Technician Tutorial: Scheduled Drugs

In the U.S., the federal Controlled Substances Act (CSA) regulates controlled substances. The U.S. Drug Enforcement Administration (DEA), which is a part of the U.S. Department of Justice, enforces the CSA. The CSA, in combination with individual state laws, dictates the specifics of the manufacturing, prescribing, and dispensing of controlled substances. In some cases, state laws are even more restrictive than federal laws. (The stricter laws always prevail.)

The CSA designates five different schedules of controlled substances, Schedule I through Schedule V. Some drugs that are designated as controlled substances include opioids (e.g., codeine, morphine, oxycodone, etc), stimulants (e.g., amphetamine, methylphenidate, etc), and sedatives (e.g., barbiturates [phenobarbital, etc], benzodiazepines [alprazolam, diazepam, lorazepam, etc]). Factors that are considered when drugs are scheduled include abuse potential, history of abuse and current pattern of abuse, significance of abuse, and whether the substance is a precursor of another substance that is already scheduled.

Schedule I controlled substances won’t be seen in a pharmacy. These drugs have a high potential for abuse, lack data on safe use in humans, and have no currently accepted medical use. Heroin, for example, is a Schedule I controlled substance. This might seem odd, but it’s important to remember that the CSA doesn’t apply just to health care settings. The CSA was written for the purpose of general drug abuse prevention and control. Its application in health care is just one aspect.

Drugs that are Schedule II through V are commonly prescribed and dispensed to patients. These drugs do have accepted medical uses. Schedule II drugs, often called “C-IIIs,” have the highest potential for abuse and psychological dependence or addiction. Schedule V drugs have the lowest potential for abuse and addiction. Scheduled drugs will always have a large letter “C” on the label, with a Roman numeral designating the schedule.

The schedule of a drug affects the way it can be prescribed, dispensed, stored in the pharmacy, and ordered from the wholesaler or manufacturer. In general, Schedule II drugs have the most stringent requirements.

Here are some examples of scheduled drugs. A complete list can be found at http://www.deadiversion.usdoj.gov/schedules/index.html.

Schedule II:
- cocaine
- codeine (single ingredient)
- fentanyl (Actiq, Duragesic, Fentora, etc)
- hydrocodone (Zohydro ER)
- hydrocodone combinations (Lortab, Vicodin, etc)
- hydromorphone (Dilaudid, etc)
- meperidine (Demerol)
- methadone (Dolophine, etc)
- methylphenidate (Concerta, Ritalin, etc)
- nabilone (Cesamet)
- opium tincture
- oxycodone products (OxyContin, Percocet, etc)
Schedule III:
- acetaminophen/codeine (not more than 90 mg codeine per dosage unit)
- anabolic steroids
- buprenorphine (Buprenex, Butrans, etc)

Schedule IV:
- alprazolam (Xanax)
- butorphanol (Stadol)
- carisoprodol (Soma)
- clonazepam (Klonopin)
- diazepam (Valium)
- eszopiclone (Lunesta)
- lorazepam (Ativan)
- modafinil (Provigil)
- tramadol (Ultram, etc)
- zaleplon (Sonata)
- zolpidem (Ambien)

Schedule V:
- codeine combination products with no more than 200 mg of codeine per 100 mL (Robitussin AC)
- diphenoxylate combination products with no more than 2.5 mg of diphenoxylate and not less than 25 mcg of atropine sulfate per dosage unit (Lomotil)
- pregabalin (Lyrica)

Note that some Schedule V drugs may not require a prescription in some states. However, they must be dispensed by a pharmacist because of DEA rules.

Federal law restricts the sale of pseudoephedrine, since it’s a precursor of methamphetamine. However, it’s not scheduled in II-V according to federal law. In some states, pseudoephedrine is scheduled.

Mr. Smith, a 65-year-old man who was diagnosed with bone cancer this year, brings in the following prescription:
Mr. Smith has been getting oxycodone for a few months. This is the first time he’s used Duragesic. This prescription is interpreted as “Duragesic 25 mcg/h patch, apply one patch every three days.”

What are the requirements for prescriptions for Schedule II-V controlled substances?
According to federal law, prescriptions for all controlled substances must include:
- Date of issue
- Patient’s name and address
- Prescriber’s name, address, and DEA registration number
- Drug name
- Drug strength
- Dosage form
- Quantity prescribed
- Directions for use
- Number of refills

Schedule II prescriptions have the following additional restriction:
- No refills

According to federal law, Schedule III through V prescriptions can be faxed, verbal, electronic, or written. This means, for example, a diazepam prescription can be faxed to the pharmacy by the prescriber. Or it can be called into the pharmacy or sent over electronically by the prescriber. But remember, state laws may have further restrictions for accepting and filling faxed, verbal, or electronic prescriptions for scheduled drugs.

Schedule II prescriptions are different, and cannot be called in over the phone or faxed to the pharmacy in most cases. These prescriptions generally must be handwritten and signed by the prescriber, or electronically prescribed through a valid e-prescribing system.

There are exceptions to this rule though. Federal law allows Schedule II prescriptions to be called into the pharmacy in an emergency situation. The prescription can only be for the amount of drug needed during the emergency period. The pharmacist must then obtain a written, signed prescription from the prescriber within seven days of their authorizing the emergency situation. Keep in mind this is another area where state laws may have further restrictions. In some cases, days’ supplies are limited or the original prescription must be received in three days instead of seven days.

Federal law also allows Schedule II prescriptions to be faxed to the pharmacy by the prescriber’s office under limited circumstances. For example, in order to expedite the filling of a prescription, a prescriber can fax a C-II prescription to the pharmacy. But before the pharmacist can dispense the med to the patient, the pharmacist must have the original, written Rx in hand. This way the pharmacist can verify the prescription first. Faxed C-II prescriptions are also allowed in long-term care facilities, and for certain hospice patients. In these cases, the faxed prescription is considered the original prescription. The pharmacy generally isn’t required to obtain the original, written prescription.

What is the significance of a prescriber’s DEA number? How can pharmacists or technicians verify that a prescriber’s DEA number is valid?
A prescriber’s Drug Enforcement Administration number, or DEA number, is assigned when the prescriber registers with the DEA. A DEA number is required to prescribe for controlled substances. The DEA number always has nine characters. The first two characters are letters, and the last seven are numbers. The first letter is always A, B, F, G, or M. (It might also be X if a prescriber is prescribing medications such as
buprenorphine for opioid addiction.) The second letter of the DEA number is the first letter of the prescriber’s last name, although it may be different if the prescriber’s last name has changed, such as if he or she married. You can verify that a DEA number is authentic by looking at the numbers. Here’s how:

- Add the first, third, and fifth digits together.
- Add the second, fourth, and sixth digits together. Multiply the sum by 2.
- Add these two results together. The last digit on the right must match the last digit of the DEA number.

For example, Dr. Blue’s DEA number is AB2434544. To check:

- Add the first, third, and fifth digits together. (2 + 3 + 5 = 10)
- Add the second, fourth, and sixth digits together. Multiply the sum by 2. ([4 + 4 + 4] * 2 = 24)
- Add these two results together. The last digit on the right must match the last digit of the DEA number. (10 + 24 = 34. The last number of Dr. Blue’s DEA number is, in fact, 4. This DEA number checks out.)

Keep in mind that pharmacies are also required to have a DEA number to dispense prescriptions for controlled substances. Insurance companies may request the pharmacy’s DEA number for questions regarding payment for controlled substance prescriptions. It may also be required when a pharmacy transfers a controlled substance prescription to or from another pharmacy. The pharmacy DEA number is often found in an easily accessible location in the pharmacy, such as on a piece of paper taped to the computer monitor.

**What is the maximum days’ supply of a Schedule II drug that can be authorized per prescription?**

Federal law doesn’t dictate the maximum days’ supply of a Schedule II drug that can be authorized per prescription. Nor does federal law dictate that a C-II prescription be filled within a certain amount of time after it was issued. Instead, this is determined by state law. Check with your state board of pharmacy for specific laws in your state.

**Can a prescriber provide a patient with more than one prescription for a Schedule II drug on the same day? For example, would it be acceptable for Dr. Blue to give Mr. Smith extra prescriptions to put “on hold” to be filled in future months?**

Federal law does allow a prescriber to write multiple C-II prescriptions, for the same drug, for an individual patient, on the same day. These prescriptions can be written for a total of 90 days’ supply. This is beneficial for stable patients, when the prescriber judges that there is not a need to see the patient on a more frequent basis. Each prescription must include the actual date that it was written, and the earliest date that it can be filled. If a state has stricter rules that prohibit this practice, the state rules prevail.

It is important to consult the pharmacist about the appropriateness of multiple C-II prescriptions. This practice is most often used for patients on a maintenance dose of a Schedule II drug, such as a child on long-term therapy with stimulant medication for the treatment of attention deficit hyperactivity disorder. In this case, it would not be appropriate for Dr. Blue to write multiple Duragesic prescriptions for Mr. Smith since it’s a new medication for Mr. Smith and his dose may still need to be adjusted.

**Can prescriptions for controlled substances be refilled?**

Per federal law, prescriptions for Schedule II drugs cannot be refilled. Prescriptions for Schedule III and IV drugs can include up to five refills, and can be refilled for up to six months after the date of issue. This is in comparison to noncontrolled substances, which can be refilled for up to one year from the date when the
prescription is issued, depending on the state. Schedule V substances can be refilled as authorized by the prescriber according to federal law.

**What should you think about when dispensing controlled drugs?**

**Legal requirements.** Especially for C-IIIs, there are restrictions on dispensing. Remember that a written prescription is required for C-IIIs, and that refills for C-IIIs are not allowed. Partial fills are another issue for C-IIIs. Partial fills are allowed, but the remainder of drug must be dispensed within 72 hours. After 72 hours, the prescription is void. This is discussed in more detail in one of the following sections.

**Amount dispensed.** Always follow your pharmacy’s procedures for counting and documenting the number of tablets, capsules, etc. dispensed in a controlled substance prescription. For example, many pharmacies require pharmacists or technicians to double-count and initial controlled prescriptions to support inventory control. Pharmacies may “back-count” the bottle, or count the number of pills remaining in the stock bottle to verify it against existing inventory levels. These procedures can also help verify the amount dispensed if a discrepancy is later identified by the patient.

Keep in mind that the role of the technician in preparing controlled substance prescriptions may vary depending on the practice and the supervising pharmacist. Check with your pharmacist if you are unsure about your role in handling controlled substances.

**Auxiliary labels.** The majority of controlled substances (e.g., barbiturates [phenobarbital, etc], benzodiazepines [alprazolam, diazepam, lorazepam, etc], opioids [codeine, hydrocodone, morphine, etc]) will require an auxiliary label warning about drowsiness or sedation. However, drugs like amphetamine, methylphenidate, and modafinil are stimulants. These have the opposite effect, and will not require a label warning about sedation. Check with your pharmacist if you are unsure about auxiliary labeling requirements for a controlled prescription.

**Safe use and disposal.** Some controlled substances, such as opioids, are considered high-risk medications. These drugs aren’t necessarily more likely to be misused or to be involved in medication errors. However, they do have a relatively heightened risk of causing significant patient harm when they are used in error. Fentanyl patches have made headlines in recent years for causing deaths when misused.

Improper disposal of some controlled substances can be dangerous. This is especially true when there is still active drug available, as with unused drugs, or with some used transdermal patches, and with partially used lozenges, like Actiq. The CSA does not allow controlled substances to be returned to a pharmacy for disposal. Instead, most should be flushed down the toilet, not placed in the trash where they could be retrieved by kids or pets. Fentanyl patches should be folded, with the sticky side stuck together, and then flushed. Use our PL Patient Education Handout, Medication Disposal Guide, to help inform patients and caregivers of steps to dispose of unused or partially used drugs. This is very important to avoid potentially disastrous consequences.

**As you are filling the prescription, you realize that there are only eight Duragesic patches available in your inventory. What are the options for filling Mr. Smith’s prescription?**

Mr. Smith’s prescription will require a “partial fill.” If only eight patches are dispensed, the prescription will become void if the remainder of the prescription isn’t filled within 72 hours.

If your pharmacy can either order or borrow the remaining two patches and receive them within 72 hours, Mr. Smith could get his full ten patches from your pharmacy with no other action necessary. If the patches can’t be obtained by your pharmacy within 72 hours, the pharmacist could call the prescriber, another prescription could be written for the remaining two patches, and Mr. Smith or his caregiver could pick them
up before he needs them. Alternately, the pharmacist might refer Mr. Smith to another pharmacy that has the full ten patches in stock.

Keep in mind that there is an exception to the rule for partially filling a C-II. This applies to patients who are in a long-term care facility or who are terminally ill. “Terminally ill” or “LTCF” must be noted on face of the prescription. The date of the partial fill, the quantity dispensed, the remaining quantity to be dispensed, and the pharmacist’s initials must be noted on the back of the prescription.

**Are there special procedures for ordering and storing controlled drugs?**
The CSA requires that Schedule II controlled substances are ordered using a special form called the DEA Form 222. It’s available either as a paper form or electronically. The paper form is supplied in triplicate. The first and second copies are sent to the supplier, and the third copy is kept for pharmacy records. The second copy gets sent on to the DEA by the supplier. As each order arrives in the pharmacy, the pharmacy’s copy of Form 222 should be pulled and the date and amount of drug received must be documented on that form. The form should be re-filed and saved for two years. Other scheduled drugs can be ordered through a supplier or wholesaler without a special form.

Since prevention of drug abuse and diversion is the main reason for scheduling controlled substances, inventory control is extremely important. The idea behind storage requirements for controlled substances is to prevent theft and diversion. All controlled substances must be stored in a securely locked cabinet or dispersed throughout the pharmacy shelves with noncontrolled medications.

Many pharmacies keep their C-IIs in a safe, a cabinet, or locked drawers. But don’t be surprised if your pharmacy stores C-IIs on the pharmacy shelves with other meds. This is okay as long as your state law doesn’t restrict this practice. The meds just shouldn’t be in a section by themselves designated “controlled meds” or “C-IIs” without being locked up. The idea is to make it harder for a person trying to steal to find them.

Many pharmacies store their Schedule III, IV, and V medications on pharmacy shelves with other noncontrolled meds. They don’t have to be locked up. They can be stored alphabetically with other meds. The only requirement is that the area be secure. So it is important to keep the pharmacy doors locked and only allow pharmacy personnel in the pharmacy.

All prescription and inventory records for C-II medications must be kept separately from all other pharmacy records. This means written prescriptions must be stored separately from other controlled substance and noncontrolled substance prescriptions. The same goes for electronic prescriptions, DEA 222 forms, and biennial inventory reports for C-II medications.

Prescription records for Schedule III, IV, and V drugs must be kept either separately from C-II and noncontrolled substance records, or together with noncontrolled substance records. But the catch is that these records must be readily retrievable if the pharmacy is audited by DEA. These rules apply to electronic prescriptions, as well as inventory and order records.

Some pharmacies will have three separate files for prescription records: one for C-II prescriptions; one for Schedule III, IV, and V prescriptions; and one for noncontrolled prescriptions. They’ll also do this for their orders and inventories. It helps keep everything separate and easily retrievable if audited by the DEA.

The DEA requires that pharmacies hold onto prescription and order records for at least two years. This is the same amount of time that is required for controlled substance inventory records. Many states or employers require you to hold on to them for longer.
**What should I do if there is a discrepancy in the count of a controlled substance?**
If there’s a discrepancy between the amount of drug you should have and the amount of drug you actually have, steps must be taken to resolve the discrepancy. Double-checking arithmetic and comparing dispensing records and orders received to check for omissions or duplications in the inventory record are steps that can be taken to resolve discrepancies.

**How should controlled substances be disposed of in the pharmacy?**
There may be circumstances when a controlled substance needs to be destroyed and disposed of at the pharmacy level.

You’ll see this frequently if you work in a hospital. Many times the full dose of a controlled substance is not given to a patient. In these cases, technicians may be asked to witness the disposal of the remainder of the dose. This process is called “wasting” and typically requires two signatures, the one destroying the medication and the witness. Many hospitals are given a blanket approval from the DEA for regular, periodic destruction.

Community pharmacies are also allowed to destroy controlled substances at the pharmacy level. However, they must request permission from DEA before destroying controlled substances. The pharmacy is required to submit a DEA Form 41 to document the destruction.

**How can I identify a forged prescription?**
Most forged prescriptions are for C-IIIs, although patients may forge prescriptions for other controlled or noncontrolled substances. If you notice something “fishy” about a prescription, alert the pharmacist discreetly and immediately. Here are some things to watch out for:

- Altered quantity to dispense
- Prescriptions that are written on stolen or photocopied prescription forms, or on prescription forms from hospitals that don’t have a physician’s name on them
- Prescriptions that are from other cities or other states
- Altered DEA number, or a DEA number that is not authentic
- Prescriptions with a “textbook” appearance
- Prescriptions that are out of the ordinary, such as those with no abbreviations, different inks or writing, odd days’ supply, etc.
- Prescriptions with excessive quantities, doses, or directions

Depending on the situation and on pharmacy policy, the pharmacist might take a number of actions, such as contacting the prescriber to verify the prescription or returning the prescription to the patient. Keep in mind that this can be a very serious situation, and that the patient might become angry and volatile. Talk to your pharmacist if you are unsure about how to handle this type of situation in your pharmacy. Also, find out if you are able to access your state’s prescription drug monitoring program, and when this would be appropriate.

**What are some considerations about controlled drugs in the hospital setting?**
Some of the concerns in the community setting, like appropriate number of refills, getting a written prescription for all C-IIIs, etc. aren’t issues for hospital inpatients. Here are some things for technicians to consider that are specific to hospital practice:

- When controlled drugs are kept on a patient care unit, they must be stored in a secure, locked place. Often, an automated dispensing machine, like Pyxis, is used for this purpose.
- When you’re delivering controlled drugs to a patient care unit, be sure to never leave them unattended on a cart in an elevator or hallway.
• Since each patient care unit is likely to have its own inventory of controlled substances, discrepancies in the counts can occur from time to time. It is important to resolve these discrepancies as soon as they are discovered. Know your pharmacy’s procedure for resolving and reporting discrepancies.
• If you are delivering a controlled drug directly to a nurse, it’s likely that he or she will need to “sign” for it. Know your pharmacy’s procedure for this. In general, controlled substances should not be sent to patient care units via pneumatic tube system.
• Since the full dose of a controlled substance might not always be given to a patient, you may be asked to witness the disposal of the remainder of the dose. This is called “wasting” and typically requires a double signature. If an automated dispensing system is used, you will have to enter your username and password instead.
• Injectable opioids are considered high-risk drugs, so they may require special auxiliary labels. Know your pharmacy’s policy for this.

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