the pharmacy in written form and signed by the prescriber.[9] There are no federal quantity limits on Schedule II prescriptions.[3] In addition, there is no time limit on when a Schedule II prescription must be filled after being signed by a prescriber. That being said, the pharmacist must ensure that the controlled substance prescription is being prescribed for a legitimate medical purpose; issues such as quantity of medication prescribed and time between signing and filling of a prescription may play a role in this decision. Note that state laws may have stricter rules.

Phoning in a prescription for a Schedule II medication may only be done in an emergency situation.[9] If this is done, the prescriber must follow-up the phone prescription with a written prescription to the pharmacy within 7 days. Faxed Schedule II prescriptions are generally permitted, however, the pharmacist must receive the original, signed written prescription before actual dispensing of the Schedule II controlled substance to the patient.[2] The exception to this rule is if an emergency Schedule II prescription was faxed to the pharmacy.[3] If this is done, the prescriber must follow-up with a written prescription similarly to when an emergency Schedule II prescription is phoned into the pharmacy. There are 3 situations where a facsimile Schedule II prescription may serve as an original written prescription. These include the following:

1. The healthcare provider is prescribing a Schedule II narcotic to be compounded for direct administration to a patient by intravenous (i.e. into the vein), intramuscular (i.e. into the muscle), subcutaneous (i.e. under the skin), or intraspinal infusion.
2. The provider is prescribing Schedule II medications to patients within a long term care facility, which are normally filled and delivered to the patients within the facility by the pharmacy.
3. The provider is prescribing Schedule II medications to a patient in hospice care as certified by Medicare or licensed by the state.

Prescriptions for Schedules III to V controlled substances may be written, orally communicated, or faxed to the pharmacy.[9]

Not all prescriptions for controlled substances can be refilled.[9] Schedule II medications may not be refilled; a new prescription must be written every time. Medications classified as Schedule III or IV controlled substances may be refilled up to 5 times in a 6 month period. Schedule V medications may be refilled as authorized by the prescriber. When a refill of any controlled substance occurs, the dispensing pharmacist's initials, date of refill, and amount dispensed must be written on the back of the prescription.[3]

One mechanism to verify the validity of a controlled substance prescription is through the DEA registration number provided by the practitioner.[3] DEA registration numbers contain 2 letters followed by a computer-generated sequence of 7 numbers. The first letter in the DEA registration is generally an A, B, or M. Prior to October 1, 1985, DEA registration numbers began with the letter A. Those registration numbers issued after this date start with the letter B. Mid-level practitioners, such as advanced nurse practitioners and physician assistants, have registration numbers beginning with the letter M. The second letter in the registration number is the first letter of the practitioner's last name (i.e. J for Jackson or W for White). The computer-generated sequence of numbers can be verified using the following formula: add the sum of the first, third, and fifth digits to twice the sum of the second, fourth, and sixth digits.[4,5] The total should be a number whose last digit is the same as the last digit of the DEA number on the prescription. An example of this verification process is given in the case below.

Healthcare providers with prescribing authority, when acting within the usual course of business at a hospital or other healthcare institution, may prescribe controlled substances under the DEA registration number of the hospital or institution.[3] Examples of practitioners who may use a hospital's DEA registration number include physician interns and residents as well as medical house staff or mid-level practitioners such as physician assistants or advanced nurse practitioners.

The hospital or other institution must authorize the healthcare provider to prescribe under its registration number.[3] A specific internal code number must be assigned to each authorized practitioner. An example of a DEA registration number with an internal code is below.

AJ1234567-**134**

Hospital DEA **Physician**

Registration Number **Internal Code**

Case 1. Verification of a Prescriber's DEA Number

A patient, Mark Jackson, comes into the pharmacy with a prescription for oxycodone, a Schedule II medication. The patient has lung cancer and is using oxycodone for pain control associated with the disease. The prescription is as follows:

Date: 9/13/10 Mark Jackson
1740 W Taylor St Chicago, IL

Oxycontin 10 mg tablet every 12 hours #60

No refills

William Johnson MD
833 S Wood St Chicago, IL
DEA#: AJ1234563

In order to verify the DEA registration number, the pharmacy technician can apply the formula as written above in the following manner:

$$(1 + 3 + 5) + 2 \times (2 + 4 + 6) = 33$$

The last digit of the total from this equation "3" is the same as the last digit of the DEA number on the prescription written by Dr. Johnson.

The healthcare institution must keep an up to date list of all internal codes with the corresponding practitioner.[3] If the pharmacy has any doubt regarding a controlled substance prescription from a provider using a healthcare institution's DEA number, the pharmacist or technician may contact the institution to verify the legitimacy of the prescription.

As mentioned prior, mid-level practitioners such as nurse midwives, nurse practitioners, nurse anesthetists, clinical nurse specialists, physician assistants, and optometrists among others may be granted DEA registration numbers and prescribe controlled substances.[3] However, registration is contingent upon authority granted by the state in which they are licensed. In Illinois, mid-level practitioners do have prescriptive authority for Schedule II controlled substances under Section 303.05 of the Illinois Controlled Substances Act, which provides for limited prescribing of Schedule II medications by mid-level practitioners.[10]

Under this Section of the Act, mid-level practitioners in Illinois have limited delegated authority by a collaborating physician to prescribe, dispense, or administer Schedule II controlled substances. The limits on mid-level practitioners include:

- May not be delegated more than 5 ORAL dosage form Schedule II controlled substances (i.e. other forms may not be delegated such as patches or injections)
- May prescribe no more than a 30 day supply
- May continue a Schedule II prescription beyond 30 days ONLY after prior approval from the collaborating physician
- Must discuss the condition of any patient given a controlled substance at least monthly with the collaborating physician
- Must complete the appropriate application forms and pay fees as required by rule

Pharmacists and pharmacy technicians must be familiar with the state controlled substance act of their own state to determine which health care providers may or may not prescribe any controlled substances and if so which schedules of those they may prescribe.

On December 19, 2007, a new DEA regulation became in effect, which allows for a prescriber to issue multiple prescriptions authorizing an individual patient to receive a total of up to a 90 day supply of a Schedule II controlled substance.[3] However, this can only occur if the following conditions are met:

- Every Schedule II prescription must be written on a separate prescription blank
- Each Schedule II prescription must be written for a legitimate medical purpose by an authorized prescriber during the usual course of professional practice
- The prescriber must indicate on each prescription the earliest date on which the prescription can be filled by the pharmacy; an exception to this rule would be for the first prescription if the prescriber intends for that prescription to be filled immediately
- The prescriber determines that providing multiple Schedule II prescriptions to the patient does not increase the risk of diversion or abuse
- State law allows for the issuance of multiple prescriptions
- The individual prescriber complies fully with all other applicable requirements under the Controlled Substance Act and the Code of Federal Regulations, as well as any additional requirements under state law

In the case below, a situation involving multiple Schedule II controlled substance prescriptions is illustrated.

Ordering Controlled Substances

Pharmacy technicians may play a role in the ordering of controlled substances. Schedule I and II medications may be ordered by filling out a DEA Form-222 or electronically via the DEA Controlled Substance Ordering System (CSOS).[3] An example Form 222 may be found on the DEA Diversion web site at: http://www.deadiversion.usdoj.gov/pubs/manuals/pract/appendices/app_h/222.htm.[11] This official form is required for every distribution, purchase, or transfer of a Schedule II controlled substance.[3] In some instances, a medication may be switched from Schedule II to another Schedule at the federal level, but remain a Schedule II controlled substance at the state level. When this occurs, the stricter state law applies and many states may still require the use of Form-222 for any transaction involving a substance classified as Schedule II under the state law.

Official DEA order forms for Schedule II controlled substances must be maintained separately from other business records in the pharmacy.[3] These documents are available in books that contain 7 sets of forms. Generally, an individual pharmacy is given no more than 6 books at a time; however, more books may be allowed in specific situations. When ordering Schedule II medications, the number of packages, size of the package, and name of the item must be filled out completely on the form. Each form must be signed and dated by an authorized individual. For any individual pharmacy, there may be more than one person who is authorized to obtain and execute official DEA order forms

Case 2. Multiple Controlled Substance Prescriptions

A patient comes into the pharmacy and presents multiple prescriptions for Oxycontin®, a Schedule II controlled substance. Each Schedule II prescription has been written on a separate prescription blank. The pharmacy technician presents the prescriptions to the pharmacist. The pharmacist is familiar with the patient and knows that he has been suffering from severe back pain for many years. No medical interventions have been able to ease his pain as of yet. The issuance of multiple prescriptions is allowed under state law and the prescriber is authorized to issue such prescriptions. Is it appropriate for the pharmacist to fill these multiple prescriptions for a Schedule II controlled substance?

In this particular example, it is NOT appropriate for the pharmacist to fill these multiple prescriptions for Oxycontin®. Although state law allows for the issuance of multiple prescriptions, the Schedule II prescription appears to be written for a legitimate medical purpose by an authorized prescriber, and each prescription is written on a separate prescription blank, the prescriber must also indicate on each prescription the earliest date on which the prescription can be filled by the pharmacy. If the prescriber intends for the initial prescription to be filled immediately, then that prescription does not require a fill date; however, all other prescriptions do require such a date. The pharmacist should contact the physician regarding this error.

for Schedule II medications. To do so, the pharmacy must grant a "power of attorney" to each authorized person as seen in Table 3 below. This power of attorney must be signed by not only the individual receiving authorization responsibilities, but also by the person who signed the most recent application for registration or renewal registration for the pharmacy.

Table 3. Format for Granting and Revoking a Power of Attorney[3]

Power of Attorney for DEA Forms 222 and Electronic Orders

(Name of registrant)

(Address of registrant)

(DEA registration number)

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

(Signature of person granting power)

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

(signature of attorney-in-fact)

Witnesses:

1. _____

2. _____

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

Notice of Revocation

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

(Signature of person revoking power)

Witnesses:

1. _____

2. _____

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

Any sign of alteration on a DEA order form may be enough for a drug supplier to refuse a Schedule II controlled substances order.[3] A supplier may substitute identical drug products that differ in package size from those on the original order form. The only caveats to this substitution policy is that the actual quantity of Schedule II medication may not exceed the amount initially ordered and that the National Drug Code (NDC) number reflects that of the actual medication that was shipped to the purchaser.

Electronic ordering through the DEA CSOS is another option for ordering controlled substances.[3] The CSOS allows for secure electronic transmission of controlled substance orders without supporting paper documentation (i.e. DEA Form 222). CSOS is currently the only acceptable way to electronically transmit Schedule II controlled substance orders and requires users to obtain a digital certificate for ordering. These digital certificates may only be obtained by DEA registrants and individuals granted power of attorney by registrants. Each registrant must appoint a CSOS coordinator who acts as an agent regarding any issues related to digital certificates issued under the registrant's DEA number. Digital certificates are valid until DEA registration expires or until the DEA Certification Authority is notified that the certificate should be revoked for various reasons. Records of electronic Schedule II orders must be maintained in an electronic format for 2 years. More information on CSOS, including how to enroll, may be obtained at the DEA E-Commerce Program website (http://www.deaecom.gov/).

For Schedules III to V controlled substances, the pharmacy must maintain receipts in a readily retrievable manner.[3] A receipt may be an invoice or packing slip where the pharmacy records both the date the Schedule III to V controlled substances were received and confirmation that the order is accurate. These receipts must also contain: controlled substance name, dosage form, number of dosage units of the dosage form in each container, and number of containers ordered and received.

Recordkeeping Requirements for Controlled Substances

Pharmacies must keep an accurate record of every transaction involving a controlled substance (i.e. purchasing, receiving, dispensing, or disposal). This allows for tracking of each controlled substance from initial manufacture to final dispensing to the patient or disposal.[3] A pharmacy must maintain these records for at least 2 years. As stated earlier, records involving Schedule II medications must be maintained separately from all other records. Records for Schedules III to V medications may either be maintained separately or be stored with other ordinary business records, but have some mechanism that allows for them to be "readily retrievable". Per the DEA, readily retrievable means the following:[3]

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

Table 4 (on page 12) summarizes records that must be maintained with regard to controlled substances.

Under federal law, there are 2 options for filing controlled substances prescriptions.[3] Sometimes, state and federal laws conflict with regard to prescription filing requirements. When this occurs, the pharmacy must choose a system from the 2 options that would comply with both state and federal requirements. The 2 filing options are summarized in Table 5 (on page 12); all controlled substances prescriptions must be readily retrievable by the DEA regardless of the option chosen by the pharmacy.

In addition, the Controlled Substances Act

Table 4. Controlled Substances Records[3]

- Official order forms for Schedule II medications (DEA Form-222)
- Power of attorney authorization forms
- Receipts and invoices related to Schedule III to V medications
- All controlled substances inventory records
- Records of controlled substances distributed (i.e. returns to vendors, sales to other registrants, etc.)
- Prescriptions for controlled substances
- Forms related to loss or theft of a controlled substance
- Forms related to controlled substances surrendered for disposal
- Records dealing with transfers of controlled substances between pharmacies
- DEA registration certificate
- Self-certification certificate and logbook as required under the Combat Methamphetamine Epidemic Act of 2005 (discussed later in this module)

Table 5. Filing Options for Controlled Substances Prescriptions[3]

Options	Requirements
#1	Three separate files: • One file for Schedule II medications • One file for Schedule III to V medications • One file for all non-controlled medications
#2	Two separate files: • One file for Schedule II medications • One file for all other prescriptions (Schedule III to V and non-controlled medications)

requires that an inventory of controlled substances in a pharmacy be conducted initially (i.e. when a DEA registration has been issued) and biennially (i.e. every 2 years) thereafter.[3] The Act requires an actual physical count of all Schedule II medications and an estimated count or measure of the contents of all Schedule III to V controlled substances. The exception to the estimated count would be for containers that hold greater than 1,000 tablets or capsules. In that case, an exact count of the contents of the container must be undertaken. All inventory records must be maintained at the pharmacy in a readily retrievable manner for at least 2 years; schedule II inventory records must be maintained separately from all other controlled substances.

When performing the initial inventory, the record of the inventory must include:[3]

- Date of the inventory
- Whether the inventory was performed at the start or close of the business day
- Name of each controlled substance that was inventoried
- Finished dosage form of each controlled substance
- Number of dosage units of each finished dosage form in the commercial container
- Number of commercial containers of each finished dosage form
- Count of each controlled substance as mentioned above

The biennial inventory requires documenta-

tion of the same information as the initial inventory and may be completed on any date within 2 years of the previous inventory date.[3] Copies of either the initial or subsequent biennial inventories do not need to be submitted to the DEA.

Dispensing Requirements for Controlled Substances

Similar to other medications, prescription labels for controlled substances are required to contain all of the following elements prior to dispensing to the patient:[3]

- Pharmacy name and address
- Prescription number
- Patient name
- Initial dispensing date
- Name of the prescriber
- Directions for use
- Cautionary statements, if applicable

Labels for Schedule II to IV medications are also required by the Food and Drug Administration (FDA) to contain the following statement: "CAUTION: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."[3]

Emergency dispensing comes into play with Schedule II controlled substances.[3] In general, prescriptions for Schedule II medications must be presented to the pharmacy in written form prior to dispensing to the patient. However, the DEA acknowledges that there may be certain emergent situations that require dispensing of a Schedule II medication without a written prescription. The DEA defines an emergency as "the immediate administration of the drug is necessary for proper treatment of the intended ultimate user, that no alternative treatment is available (including a drug which is not a Schedule II controlled substance), and it is not possible for the prescribing practitioner to provide a written prescription for the drug at the time."

In emergencies, an authorized prescriber may phone or fax in a prescription for a Schedule II medication and the pharmacist may dispense the controlled substance to the patient provided that all of the following conditions are met:[3]

- The amount of Schedule II medication prescribed and dispensed must be limited to the quantity needed to treat the patient during the duration of the emergency only
- The pharmacist immediately reduces the verbal or faxed emergency prescription to writing with all necessary information except for the prescriber's signature
- The pharmacist makes a good faith effort to verify that the verbal order is coming from an authorized prescriber if the order is from an unknown healthcare provider

The prescriber must present a written, signed prescription for the emergency Schedule II verbal order within 7 days.[3] This prescription must contain the words "Authorization for Emergency Dispensing" on its face. The pharmacist must attach the written, signed prescription to the one that was reduced to writing previously. If the prescriber fails to present a written, signed prescription for the Schedule II medication to the pharmacy within the 7 day period, the pharmacist must report this infraction to the nearest DEA Diversion Field Office. Failure to report the infraction can result in revocation of the pharmacist's authority to dispense without a written prescription.

Partial dispensing of a Schedule II controlled substance is allowed; however, the pharmacist must note the partial quantity dispensed on the front of the prescription and dispense the remaining portion of the prescription within 72 hours of the initial dispensing.[3] If the rest of the prescription is not dispensed within the 72 hour period, the pharmacist must notify the prescriber and a new prescription is warranted. Schedule III to V controlled substances may also be partially dispensed; however, each partial fill must be recorded in the same manner as a refill, the total quantity dispensed in all partial fillings must not exceed the total amount prescribed, and no partial dispensing can occur beyond 6

months from the original issue date for the prescription.

There are controlled substances that are listed in Schedules II to V, but are NOT considered prescription medications under the Federal Food, Drug, and Cosmetic Act.[3] An example would be controlled substances containing opium. These controlled substances may be dispensed without a prescription provided that the requirements listed in Table 6 are met.

Table 6. Requirements for Dispensing a Controlled Substance Without a Prescription[3]

- Dispensing of the controlled substance is only performed by a pharmacist and not by a non-pharmacist employee (i.e. pharmacy technician) even if the non-pharmacist employee is under the direct supervision of the pharmacist
- In any given 48 hour period, no more than the following amounts may be dispensed to the same purchaser: 240 mL of any controlled substance containing opium, 120 mL of any other controlled substance, 48 dosage units of any controlled substance containing opium, or 24 dosage units of any other controlled substance
- Pharmacist must verify that the purchaser is at least 18 years of age
- A bound record book must be maintained by the pharmacy that includes all of the following information: name and address of the purchaser, name and quantity of purchased controlled substance, purchase date, and the name or initials of the pharmacist who dispensed the controlled substance to the purchaser
- A prescription is not required for the controlled substance under Federal, State, or local laws

Electronic Controlled Substances Prescriptions

In recent years, advances in technology have turned the potential for electronically written prescriptions into a reality. However, the DEA only began to officially address the issue of electronic controlled substances prescriptions in 2010. On March 31, the DEA published an interim final rule on electronic prescriptions for controlled substances with request for comment in the Federal Register.[12] This rule became effective on June 1, 2010 and provided healthcare practitioners with the option of writing prescriptions for controlled substances electronically.[13] Under this new rule, pharmacies are not required to accept electronic prescriptions for controlled substances for dispensing to the patient; acceptance of controlled substances prescriptions in this manner is purely at the discretion of the pharmacy.[14] In addition, it is important to keep in mind that these new electronic controlled substances prescription regulations are in addition to, not a replacement of, existing rules regarding controlled substances prescriptions.[13]

If a pharmacy chooses to accept electronic controlled substances prescriptions, the pharmacy may archive the prescriptions in an electronic format; however, this archiving is subject to provisions within the rule regarding security and retrievability.[13] Basic required components of the technology application for electronic controlled substances prescriptions are summarized in Table 7. In the end, it is the responsibility of the DEA-registered pharmacy to ensure that any technology application meets the standards within the rule prior to the pharmacy accepting electronic controlled substances prescriptions.

The contents of an electronic controlled substances prescription cannot be altered during electronic transmission between the healthcare provider and the pharmacy (i.e. an intermediary may not alter any aspect of the prescription).[13] Content changes may be made to a prescription upon pharmacy receipt. For

Table 7. Required Components of the Technology Application for Electronic Controlled Substances Prescriptions[13]

Required components include:

- Ability to digitally sign and archive the prescription OR import and archive the record digitally signed by the last intermediary (i.e. a vendor that receives and transmits an electronic prescription between the healthcare provider and the pharmacy)
- Electronically accept and store all information required by the DEA regarding dispensing of the prescription
- Allows the pharmacy to limit access to controlled substance prescription information to specific individuals or roles (i.e. pharmacy technician, pharmacist)
- Provides an internal audit trail mechanism that documents whenever a controlled substance prescription has been received, altered, or deleted
- Conducts a daily internal security audit that can not only identify security concerns, but also generates a report for pharmacy review once a concern has been identified

controlled substances, especially Schedule II prescriptions, specifically what changes are allowed remains an area of controversy that the DEA hopes to resolve in the future through the rulemaking process. Until that time, the DEA recommends that pharmacists adhere to State regulations or policies regarding what changes may be made to Schedule II electronic prescriptions. More information regarding electronic controlled substance prescriptions may be found in the Pharmacist's Manual (see the reference listing at the end of this module).

Combat Methamphetamine Epidemic Act of 2005

In 2006, the Combat Methamphetamine Epidemic Act was signed into law as part of the Controlled Substance Act.[3] Under the Combat Methamphetamine Epidemic Act, regulated sellers, such as retail pharmacies, must follow new requirements for the sale of over-the-counter List 1 chemicals (i.e. ephedrine, pseudoephedrine, and phenylpropanolamine). All of these chemicals may be used to manufacture methamphetamine illegally, thus the drive by the federal government to restrict the availability and distribution of these products.

The Combat Methamphetamine Epidemic Act created an entirely new category of drug products called "Scheduled Listed Chemical Products" or SLCPs.[3] Scheduled Listed Chemical Products include any legally marketed or distributed nonprescription product in the United States that contains pseudoephedrine, ephedrine, or phenylpropanolamine. The Act has many requirements that impact pharmacies including:

- SLCPs must be either placed behind the pharmacy counter or in locked cabinets in order to eliminate easy access
- The identity of every purchaser of SLCPs must be verified and the pharmacy must maintain a log book of each SLCP sale that includes the name and address of the purchaser, signature of the purchaser, name of the product sold, quantity sold, and date and time of purchase
- The logbook with the aforementioned information must be maintained by the pharmacy for at least 2 years
- All employees, including pharmacy technicians, must be trained on the requirements of the Combat Methamphetamine Epidemic Act and the pharmacy must certify to the DEA that training has been completed

The Act also places quantity limits on SLCPs.[3] Pharmacies can sell no more than 3.6 grams of a SLCP to an individual in a single day regardless of the number of transactions. For SLCPs in a nonliquid form, product packaging is limited to blister packs containing no more than 2 dosage units per blister. If blister packs are not feasible, the product must be packaged in unit dose packets or pouches. In a 30 day period, no more than 9 grams of a SLCP can be purchased by an individual in a retail setting; no more than 7.5 grams via mail order. Tables 8 and 9 provide information on retail daily sale limits and 30-day sale limits of SLCPs, respectively.

This federal law also requires regulated sellers to complete a "self-certification" process with the DEA.[3] Training of employees, such as pharmacy technicians, is included in this self-certification process. Self-certification may be completed on-line at: http://www.deadiversion.usdoj.gov/meth/index.html.[15] A regulated seller must complete self-certification on an annual basis.[3]

Controlled Substances – State Laws

Individual states may enact laws regulating controlled substances as long as these laws do not conflict with federal law.[2] In essence, state laws regarding controlled substances may never be "less strict" than their federal counterpart. An example of such a conflict was presented earlier in this module where a controlled substance is switched from Schedule II to another Schedule at the federal level, but remains a Schedule II controlled substance at the state level. When this occurs, the stricter state law applies and the states may still require the use of Form-222 for any transaction involving the controlled substance classified as a Schedule II under the state law. Another example from case law is *Lemmon Co. v. State Board of Medical Examiners*.[2] In this case, 2 pharmaceutical manufacturers challenged a regulation enacted by the New Jersey Board of Medical Examiners that prohibited the use of certain amphetamines and amphetamine-containing medications as weight loss agents for the treatment of obesity. Among the various arguments made by the manufacturers, one involved conflict with federal law. The lawyers for the manufacturers argued that the state law conflicted with federal law because "federal law does not so restrict the use of these drugs." The court ruled against the manufacturers stating that the regulation was not inconsistent with any existing federal law and was reasonably related to a genuine state interest that of controlling the traffic of controlled substances in New Jersey.

Table 8. Not to Exceed Amounts of SLCP Per Purchaser on a Daily Basis[3]

SLCP Ingredient	Number of tablets = 3.6 grams*
Ephedrine HCl 25 mg	175
Ephedrine Sulfate 25 mg	186
Pseudoephedrine HCl 30 mg	146
Pseudoephedrine HCl 60 mg	73
Pseudoephedrine HCl 120 mg	36
Pseudoephedrine Sulfate 30 mg	155
Pseudoephedrine Sulfate 60 mg	77
Pseudoephedrine Sulfate 120 mg	38

*3.6 grams is the daily individual sale limit for a regulated seller. Although phenylpropanolamine is classified as a SLCP, the FDA issued a voluntary recall of this ingredient as being unsafe for human consumption.

Table 9. Not to Exceed Amounts of SLCP Per Purchaser for a 30-Day Period[3]

SLCP Ingredient	Number of tablets at retail = 9 grams*	Number of tablets via mail order = 7.5 grams*
Ephedrine HCl 25 mg	439	366
Ephedrine Sulfate 25 mg	466	389
Pseudoephedrine HCl 30 mg	366	305
Pseudoephedrine HCl 60 mg	183	152
Pseudoephedrine HCl 120 mg	91	76
Pseudoephedrine Sulfate 30 mg	389	324
Pseudoephedrine Sulfate 60 mg	194	162
Pseudoephedrine Sulfate 120 mg	97	81

*9 grams is the 30-day individual sale limit for a regulated seller; 7.5 grams is the 30-day individual sale limit via mail order. Although phenylpropanolamine is classified as a SLCP, the FDA issued a voluntary recall of this ingredient as being unsafe for human consumption.

All states have a controlled substances act; however, only Alaska and Maine are the same as existing federal regulations.[16] Table 10 (on pages 18-20) presents some differences between states with regard to aspects of controlled substances law (i.e. laws regarding OTC sales of pseudoephedrine, allowing controlled substance prescriptions from out-of-state prescribers, and presence or absence of a controlled substance prescription monitoring program within a state). A controlled substance prescription monitoring program is a "statewide electronic database which collects designated data on substances dispensed in the state".[17] This electronic database is usually stored within a specific statewide regulatory, administrative, or law enforcement agency and the DEA has no oversight involvement. Information from the database may be distributed to individuals authorized under state law to receive such data for purposes related to their professional practice. Prescription drug monitoring programs serve several purposes with regard to controlled substances including:

- supporting access to legitimate medical use of controlled substances,
- identifying and deterring or preventing drug abuse and diversion,
- facilitating and encouraging the identification, intervention with, and treatment of persons addicted to prescription drugs,
- informing public health initiatives through outlining of use and abuse trends, and
- educating individuals about prescription drug monitoring programs and the use, abuse and diversion of and addiction to prescription drugs.

Specific state laws on prescription drug monitoring programs may be found at the National Alliance for Model State Drug Laws website (www.namsdl.org).

Table 10. State Laws for Drug Control Regulations and Prescription Requirements Related to Controlled Substances[16]

State or U.S. Territory	Does the state have laws/regulations on OTC sales of pseudoephedrine?	Is prescription allowed for controlled substance from an out-of-state prescriber?	Does the state have a controlled substance prescription monitoring program?
Alabama	Yes	Yes	Yes
Alaska	Yes	Yes	No
Arizona	Yes	Yes	No
Arkansas	Yes	Yes	No
California	Yes	Yes	Yes for Schedules II to IV
Colorado	Yes	Yes	Yes
Connecticut	No	Yes	No
Delaware	Yes	Yes; must verify physician's DEA number and receive a positive photo ID from the patient presenting the prescription	No
District of Columbia	Yes	Yes	No
Florida	Yes	Yes, but some restrictions apply	No
Georgia	Yes	Yes; allowed only if written at the office of the prescriber, not if in transit through the state; in addition, no prescriptions from out-of-state physician assistants or nurse practitioners are accepted	No
Guam	Yes	Yes	No
Hawaii	Yes	Yes	Yes
Idaho	Yes	Yes	Yes, electronic tracking of all Schedule II to IV medications
Illinois	Yes	Yes	Yes, utilizes an electronic data capture system
Indiana	Yes; purchaser must sign a log book and provide identification; all products must be either behind the pharmacy counter or within the line of sight of the pharmacy	Yes	Yes, Schedules II to V
Iowa	Yes	Yes, but some restrictions apply and the prescriber must be licensed in a state or territory in the U.S.	Yes, Schedules II to IV

Table 10. State Laws for Drug Control Regulations and Prescription Requirements Related to Controlled Substances[16] *Continued*

State or U.S. Territory	Does the state have laws/regulations on OTC sales of pseudoephedrine?	Is prescription allowed for controlled substance from an out-of-state prescriber?	Does the state have a controlled substance prescription monitoring program?
Kansas	Yes	Yes	Yes, from physician prescriber
Kentucky	Yes	Yes	Yes, electronic transmission of all schedule prescriptions and special, secure prescription blank required
Louisiana	Yes	Yes, but relies on professional judgment of the pharmacist; must also meet the same requirements as an in-state prescription and the prescriber has to have an individual DEA number	Yes
Maine	Yes	Yes	No
Maryland	No	Yes	No
Massachusetts	Same as federal regulations	Yes	Yes
Michigan	Yes	Yes, but has to be from a land border physician prescriber	Yes
Minnesota	Yes	Yes	Yes
Mississippi	Yes	Yes	Yes
Missouri	Yes	Yes	No
Montana	Yes	Yes	No
Nebraska	Yes	Yes, but must meet the same scope of practice requirements as in-state practitioners	No
Nevada	Yes	Yes	Yes
New Hampshire	No	Yes	No
New Jersey	Yes	Yes	No
New Mexico	Yes	Yes, but must meet the same requirements as an in-state prescription	Yes
New York	No	Yes	Yes, all written prescriptions must be issued on a serialized official New York State prescription form

Table 10. State Laws for Drug Control Regulations and Prescription Requirements Related to Controlled Substances[16] *Continued*

State or U.S. Territory	Does the state have laws/regulations on OTC sales of pseudoephedrine?	Is prescription allowed for controlled substance from an out-of-state prescriber?	Does the state have a controlled substance prescription monitoring program?
North Carolina	Yes	Yes if the prescriber is licensed in North Carolina	Yes
North Dakota	Yes	Yes	Yes
Ohio	Yes	Yes	Yes
Oklahoma	Yes	Yes, but out-of-state prescriptions are limited to prescribers with full prescribing authority in the state	Yes, utilizes an electronic data capture system
Oregon	Yes; pseudoephedrine is a Schedule III medication requiring a prescription	Yes	Yes
Pennsylvania	No	Yes	Yes
Puerto Rico	Same as federal regulations	Yes	No
Rhode Island	No	Yes	Yes, electronic data transmission of Schedules II to V
South Carolina	Yes	Yes, but relies on the professional judgment of the pharmacist	Yes
South Dakota	Yes	Yes	No
Tennessee	Yes	Yes	Yes
Texas	Yes	Yes	Yes, includes Schedules II to V
Utah	Yes	Yes	Yes
Vermont	No	Yes	No
Virginia	Yes	Yes, but must meet the same requirements as an in-state prescription	Yes
Washington	Yes	Yes, but out-of-state prescriptions are limited to prescribers with full prescribing authority in the state	No
West Virginia	Yes; ephedrine, pseudoephedrine, and phenylpropanolamine OTC sales are limited to 2 packages per sale, 3 gram limit per package	Yes, if prescriber licensed in a state or territory in the US	Yes, all Schedule II to IV prescriptions electronically reported
Wisconsin	Yes	Yes	No
Wyoming	Yes	Yes	Yes

Fraudulent Controlled Substances Prescriptions

Under the Controlled Substances Act, pharmacists and pharmacy technicians play key roles in preventing controlled substances prescription fraud and identifying prescriptions that are illegitimate. Patients may go to great lengths to fraudulently obtain a controlled substance including:[3]

- Altering a legitimately prescribed prescription
- Printing prescription pads with a legitimate healthcare provider's name, but with an accomplice's call back number that is answered when the pharmacy calls to verify the prescription
- Calling in their own prescription with their own telephone number as a call-back for verification
- Stealing legitimate prescription pads from a healthcare provider's office or hospital
- Going to an emergency room department with complaints of pain simply to receive a prescription for a controlled substance

Obviously, patients have become more inventive with ways to obtain controlled substances illegally. Therefore, pharmacists and pharmacy technicians need to be aware of criteria that may aid them in identifying both controlled substances prescriptions that are issued for illegitimate medical purposes as well as criteria for identifying forged prescriptions – see Table 11.

In addition to the criteria listed in Table 11, pharmacists and pharmacy technicians can employ simple prevention techniques that may significantly reduce controlled substance prescription fraud. These include knowing the prescriber and his/her signature, being familiar with a prescriber's DEA registration number, knowing the patients who come to the pharmacy, and checking the date on the controlled substance prescription to assess whether or not

Table 11. Criteria for Identifying Illegitimate and Forged Controlled Substances Prescriptions[3]

Criteria for identifying prescriptions not issued for a legitimate medical purpose	Criteria for identifying a forged prescription
• Healthcare provider writes significantly more controlled substance prescriptions (or writes for larger quantities) than other prescribers in the area • Patients return to the pharmacy too frequently (i.e. a prescription which should last a month for a legitimate medical purpose is being refilled weekly or daily) • Healthcare provider writes for drugs with "antagonistic" effects (i.e. drug abusers often request prescriptions for "uppers and downers" at the same time) • Patient presents prescriptions to the pharmacy written for other individuals other than the patient • Similar prescriptions from the same healthcare provider are presented to the pharmacy by a variety of individuals at the same time • Patients who are not regular customers, or who do not live in the area, present prescriptions to the pharmacy from the same healthcare provider	• Prescription looks "too good" (i.e. the handwriting of the prescriber is too legible) • Medication quantity, directions for use, or dosages vary from usual medical usage • Prescription does not contain acceptable standard abbreviations or appears too "textbook" • Prescription appears to be a photocopy and not an original • Directions for use are written out in full with no standard abbreviations • Different color ink or different handwriting is used on the prescription

it has been presented to the pharmacy for filling in a reasonable time frame.[3] If there is any doubt regarding the validity of a controlled substance prescription, the pharmacist should make every effort to contact the prescriber for verification. The case below illustrates ways a pharmacist or pharmacy technician may identify a fraudulent controlled substance prescription.

For Further Information

There are a variety of internet resources that pharmacy technicians may find useful with regard to the Controlled Substances Act, drug abuse, and legal/policy issues related to controlled substances. These include:

DEA Office of Diversion Control (http://www.deadiversion.usdoj.gov/): This site is the home for the Pharmacist's Manual – an information outline of the Controlled Substances Act. The site also contains common questions and answers for pharmacy personnel on a variety of topics within the Act.

DEA Home Page (http://www.justice.gov/dea/index.htm): The home page for the DEA contains drug information resources, information regarding drug prevention for young adults and parents, resources on diversion control and prescription drugs, and information on federal drug policies.

Office of National Drug Control Policy (http://www.whitehousedrugpolicy.gov/): The Office of National Drug Control Policy establishes policies, priorities, and objectives for the national drug control program. The goals of the program are to reduce illicit drug use, manufacturing, and trafficking. This website contains information related to these goals such as drug policy development and information on substance prevention, treatment, and recovery.

Food and Drug Administration (www.fda.gov): The FDA website is another avenue to access specific information in the Controlled Substances Act. This site also contains drug information on controlled substances such as warning updates or risk evaluation and mitigation strategies (REMS).

Case 3. Identification of a Fraudulent Controlled Substance Prescription

A patient comes into the pharmacy with a new Schedule II controlled substance prescription. The patient is unknown to the pharmacy technician; however, the prescription appears to have all the required elements for a Schedule II prescription. In fact, the prescription looks almost too precise and well written. In addition, the directions for use are written out in full with no standard abbreviations that are normally observed. The technician presents the prescription to the pharmacist and points out her concerns. The pharmacist also does not know the patient and mentions that there have been similar prescriptions from the same prescriber presented to the pharmacy by a variety of different individuals as of late.

In the above example, what "tipped off" both the pharmacy technician and the pharmacist regarding the potential fraudulent nature of the Schedule II prescription?

1. The prescription itself was "too good". Technicians should be concerned with these types of prescriptions where the prescriber's handwriting is too legible.
2. The directions for use were written out in full with no standard abbreviations.
3. The patient is not a regular customer and is unknown to both the pharmacy technician and the pharmacist.
4. Recently, the pharmacist has seen similar prescriptions from the same prescriber being presented to the pharmacy for filling from a variety of individuals.

All of these aspects should raise doubt regarding the legitimacy of the prescription and the pharmacist should make every effort to contact the prescriber for verification of the prescription.

Substance Abuse and Mental Health Services Administration (SAMHSA) (http://www.samhsa.gov/index.aspx): The mission of SAMHSA is to reduce the impact of substance abuse and mental illness in communities across the United States. Their website contains a variety of information on these topics including prevention of substance abuse, health reform initiatives, and public awareness and support.

National Association of Boards of Pharmacy (www.nabp.net): This website contains regularly updated news items on issues related to the Controlled Substances Act among other issues concerning the practice of pharmacy. These updates may include changes to the Act or news reports regarding pharmacists who have been charged or convicted for violating the Act.

National Association of State Controlled Substances Authorities (http://www.nascsa.org/): The purpose of NASCSA is to provide a continuing mechanism through which state and federal agencies can work to increase the effectiveness of state and national efforts to prevent and control drug diversion and abuse. NASCA facilitates and coordinates the gathering and distribution of controlled substances information and provides networking opportunities for individuals responsible for controlled substances issues.

National Alliance for Model State Drug Laws (http://www.namsdl.org/home.htm): The National Alliance for Model State Drug Laws is a resource for various professionals "striving for comprehensive, effective state drug and alcohol laws and policies." This site specifically contains a lot of information on prescription drug monitoring programs.

SUMMARY

Pharmacy technicians need to have a general understanding of the important aspects of the Federal Controlled Substances Act. The goal of the Act is to improve the manufacturing, importation/exportation, distribution, and dispensing of controlled substances; essentially resulting in a closed system for controlled substances distribution in order to prevent diversion, illegal use, and abuse. This closed system allows for controlled substances to be traced from initial manufacture to final dispensing to a patient in the pharmacy.

The Controlled Substances Act classifies controlled substances into different Schedules based on abuse potential, requires pharmacy registration with the DEA, and details a variety of requirements for controlled substance prescriptions, ordering, recordkeeping, and dispensing. Beyond the federal Act, many states have enacted laws regulating controlled substances as well. These state laws may never be "less strict" than the federal law and if there is ever a conflict between state and federal controlled substance law, the pharmacy technician should remember that the stricter law always applies.

Finally, the pharmacy technician should be aware of the various criteria for identifying illegitimate and forged controlled substances prescriptions. Patients have become more inventive with regard to ways to obtain controlled substances fraudulently over the years. Pharmacy technicians can play a key role in preventing controlled substance prescription fraud and identifying prescriptions that are illegitimate. ■

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