Technician Tutorial:  
Dispensing C-II Controlled Substances

Schedule II controlled substances, commonly referred to as “C-IIs” are among the most tightly regulated drugs that U.S. pharmacies are allowed to dispense. C-IIs are often set apart from other controlled substances (Schedules III-V) in that they have their own set of rules for how prescriptions must be written, how they are dispensed, how they are ordered, and so on. Besides taking the special steps required by federal and state law, there are things that pharmacy technicians can do to help patients be safe with their Schedule II controlled substances.

Angelica Copenhagen brings in the above Rx for 400 mcg fentanyl lozenges, one or two every six hours as needed, into your pharmacy. You know that she has been diagnosed with pancreatic cancer, and fentanyl is just one of several medications she has been using over the past several months for pain and other problems associated with her cancer. This strength of fentanyl lozenge is higher than the prescription she got filled one week ago.

[NOTE: The following information is based on U.S. federal regulations of controlled substances.]

Why are Schedule II controlled substances so tightly regulated?
Medications are scheduled according to the U.S. federal Controlled Substances Act (CSA). Factors that are considered when medications are scheduled include benefits, such as pain control, and risks, such as abuse potential. Of all the scheduled drugs available for medical use, Schedule II drugs have the highest potential for abuse and psychological dependence or addiction. This is the reason for tight regulation.

Most opioids (e.g., hydromorphone, morphine, oxycodone, etc) are Schedule II controlled substances. These are also considered to be “high alert” medications. This doesn’t mean they’re more likely to be involved in med errors. It DOES mean that med errors involving these drugs are more likely to result in serious patient harm. In fact, fentanyl patches have gotten all sorts of press because of deadly errors or misuse. We have a PL Technician Tutorial, Safety Considerations with Opioids, to fill you in on the details.

Note that hydrocodone combination products have been rescheduled from C-III to C-II on the federal level. This is official on October 6, 2014. Hydrocodone combinations are the most frequently prescribed...
opioid in the U.S., and also the most misused and abused. This change is a big deal for pharmacies, prescribers, and patients. The more strict rules for C-IIs (all of those that you will read about in the following sections) will need to be followed for hydrocodone combination products starting on October 6th. We have a PL Patient Education Handout, Changes for Hydrocodone Combinations and a fax letter for prescribers, Hydrocodone Combinations are Moving from Schedule III to Schedule II, that your pharmacy can use to help everyone understand the change.

What drugs are considered Schedule II controlled substances, or “C-IIs”?
Under the Controlled Substances Act, Schedule II drugs include:
- Cocaine
- Codeine (single-ingredient)
- Fentanyl (Abstral, Actiq, Duragesic, etc)
- Hydrocodone (both single-ingredient [Zohydro] and as of October 6, 2014, combinations such as Lortab, Tussionex, Vicodin, etc)
- Hydromorphone (Dilaudid, etc)
- Meperidine (Demerol, etc)
- Methadone
- Methylphenidate (Concerta, Ritalin, etc)
- Nabilone (Cesamet)
- Opium tincture
- Oxycodone products (OxyContin, Percocet, etc)

You can find a list of drugs that fall under Schedules III-V in our PL Technician Tutorial, Scheduled Drugs.

Who makes the rules for how C-IIs must be handled?
In the U.S., the U.S. Drug Enforcement Administration (DEA), which is a part of the U.S. Department of Justice (DOJ), makes rules on the federal level for how C-IIs must be handled with regard to prescribing, dispensing, etc. However, some states have made rules that are stricter than federal rules. For example, Pennsylvania has more stringent restrictions on quantities and expirations of C-II prescriptions. When this is the case, the stricter rule must be followed.

Who can write prescriptions for C-IIs?
This can vary from state to state, so it’s important to know your state’s rules. For example, Illinois allows prescribers other than doctors, dentists, veterinarians, and podiatrists to write controlled substance prescriptions. This means prescribers such as nurse practitioners (NPs), optometrists (ODs), and physician assistants (PAs) can order scheduled drugs, but with limits. For example, nurse practitioners and physician assistants are permitted to prescribe up to a 30-day supply of a C-II. Optometrists can’t prescribe any C-II medications.

What are some of the differences between the way prescriptions for C-IIs must be handled in comparison with other scheduled drugs and nonscheduled drugs?
As mentioned before, Schedule II controlled substances can have requirements that set them apart from other controlled substances and noncontrolled drugs that are dispensed in health care settings. Some of these requirements that are relevant to the practice of pharmacy technicians, as well as tips for providing patients with helpful information, are listed below.

 Rx requirements. Prescriptions for Schedule II controlled substances must be written by the prescriber. Each written C-II prescription must include the following:
- 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
• Manual signature of prescriber

There are a few exceptions to the requirement that prescriptions for C-IIIs be written. The following are according to federal law, but remember that laws in your state might be stricter:

• C-IIIs can be e-prescribed.
• Prescriptions for C-IIIs can be faxed or phoned for patients in long-term care facilities or for hospice patients. There are some very specific requirements in order for these faxed prescriptions to be legal. However, it’s important to know that the faxed prescription in these cases serves as the original.
• A prescriber can phone in a prescription for a C-II in an emergency. However, the prescription can only be for the amount of drug needed during the emergency period, and the pharmacy must obtain a written prescription to cover the phoned-in prescription within seven days.

You know that fentanyl is a C-II. The written Rx contains all the necessary information, including the prescriber’s DEA number and manual signature. You’re sure that the fentanyl lozenge is Actiq or its generic, but you double-check with the pharmacist to make sure since there are several of these types of products on the market, including Abstral (sublingual tablet), Actiq (lozenge), Fentora (buccal tablet), and Onsolis (buccal film).

Refills/days’ supply. Prescriptions for C-IIIs cannot be refilled. (Note, however, that valid refills from prescriptions for hydrocodone combinations written before October 6, 2014, can be dispensed according to federal law up until April 8, 2015. However, your state board of pharmacy, employer, and computer system will further determine how these should be handled. Talk to your pharmacist to get the specifics.)

Even though C-IIIs cannot be refilled, according to federal law, multiple prescriptions for a C-II can be issued to a patient at one time by a prescriber, for up to a 90-day supply of the med. The actual date that the Rx was written as well as the earliest date that each Rx can be filled must be written on the prescription.

There is no maximum days’ supply for Schedule II drugs according to federal law. However, your state may have limits on days’ supply or quantity that can be dispensed at one time.

Filling. Federal law does not dictate that a prescription for a Schedule II drug be filled within a certain amount of time after it’s issued. However, this may be limited by state law. For example, in Illinois, a C-II Rx must be filled within 90 days of issue.

Another important thing to remember when filling an Rx for a C-II is that although partial fills are allowed, the remainder of the drug must be dispensed within 72 hours. If the remainder is not filled within 72 hours, the Rx is void.

The role of the technician in preparing prescriptions for C-IIIs may vary depending on the practice and the supervising pharmacist and on state law. For example, some pharmacists personally count and verify all prescriptions for Schedule II controlled substances to ensure that they can account for each tablet, capsule, etc. In other practices, pharmacists ask technicians to pull Schedule II drugs and perform a first count, while the pharmacist double-counts the technician and personally records the amount of drug
dispensed in a C-II logbook. Pharmacies may require a “back-count” when a C-II Rx is filled, which means counting the number of pills remaining in a 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.

**Labeling.** Be sure to enter **clear directions** for use on C-II Rxs. Meds that are used to treat episodes of breakthrough pain, such as the oral transmucosal fentanyl products (Abstral, Actiq, etc) and immediate-release oxycodone, morphine, etc. can be particularly confusing. Use extra space on the label if needed, to make the directions very clear. Make sure you use language that specifies the correct dosage form, such as “apply a patch,” “place a sublingual tablet under the tongue,” etc.

Most Schedule II controlled substances (e.g., codeine, fentanyl, morphine, etc) will require an **auxiliary label warning about drowsiness or sedation.** However, drugs like methylphenidate 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.

Some C-IIs such as fentanyl products and oxycodone require that a **MedGuide** be dispensed. You can get these and any other MedGuide you need on our website.

Improper **storage and disposal** can be a source of big problems with Schedule II controlled substances. Help patients remember not to advertise to friends and family that they’re taking these drugs. Theft from the home is not unusual since many of these drugs can have high street values. Keeping these meds (and all meds) in a locked area is prudent to prevent both theft and accidental access. Opioids can be very dangerous to kids and pets, even if they have already been used (e.g., fentanyl lozenges or patches) since it takes just a little bit of drug to slow their breathing and drop their blood pressure. Use our **PL Patient Education Handouts, Medication Disposal Guide and Prevent Medication Poisonings in Your Home**, to help patients keep their meds from falling into the wrong hands (or paws!).

*You carefully type the instructions for Ms. Copenhagen’s Rx so they appear neatly on the label. However, you see that there are only 20 doses in your inventory. You tell the pharmacist and she confers with Ms. Copenhagen. Ms. Copenhagen confirms that she can pick up the remaining ten doses two days from today. The pharmacist makes a note to order the fentanyl lozenges so they will be available when she comes to get them. You make sure to apply an auxiliary label to the partially filled Rx for Ms. Copenhagen, to help her remember that the fentanyl might make her drowsy.*

**Are there special requirements for ordering and keeping inventory of Schedule II controlled substances?**

Schedule II controlled substances can’t be ordered through your wholesaler the same as other drugs such as antibiotics, blood pressure meds, etc. The Controlled Substances Act 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. Scheduled drugs should be stored in a locked cabinet or
secure area. Records and inventory of C-IIs must be kept and separated from all other pharmacy records. 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. When stock is back-counted as prescriptions are filled, as described in the section about filling prescriptions for C-IIs, this is referred to as perpetual inventory.

When C-IIs have passed their expiration date, DEA Form 106 must be completed and destruction of the expired drugs must be witnessed. Follow your pharmacy’s policy.

When you place an order for Schedule II controlled substances on DEA Form 222, you make sure to order enough fentanyl 400 mcg lozenges for Ms. Copenhagen. You get two boxes of 30 doses each, since it’s possible she will come back in to get more within the next couple of weeks. The pharmacist signs the form and thanks you for remembering to order the fentanyl.

What are some considerations about Schedule II controlled substances in the hospital setting?

Some of the concerns with scheduled drugs in the community setting, like appropriate number of refills, getting a written prescription for all C-IIs, etc., aren’t issues for hospital inpatients. Here are some things for technicians to remember that are specific to hospital practice:

- Opioids (any dosage form) may require “high-alert” auxiliary labels.
- When controlled drugs are kept on a patient care unit, they must be stored in a secure, locked place. Often, an automated dispensing machine (ADM), 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’s 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 a 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 usually 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.

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