Law: Connecticut's Pharmacy Managers Promoting a Constant State of Readiness

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●Welcome to this training activity for pharmacy managers, potential pharmacy managers, and other interested individuals. The Connecticut Department of Consumer Protection and the University of Connecticut School of Pharmacy have collaborated to produce this program. In it, you'll learn about Connecticut's laws regarding pharmacies and the pharmacy manager's specific responsibilities.

●Our goal is to promote a constant state of readiness. This means that whenever a representative from the state of Connecticut visits your pharmacy to conduct an investigation or an inspection, you'll be ready, willing, and able to respond to their requests efficiently and effectively.

This slide kit was assembled by a team of mainly volunteers.

We thank the following individuals for their work:

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OBJECTIVES

1. Describe the role of the Department of Consumer Protection with respect to Pharmacy Operation/Compliance
2. Recognize the pharmacy manager's responsibilities to the Department of Consumer Protection
3. Explain the pharmacy manager's responsibilities to the store operation
4. Recall the laws pertaining to being a pharmacy manager
5. Outline the manager's responsibilities with regard to the pharmacy staff
6. Differentiate between legal obligations and your organization or store responsibilities

●These are our objectives for this continuing education activity. Again, our main audience is pharmacy managers and potential pharmacy managers, but other pharmacy employees or administrative personnel may be interested in taking this training so they'll know our expectations of pharmacy managers. The pharmacy manager's responsibilities are quite broad, and to be fully successful, pharmacy managers need complete cooperation from staff and other employees in their organizations.

●We also will examine the manager's obligations with regard to monitoring personnel, and all laws that pharmacy managers need to be aware of to successfully do their jobs.

●Whenever possible, we will emphasize the difference between the pharmacy manager's legal obligations and his or her organizational responsibilities as outlined in local policies and procedures. These differ, and a key point to remember is that regardless of how or when your organization directs you to do a task, if the state regulations require that you do that task in a different way or at a different time, local policy and procedure never absolves you of state-mandated responsibilities.

The Department of Consumer Protection

- Performs reviews, inspections, or investigations regarding qualifications of licenses
- Follows up on consumer complaints
- Seeks Superior Court assistence if involved parties refuse to cooperate

Oversight for all pharmacy and pharmacy-related activity in the State of Connecticut is delegated to the Department of Consumer Protection, or DCP. DCP is the agency that is responsible for pharmacy wholesale drug distribution, controlled substance oversight, and all different kinds of pharmacies.

●DCP's drug control agents (also referred to as inspectors) review, inspect or investigate each applicant's qualification for licenses—Applicants could be wholesale operations, pharmacies, or individuals who require licenses to operate in the state
●DCP's agents follow up on consumer complaints, which is why each pharmacy manager needs to understand how to handle medication errors and how to establish and use a legally-required quality assurance program within the pharmacy. We'll talk about this later.
●DCP's agents will seek intervention from the Connecticut Superior Court in the event that someone refuses to cooperate with one of their investigations.

DCP follows the flow of drugs from the manufacturer to the wholesaler to the pharmacy, hospital, pharmacist, nurse, and/or the patient. Anytime you see an indication of a break in the flow, you need to notify DCP so it can start an investigation. For example, if you expect a shipment from UPS and the shipment is lost in transit, you need to document properly and notify DCP. That means you must document all the steps you took, including WHO you talked to, WHEN, and HOW to contact that person. Remember that many times, people sign with a scrawl. Be sure to print the person's name clearly!

The Commissioner of Consumer Protection

- Hires inspectors who
  - Inspect all places in which drugs and devices are or may be dispensed or retailed
  - Inspect each retail pharmacy not less than once every four years
  - Use an established methodology to sample prescriptions dispensed by retail pharmacies for compliance with state laws
  - Report any violations
- Revokes or suspends licenses or permits if deemed in violation

●The Commissioner of Consumer Protection is the "in charge" person for DCP. The State of Connecticut delegates responsibility for all pharmacies and pharmacists to DCP. The Commissioner hires drug control agents to inspect all places in which drugs and devices are or may be dispensed or sold. These inspectors inspect all of Connecticut's **X thousand** pharmacies at least once every four years. Their inspections follow a carefully planned methodology, and inspectors sample prescriptions to ensure that the pharmacy adheres to state laws.

●Again, drug control agents also investigate complaints when citizens notify DCP that a pharmacy-related problem may have occurred.

●When violations occur, DCP's inspectors refer the problem to the Commission of Pharmacy, or CoP. The Commission of Pharmacy is the enforcement body for pharmacy, and determines the appropriate disciplinary action. DCP regulates both the pharmacy and pharmacists who work there.

Slide 5

JN9 How many pharmacies are there in CT to date?
Joanne Nault, 9/18/2020

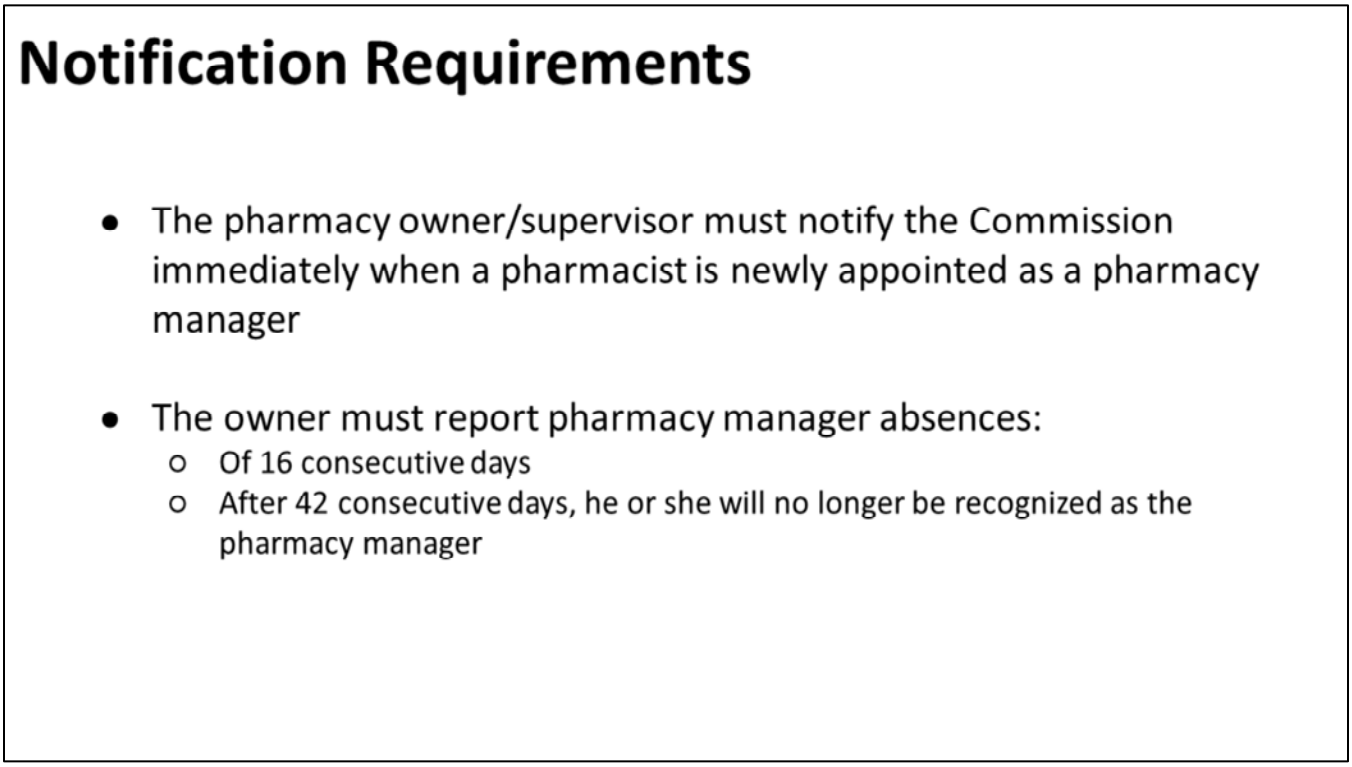
Who is a Pharmacy Manager?

- The individual responsible to the Commission of Pharmacy for all activities on the pharmacy premises
- A newly designated pharmacy manager must appear before the Commission for a personal interview related to the knowledge and responsibilities of a pharmacy manager
- The Commission of Pharmacy recommends that all first time pharmacy managers be licensed as a pharmacist for a minimum of six (6) months and working within Connecticut

●So let's get directly to the point and discuss pharmacy managers. Pharmacy managers are the individuals who are responsible for all activities on a pharmacy's premises. Each pharmacy has one pharmacy manager.

●Newly designated pharmacy managers must appear before the Commission for a personal interview before they can assume these new responsibilities. During the interview, the Commission will educate individuals about their responsibilities, and assess their knowledge.

●The Commission of Pharmacy recommends that pharmacy owners select potential managers who have been licensed for at least six months, and have some experience practicing as a pharmacist. Note that this is not a formal regulation in Connecticut, but instead, a "handshake agreement" between DCP and pharmacy owners. Candidates should also have worked in Connecticut. As you navigate this activity, you'll see that the pharmacy manager's responsibilities are quite broad, and newly licensed pharmacists are not the best candidates to assume these responsibilities. Pharmacists ideally need some experience dealing with the public, working with the many types of employees we see in pharmacies, and handling the paperwork necessary to run a pharmacy.



The pharmacy's owner must notify the Commission when a pharmacy manager leaves and a new pharmacy manager is appointed.

The regulations require the pharmacist who is stepping down as manager to also notify the Commission that he or she is no longer the pharmacy manager. This doesn't always happen. For example, DCP has been notified that the pharmacy manager is changing, and the store reports that Joe Smith is replacing Jane Green. When DCP updates the record in its possession, that record indicates that Alison Jones is the manager of record. When they ask questions, they find that Alison Smith left five months ago, and was replaced by Jane Green—no one ever notified DCP of that change! This isn't uncommon! Make a note that when you step down, you need to let DCP know.

Pharmacists must notify the Commission when they step down from pharmacy manager positions; the pharmacy owner is also responsible for notifying the Commission. All those these notifications may seem redundant, it ensures that DCP knows who is responsible in every pharmacy at all times. And here's something to note: Sometimes supervisors will contact the Commission to report an emergency change of manager because the previous manager had a baby. This is not considered an emergency change of manager; everyone in the organization would have known about the pregnancy for months! Emergencies are things like acute or exacerbated chronic illness, accident, and so forth.

Pharmacy managers need to be present more than they are absent. In the event a pharmacy manager is absent for 16 days, the owner must notify the commission, and designate an acting manager. If 42 days pass and the pharmacy manager doesn't return,

the owner must notify the commission and provide the name and license number of the new manager.

AGAIN, DCP inspectors often arrive at a pharmacy and find that the manager they expect to see left the position months ago, and no one notified DCP. Don’t let that happen at your pharmacy!

Operation Responsibilities

- Post the pharmacy manager's name so it is visible to the public
  - The law says, "consipcuously posted"
- Maintain open hours of at least 35 hours per week
- Post hours of operation for the public to see
  - Cannot be closed >18 days/365 days AND twice in 30-day period
  - Report unexpected closures to the Commission within 72 hours
  - Request approval for a reduction of hours from the Commission and post the change 30 days in advance
  - Report an increase in hours within 5 days of change

Customers need to know who the pharmacy manager is so they can voice concerns and ask questions if necessary. Many pharmacies post a sign within the pharmacy, and others simply post the pharmacy manager's name on the front door. Either of these methods is perfectly acceptable, but the sign must be **CONSPICUOUS**. If your front end manager puts a display in front of it or promotion poster over it, object! Tell that front end manager to move the items blocking the sign.

Here are a few facts that owners and pharmacy managers need to know:
●The pharmacy manager must be a full-time employee, i.e., they must work 35 hours/week. Designating a part time employee to be the pharmacy manager is inappropriate because that individual will be absent more often than not. The pharmacy manager needs to be on the premises and available to customers during most of the pharmacy's open hours.
●The pharmacy manager is also responsible for any unexpected pharmacy closures, as patients need to have access to their medications at all times. If the pharmacy experiences an unanticipated closure, the pharmacy manager must leave a sign on the door directing patients how and where they can get their medications.
●Pharmacy managers also need to be aware that DCP has a process for pharmacies to post if they are open during an emergency. For example, some pharmacies may remain open during epidemics and they should post signs indicating they are open. It would also be appropriate to change voicemail messages, and make note of this fact on social media pages and websites if possible.

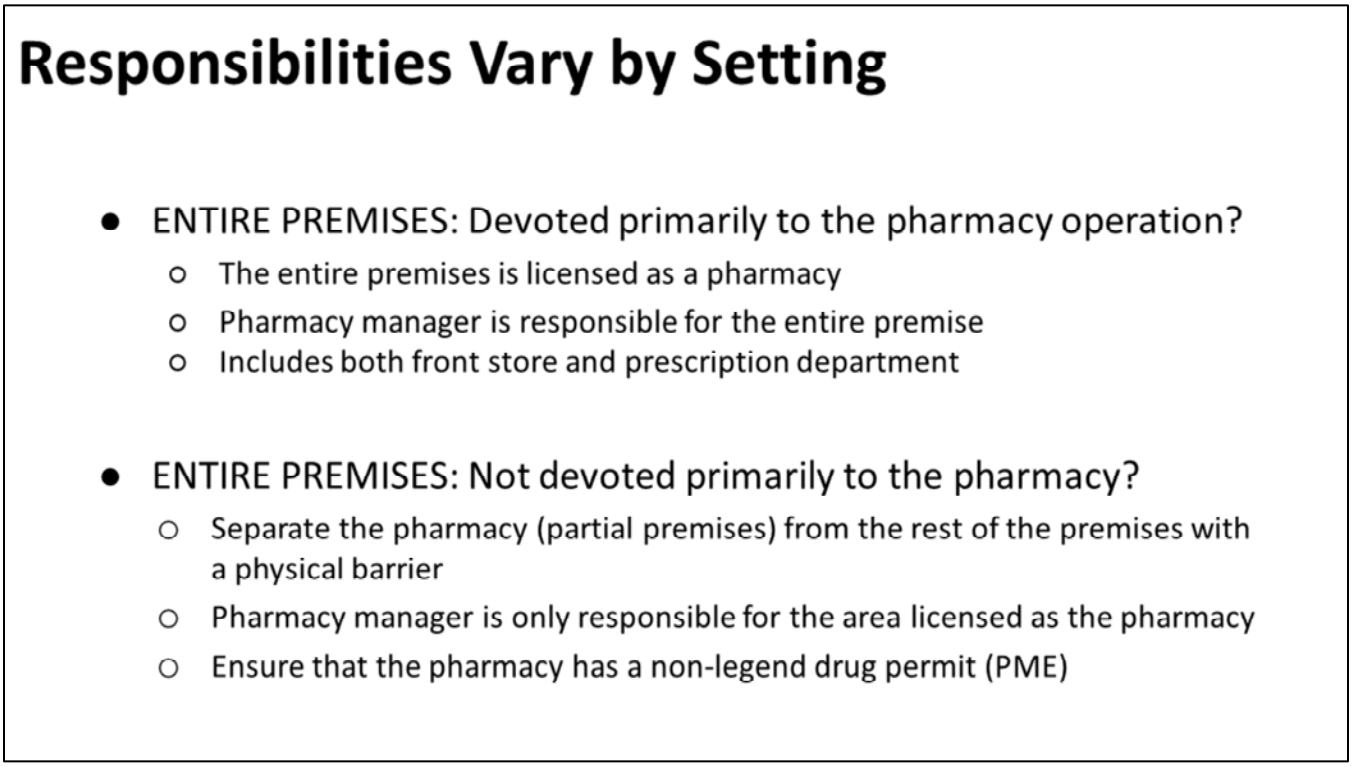
SIGNAGE: The Specifics

SIGNAGE

- Shall be **conspicuously posted** within the pharmacy within the prescription dept of a pharmacy or in immediate proximity

- Hours of operation of the prescription dept SHALL be posted at all entrances to the pharmacy in BLOCK letters at least 1/2" in height

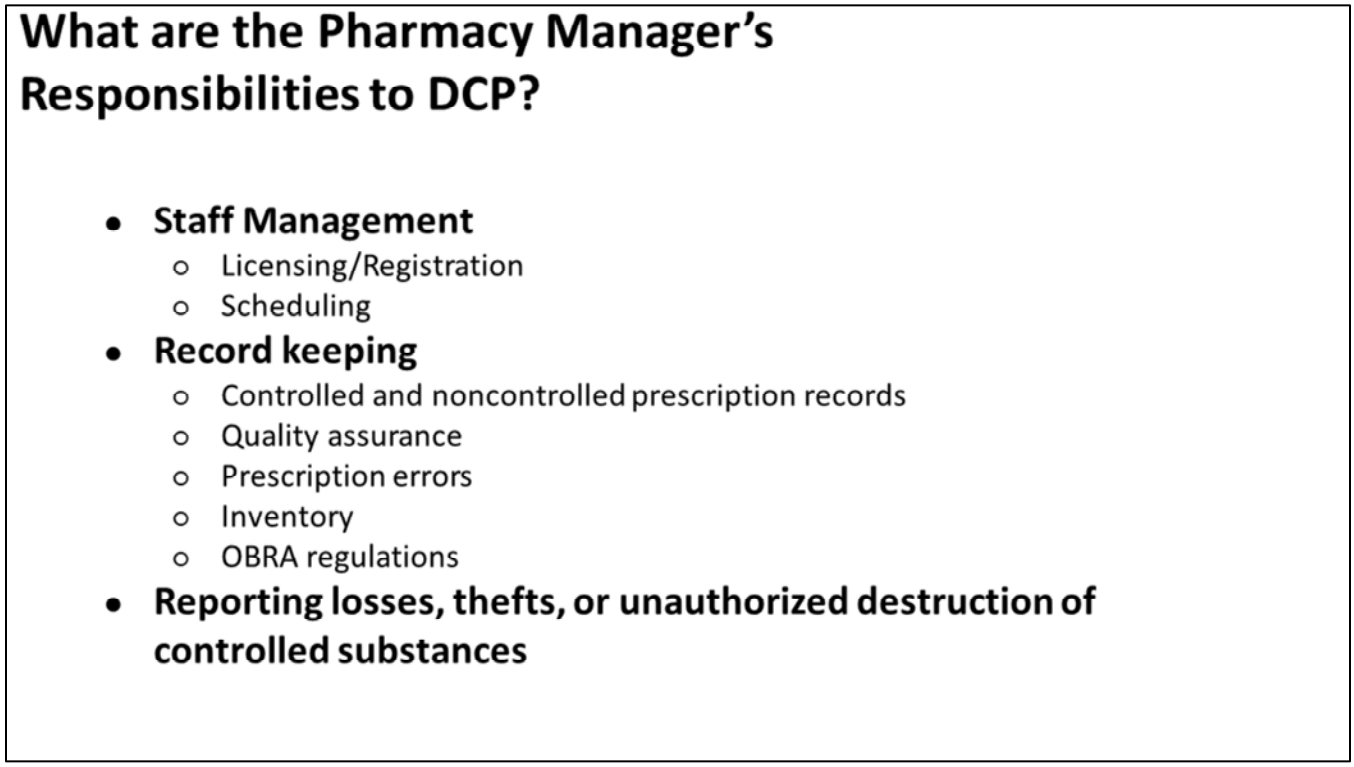
●This slide emphasizes the point we made in the previous slide and tell you exactly what you need to do.



New pharmacy managers often have questions about the scope of their responsibilities. They often ask, "Am I responsible for the pharmacy or for the whole store?" The answer to this question depends on the pharmacy's location.

Some pharmacies are stand-alone entities, and the entire premises is the pharmacy. Freestanding independent pharmacies and chain pharmacies whose primary business is pharmacy are examples. In this case, the entire premises are licensed as a pharmacy, and the pharmacy manager is responsible for the entire store.

Some pharmacies are located with an other business entities. For example, pharmacies that are located inside supermarkets or big-box stores may be open for fewer hours than the surrounding store is. In this case, the pharmacy must be separated from the remainder of the store with physical barriers, able to be secured to prevent illegal access, and the pharmacy manager is responsible only for the pharmacy.



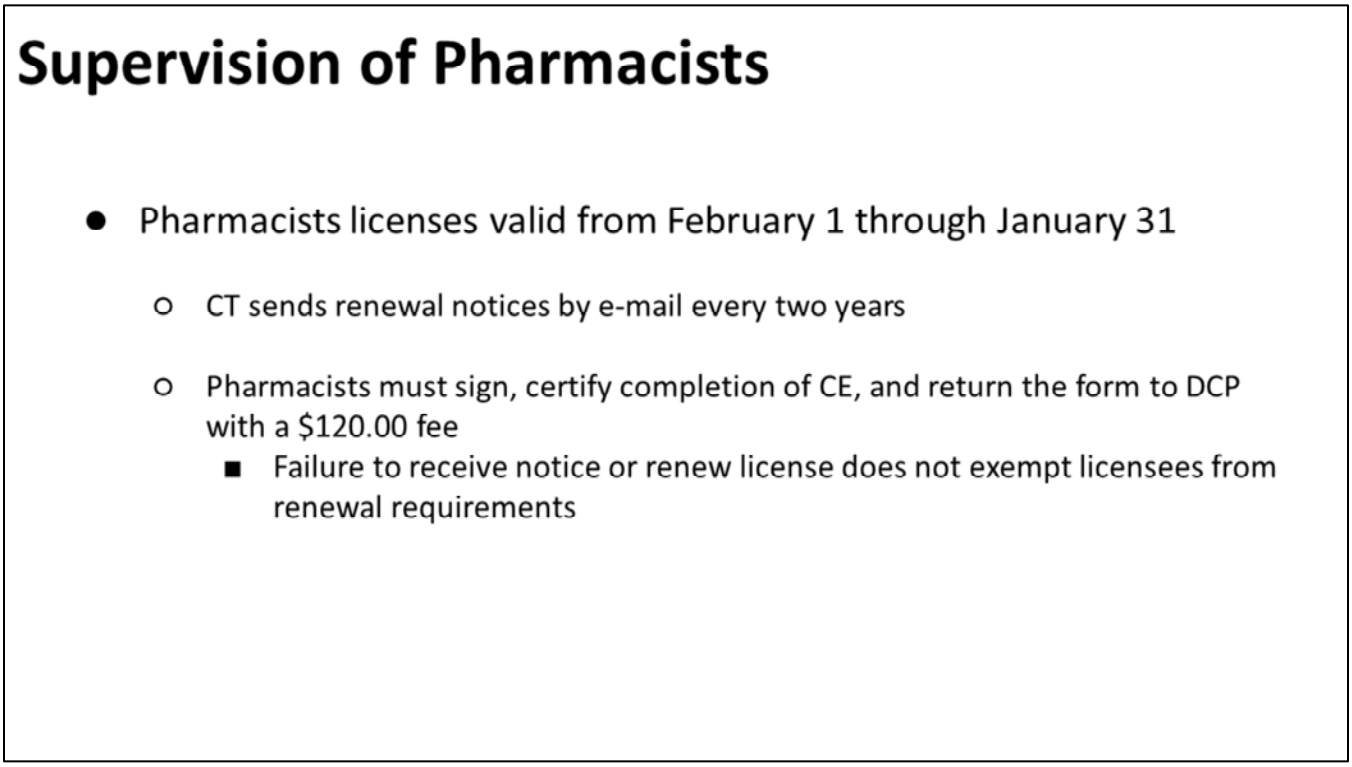
This slide emphasizes that the pharmacy manager's responsibilities are quite broad and fall into three primary categories.

○First, pharmacy managers are responsible for ensuring that all staff employed by the pharmacy are licensed or registered appropriately, and that scheduling complies with Connecticut state law.

○Next, pharmacy managers are responsible for all record-keeping. This means that you need to supervise your staff and ensure that they comply with all mandates that cover prescription records, quality assurance, prescription errors, inventory, and OBRA regulations.

○Finally, it's the pharmacy manager who is responsible for reporting losses, thefts, or on authorized destruction of control substances.

We'll discuss each of these responsibilities in further detail as we go through this activity.



An obvious state requirement is that all pharmacists who practice in any pharmacy must be licensed. DCP licenses Connecticut's pharmacists for a two-year period starting on February 1 of each even year, and ending on January 31 two years later. DCP sends renewal notices by email every two years. Pharmacists can expect to see this email sometime in mid December of the odd numbered years before their licenses expire. Every calendar year, pharmacists licensed in Connecticut must complete 15 credits of continuing education. The state further requires that pharmacists must obtain five of the 15 CE credits in a live setting, and one credit must be in law. Pharmacists who are immunizers are also required to take one hour of CE each year on any immunization-related topic. The key point to remember here is that although Connecticut has now moved to a biennial pharmacist license renewal cycle, pharmacists must continue to obtain continuing education on a calendar year basis. Pharmacists need 15 credits of CE between January 1 and December 31 every year.

Pharmacists need to realize that their ability to practice is a privilege, and it is also their livelihood. Sometimes pharmacists change email addresses and fail to notify the state. This is not an excuse for failure to renew a license! It's the individual pharmacist who is responsible for renewing his or her license every other year. So here's a "Pro Tip" for pharmacy managers: every odd-numbered year, and mid-December, remind pharmacists their licenses are expiring the next January 31. Tell them to look for the e-mail, renew, and to provide you a copy of that license as soon as they do.

Supervision of Pharmacy Interns

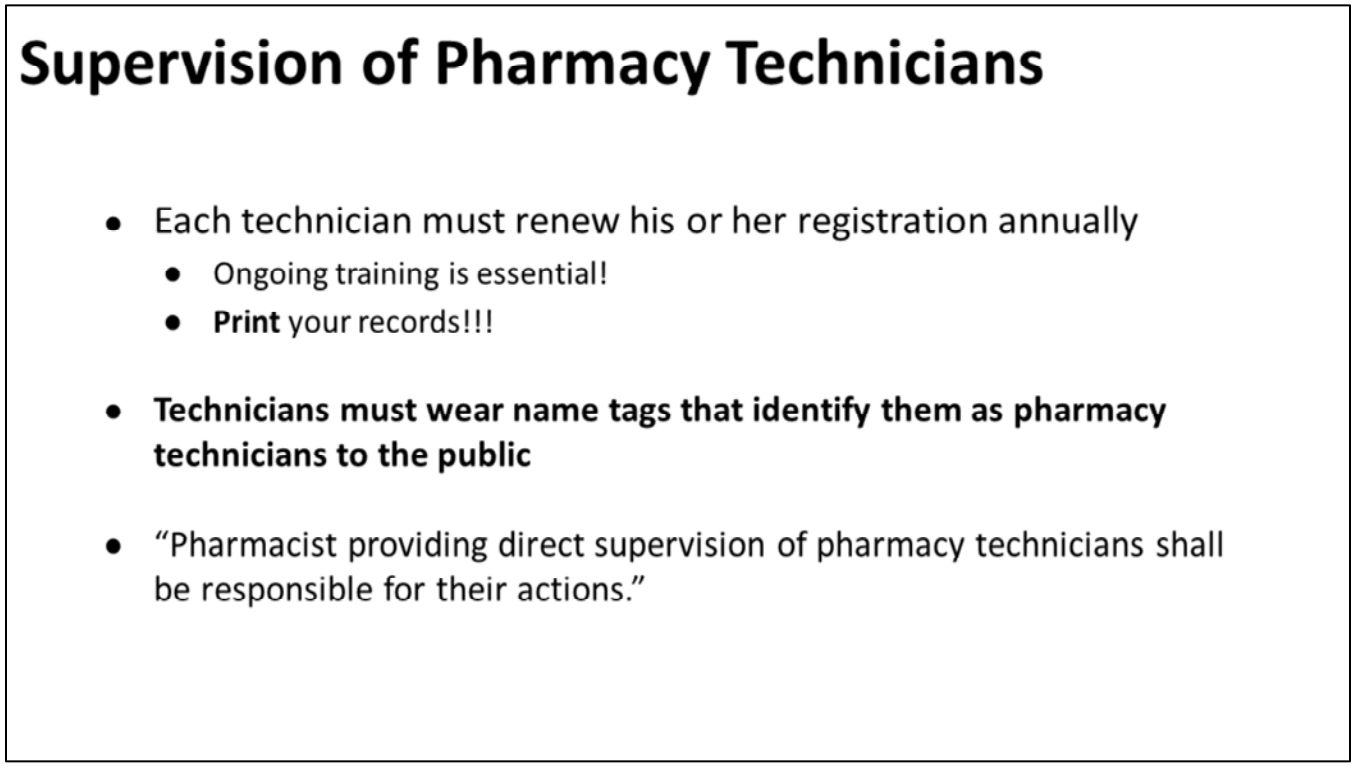
- Criteria for an intern:
  - Completed 2 years of college
  - Enrolled in a professional program accredited by ACPE
  - Approved by the Commission
- One intern per preceptor
- Interns may accumulate a maximum of 40 professional hours per week

Now let's talk about the difference between pharmacy interns, certified pharmacy technicians, and pharmacy technicians.

●Pharmacy interns are employees who are enrolled in an American College of Pharmacy Education-approved program with the intent of earning a degree in pharmacy. Employees can’t become pharmacy interns until they have completed two years of college. And in addition, the pharmacy commission needs to approve each intern's license.

●Each preceptor can supervise only one intern, and interns are allowed to accrue up to 40 professional hours per week.

●Here, let's take a minute to understand what "direct supervision" means. Pharmacists who directly supervise interns or technicians means must be physically present in the area or location where the pharmacy technician is working. and in addition, the supervising pharmacist must conduct an in-process and final check on the pharmacy technician’s work.



The state of Connecticut requires that each pharmacy technician register annually. All pharmacy technician registrations expire annually on March 31st. The pharmacy manager needs to ensure that all technicians are registered, and that they obtain continuing education as required by the state. Note that in Connecticut, the law does not stipulate that pharmacy technicians receive a specific number of CE credits, but it does indicate that employers need to ensure pharmacy technicians are educated continuously. To prove this, pharmacy managers will need to keep good records about the training they provide to their staff. Those records should include:

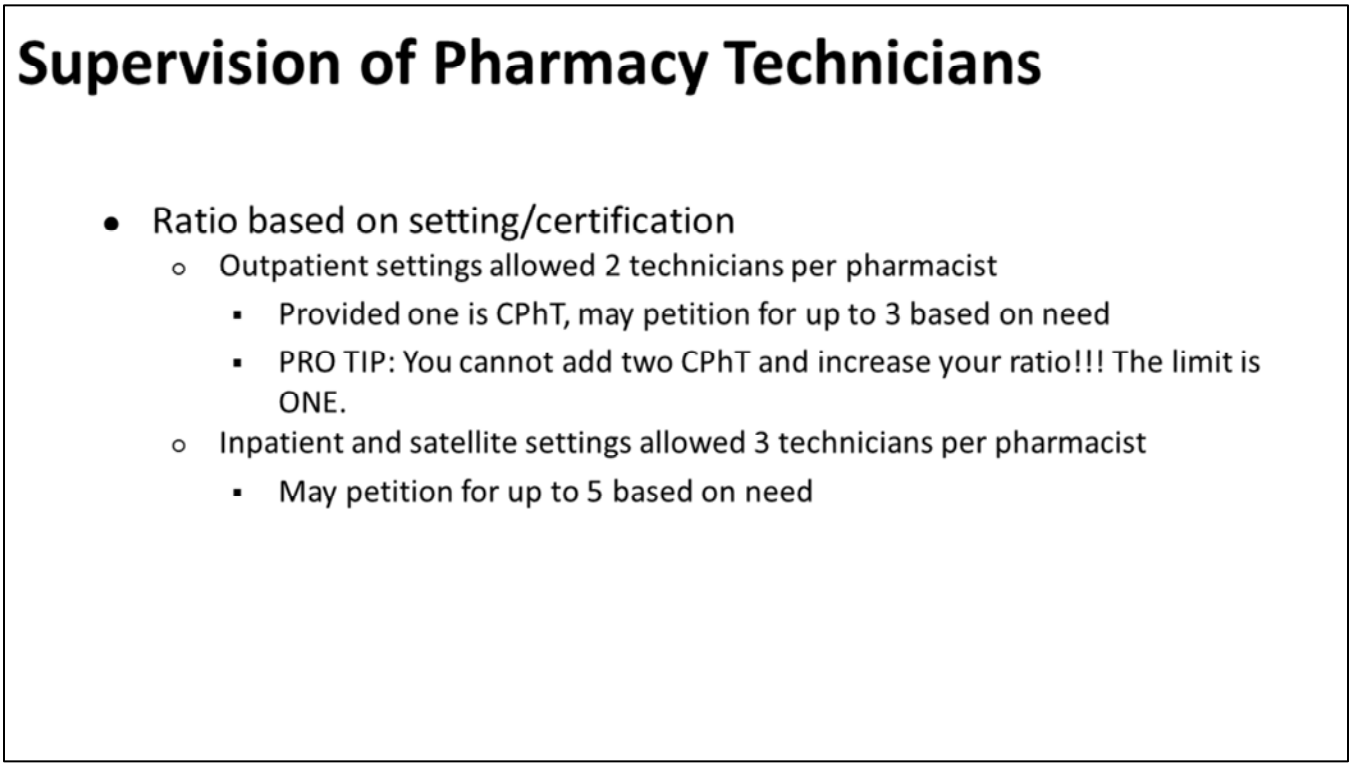
(a) the name of the individual receiving the training
(b) the date(s) of training
(c) a general description of the topics covered
(d) the name of the person supervising the training
(e) the signatures of the individual receiving the training and the pharmacy manager

The records must be in hard copy and must be signed by BOTH the technician and the manager.

Members of the public often identify anyone who is wearing a white coat or uniform or working behind the pharmacy counter as a pharmacist. Often they ask for advice and consultation, and assume that they are receiving appropriate information from a professional. For this reason, technicians must wear name tags that identify them as pharmacy technicians at all times. This is an area where drug control agents find many pharmacies in violation. It's such a simple thing, and pharmacy managers need to be sure that all technicians wear name tags. In fact, it's a good idea for all employees to wear name

tags.

When pharmacists assume the pharmacy manager role, the regualtions state that they must review all the documentation for a technician and sign it.



Connecticut's regulations also stipulate how many interns, pharmacy technicians, and certified pharmacy technicians can be on the premises and working simultaneously. Pharmacy managers may or may not be directly responsible for scheduling but they do need to audit the schedule regularly and ensure that it does not violate scheduling ratios. Take a few minutes to read the information on this slide. [[SPEAKER PAUSES]] Note the ratios, and note that if you have two nationally certified technicians, that does not permit you to increase the ratio. Drug control agents will look at the ratio of pharmacists to interns, technicians and certified pharmacy technicians when they visit, and it's a serious violation if the store is staffed with more interns and technicians than allowed by law.

A pharmacist may refuse to supervise three pharmacy technicians at one time. This must be documented with the following:

- specific statement that the pharmacist refuses to supervise three pharmacy technicians
- the names and addresses of the pharmacies involved
- the date and the signature of the pharmacist

A pharmacist may rescind any refusal by providing the pharmacist manager with a signed, dated statement. The pharmacy manager is responsible for keeping all refusals or rescissions on file in the pharmacy or in a place where they can be retrieved easily and provided to drug control agents during inspections. Note that this section does not apply to pharmacists supervising intravenous admixture and other sterile product preparation, unit dose and unit of use dispensing and bulk compounding.

Here's a situation…

It's a busy Monday morning. Your scheduler made the schedule for technicians last week. He scheduled four technicians to work today. One of them is a certified technician. No one was scheduled to run the register.

What do you do?

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●So here's a common situation that pharmacy managers may face. The individual who is responsible for scheduling created a schedule for technicians last week. You arrive on Monday morning, and four technicians arrive with you. The state indicates that you can supervise only three technicians simultaneously. What will you do?

●First, the manager needs to look at each individual technician's qualifications. One of the technicians is a certified pharmacy technician. Next, you need to know if your store has petitioned for and received permission to increase the pharmacist-technician ratio. If it has, you can have one technician run the register for the entire shift, but ensure that the technician is wearing a name tab indicating that today, he or she is a cashier. Then, the certified pharmacy technician and the other two technicians can be deployed to work in technician roles. And, remember that for the entire shift, the CPhT cannot rotate to the cash register. If he or she does, your ratio will be in violation.

●If your store has not petitioned for and received permission for a 3:1 technician to pharmacist ratio, you'll need to make a decision about what to do with the "extra" technician. That individual cannot work in the pharmacy on this Monday.

●Here's a "Pro Tip" for pharmacy managers: This situation should be unusual or rare. When it happens, it's critical to go back to the person who does the schedule and explained that it happened and why it can't happen again.

Pharmacy License

- Expires annually on August 31
- DCP e-mails the renewal notice to the pharmacy or the corporate office
  - Current fee $150.00
- Failure to receive notice of expiration or renewal does not exempt the licensee from renewal responsibility

In Connecticut, every pharmacy’s license expires on August 31 each year. It's the pharmacy manager's responsibility to ensure that your pharmacy has a current, valid license to operate. Again, DCP will email the renewal notice to the pharmacy owner or the pharmacy's corporate office approximately six to eight weeks before the license expires.

Here too, a change in email or a failure to receive the expiration notice is no excuse for failure to renew a pharmacy license.

Here's a "Pro Tip" for pharmacy managers: add this task to your tickler list for July. We'll talk about tickler lists later in this presentation. You’re responsible as a manager to ensure that the pharmacy has a current license that is valid

Pharmacy Relocation

- Pharmacy manager and licensee of the pharmacy premises must appear before the Commission
- Present a completed new pharmacy premise application or a transfer pharmacy premise application with the proper fee attached
- Include a blueprint
- The applicant or licensee is not the pharmacy manager? Applicant or licensee may designate an individual as his or her agent
- Application to move the area of the pharmacy to a different area within the business premises shall require a fee for that relocation

From time to time, pharmacies relocate either because they need more space, or the space in which they are located becomes unsuitable. Legally, pharmacies can't locate until the pharmacy manager and the pharmacy's licensee appears before the Commission of Pharmacy. There are no exceptions to this rule; the pharmacy manager can't send a supervisor or a designee to the Commission's meeting.

Pharmacy managers who appear before the commission to propose relocation need to bring blueprints that indicate several things:
●The blueprints need to clearly show the square footage of the area that will be licensed as the pharmacy.
●Pharmacies that comply with section 20-576-15 and 20-576-16 of the Regulations of Connecticut State Agencies (these are the sections that cover pharmacies operating in a larger store not entirely devoted to pharmacy) must also have blueprints that show the total square footage of the entire business entity.
●the square footage of the prescription department
●the square footage and location of areas used as storerooms or stockrooms
●the size of the prescription counter
●the location of the prescription department sink and refrigerator; controlled drug safe; toilet facilities; and patient counseling areas, if any
● any other information related to the physical plant, required by the Commission in regulations adopted pursuant to section 20-576(a)(2) of the General Statutes, concerning the licensing of various classes of pharmacies.

What would you do?

The pharmacy department has gained a lot of new business. The store owner wants to relocate the pharmacy to an empty storefront next to the store.

What requirements need to be done for this to occur?

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The pharmacy owner or the corporation that owns the chain needs to file an application and pay the associated fee. Then, the Commission will determine if the application can be approved.

Controlled Substances

- Responsible for the security of controlled substances to prevent diversion
  - Schedule II - stored and locked in their designated location
    - Must use an approved safe
    - Safe specification much match what is on record with DCP
  - Schedule III-V - must be stored under required security safeguards
  - Report all loss/theft within 72 hours
    - There is no "10% rule"

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Pharmacy managers need to be very familiar with all requirements associated with dispensing controlled substances. First and foremost, pharmacy managers need to ensure that the pharmacy is appropriately licensed and registered. We discussed licensure previously. Now let's focus on registration. The Drug Enforcement Agency (DEA) issues registrations to pharmacies, not pharmacists. That is, each pharmacy that handles controlled substances must register with the DEA and have a valid license at all times.

Pharmacy managers are responsible for controlled substance security, with an emphasis on preventing diversion. You'll note that pharmacies need to store and LOCK their controlled substances at all times. A critical point is that pharmacies need to have an approved safe for Schedule II narcotics. Approved safes have the following characteristics:

(1) They are certified by the Safe Manufacturers National Association Class A, B or C.
(2) They have been certified by the Underwriters Labs, Inc. as equipped with a re-locking device.
(3) They weigh 750 pounds or more, or rendered immobile by being securely anchored to a permanent structure of the building
(4) They have adequate interior space to store all controlled substances required to be kept within.

Controlled Substances, continued

- Invoice Records
  - **Schedule III-V:** maintain separately from non-controlled invoices and Schedule II invoices
  - **Schedule II:** Store pharmacy copy of the Official Schedule II Controlled Substance Order Form with the receipt annotated with the actual quantity of drug received

The pharmacy manager should be familiar with the process of documenting and reconciling all orders. Controlled substance invoices are managed and stored differently than other pharmacy products, and require special attention.

Pharmacy managers need to oversee record-keeping for controlled substances (i.e., the hard copies) carefully, and ensure they are filed separately from non-controlled invoices and schedule II narcotic invoices. They must also be filed in consecutive order.

Each Schedule III-V invoice needs to have the following information on it:

- the actual date of receipt—and here's an important point: You need to write the recipt date on the invoice. Circling the date on the invoice is not acceptable. Here's an example: If the wholesaler printed receipt invoice and there was a blizzard and the state shut down, the date would need to show received and not when it was printed.
- the name and address of the supplier including direct sources
- the name, strength, form and quantity of the controlled substances received

This record must be up to date including the most current items received, and must be readily available for review.

Schedule II invoices are stored similarly, but also require pharmacy staff to attached a copy of the official control substance order form [DEA 222] with the receipt documenting the actual quantity of drug received

E-prescribing of Controlled Substances

- Effective January 1, 2018
- Prescribers must employ a software system that enables them to transmit prescriptions
- Pharmacy must have the software that enables them to receive prescriptions
- And make note: If you print an e-script you MUST file the prescription in chronological/sequential order

One of the most important functions of a pharmacy manager is to stay abreast of recent changes, and educate the entire pharmacy staff about them before they occur. Beginning in January 2018, Connecticut law requires prescribers to employ a software system that enables them to transmit prescriptions directly to pharmacies. Obviously, pharmacies must have appropriate software to receive those prescriptions.

Under the new law, the electronic transmissions must be

- ○consistent with existing DEA requirements
- ○kept on file at the pharmacy for three years (minimum)
- ○readily available for inspection (same as the paper prescription)

EXEMPTIONS: E-prescribing of Controlled Substances

- Electronic transmission is unavailable due to a temporary technological or electrical failure.
- The practitioner reasonably determines that it would be impractical for the patient to obtain substances prescribed by an electronically transmitted prescription in a timely manner and that such delay would adversely impact the patient's medical condition.
- The prescription is to be dispensed by a pharmacy located outside of the State of Connecticut.
- Use of an electronically transmitted prescription may negatively impact patient care.
- The practitioner demonstrates, in a form and manner prescribed by the commissioner, that such practitioner does not have the capacity to issue electronically transmitted prescriptions

All staff and all pharmacies need to be aware of these 5 exemptions, and practitioners' obligations when they invoke these exceptions

(1) If electronic transmission is not available, the practitioner needs to document the incident in the patient chart within 72 hours of the restoration of the system

(2) If the practitioner indicates that electronic transmission is impractical for the patient and impacts him or her adversely, the prescription is limited to a five-day supply based on the directions for use, and again, the practitioner must document the reason and the patient's medical record

(3) Practitioners can use paper prescriptions if the patient plans to fill the prescription outside of Connecticut.

(4) Use of an electronically transmitted prescription may negatively impact patient care. Here, the prescriptions will most likely be for compounded products; parenteral, intravenous, intramuscular, subcutaneous, intra-spinal infusion or other similarly administered products; longer complicated directions; or an oral prescription that the prescriber communicates directly to a pharmacist for a patient in a chronic/convalescent nursing home.

(5) The practitioner demonstrates, in a form and manner prescribed by the commissioner, that such practitioner does not have the capacity to issue electronically transmitted prescriptions

Loss, theft, and unauthorized destruction of controlled substance

- A registrant must
  - Reported loss, theft or unauthorized dextruction the Commissioner within 72 hours of occurrence discovery and
  - Include a signed statement of the kinds and quantities of controlled substances and the circumstances involved
  - Make note: If in doubt, send an initial notification. You can always retract it if the CS is found

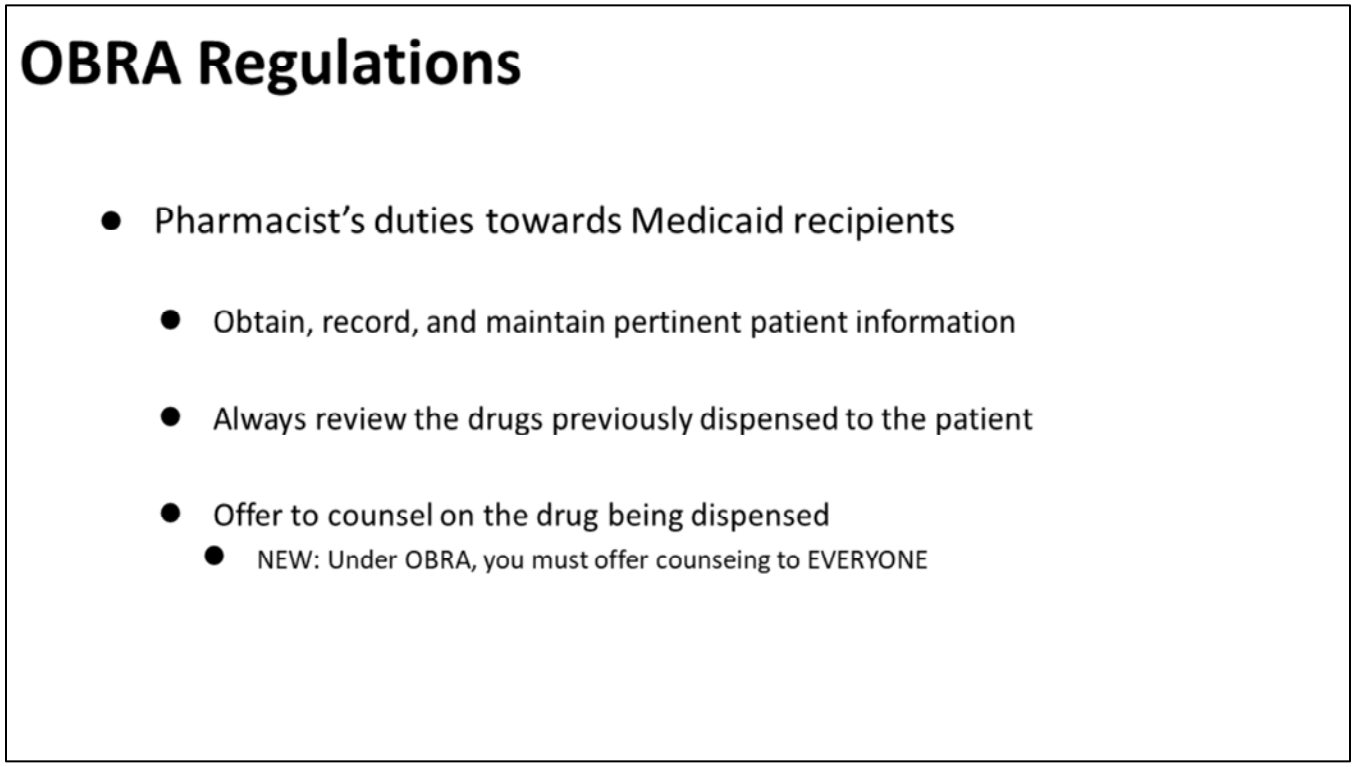
The pharmacy manager must report any loss, theft, or unauthorized destruction of controlled substances directly to the Commissioner of Consumer Protection, Drug Control Division. The Drug Control Division oversees all controlled substances. Pharmacy managers who file these reports need to include a signed statement that describes the kind and quantity of controlled substances, and also includes the circumstances involved.

Here's a "Pro Tip“ for pharmacy managers: make sure that the narrative that describes the circumstances surrounding the event includes WHO was involved, including everyone who was on duty when the event occurred if possible. Include specific dates and times, and have someone proofread your narrative to ensure it describes the event in chronological order and includes all known facts. One of the most common problems that drug control agents see is incomplete documentation.

Retention of Pharmacy Records

- Controlled Substance Prescription Records must be maintained for a **MINIMUM** of 3 years
- Third party payers or tax regulations may mandate to keep records longer

Retain records for a minimumof three years. If you store them electronically, they must be readily accessible on-line.



Pharmacists should offer counseling to all patients who enter the pharmacy and receive prescriptions. The Omnibus Budget Reconciliation Act (OBRA) of 1990 included mandates for states to improve Medicaid beneficiaries' understanding about medications. Passed in 1990, the act became law in 1993. In effect, it shifted the pharmacists focus from products to patients and required that all Medicaid beneficiaries be offered counseling from a pharmacist (and only a pharmacist) when they have prescriptions filled. Eventually, the language changed to include ALL patients, not just Medicaid beneficiaries, and Connecticut's law says the same thing. Offer counseling to EVERY ONE. OBRA is very specific in its mandate. It tells pharmacists that they need to counsel patients about

- the drug name
- its intended use an expected action
- the route, dosage form, dose, and administration schedule
- common side effects and how to avoid them or handle them if they occur
- techniques for self-monitoring
- proper storage
- potential drug-drug or food-drug interactions
- therapeutic contraindications
- prescription refill information
- what to do if the dose is missed

As you can see, OBRA requires a very thorough process for Medicaid patients.

Pharmacy managers need to be aware that Connecticut's Department of Social Services may audit your compliance with this mandate, and if they find evidence that the pharmacy has not offered counseling to Medicaid patients, they can impose financial penalties. And

the most recent changes to OBRA indicate that you must offer counseling to EVERYONE.

It’s about Quality Assurance

- Every pharmacy needs a quality assurance program to detect, identify, and prevent prescription errors
  - Document and assess prescription errors to determine causality
- **Primary Purpose:** to advance error prevention by analyzing and investigating data to determine contributing factors to prescription errors

●WIth the increase in prescription errors, Connecticut's lawmakers wrote legislation that requires pharmacies to have a quality assurance process in place to minimize errors. Ensuring that such a program is available is also a pharmacy manager's responsibility.

●Pharmacists need to use this data routinely to prevent future errors. Specifically, the pharmacy manager in conjunction with the entire staff needs to look at all errors carefully and try to determine what happened and why. They need to ask incisive questions. Was the workflow responsible for the error? Is our procedure insufficient and should we change it? Are there training opportunities here? Using the information, pharmacy managers should develop pharmacy systems, revise their procedures, offer training, or change workflow to ensure that preventable errors are caught early.

●Here's a "Pro Tip" for pharmacy managers: it's important to recognize the errors occur and that in most cases, the errors have many causes. When staff perceive that they will be chastised or disciplined for making an error, they are much less likely to report the error. Promote an environment where staff members are rewarded for reporting errors and use a process that is non-punitive whenever possible. Looking at your quality assurance data monthly or quarterly can help you identify trends, and find simple ways of preventing similar errors from occurring in the future.

Quality Assurance, continued

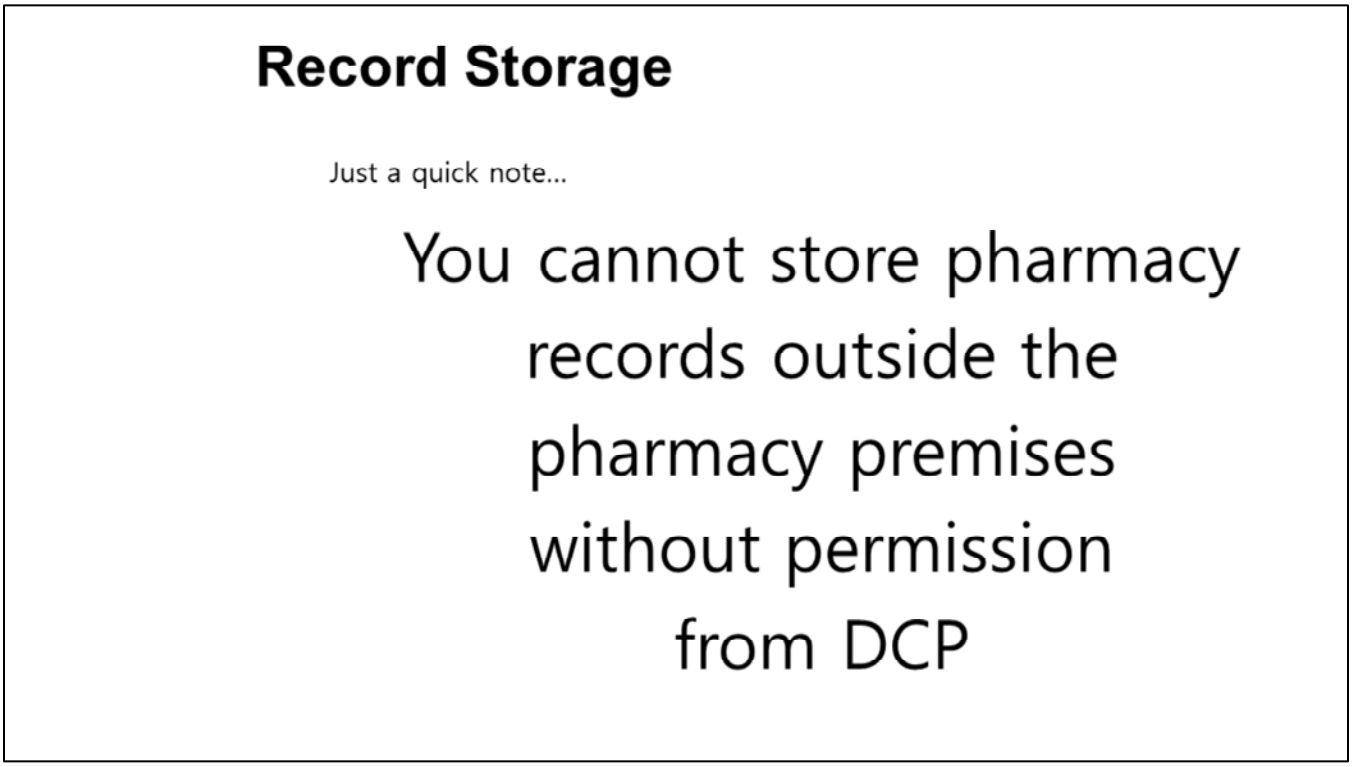
- The person who discovers or is informed of the error must complete a QA review.
  - The Pharmacy Manager must ensure that this is done, and review it with the staff as soon as a prescription error has occurred, but no later than 2 business days
- The pharmacy shall
  - Keep a record of every quality assurance review for a minimum of 3 year
  - Maintain records in an orderly fashion (filed by date)
  - Have a written copy of quality assurance policies on the pharmacy premises and readily available for staff
- Records can be stored outside of the pharmacy, but must be readily retrievable within 48 hours of request for inspection

Reviewing errors is essential to protect your patients and educate your staff. Although you're not required to report errors to the state, you are required to document each error, to have a staff meeting reviewing workflow and process, and keep records on file. Patients often report medication errors to DCP, and once they do, drug control agents are obligated to visit your pharmacy. When they arrive, you must have all necessary documentation ready for them to review immediately. And, that documentation needs to be complete and legible. **If your company has you fill out a QA form online that is NOT shareable with an agent and the one that can be shared is incomplete....then it is considered a violation. Make sure both are filled out.**

What does your record need to contain?
(1) the date or dates of the quality assurance review and the names and titles of the staff members performing the review
(2) the pertinent data and other information relating to the prescription error reviewed;
(3) documentation of the patient and prescribing practitioner contact required by section 20-635-3 of the Regulations of Connecticut State Agencies;
(4) the findings and determinations generated by the quality assurance review
(5) recommended changes to pharmacy policy, procedure, systems,or processes, if any.

And here's a "Pro Tip": when you read this report, format all of your sentences by saying WHO did WHAT and WHEN. Write the report in chronological order. Indicate WHO identified the error, and WHO reported it to the pharmacy and WHEN. Be sure to say WHO

filled, and WHO approved the prescription for dispensing, and what they recall about the incident. Many times, pharmacists will look at an error when it comes back and remember exactly what was going on when they were working on the prescription. Identify areas that may help prevent this error in the future, and say exactly WHO will make changes, HOW they will make the changes, HOW they will communicate the changes to staff, and WHEN the changes will be fully implemented. And please don't forget to say WHO talked with the prescriber and the patient and WHAT they recommended



●Here’s a quick reminder that pharmacy records need to be store securely within the pharmacy premises. If you want or need to store them outside the premises, you must ask for permission. This ensures that all records will be stored safely, and no inadvertent breaches occur.

Another note about signage

●Is a sign required? YES IT IS!
●Each pharmacy that dispenses a prescription to a consumer shall include the following printed statement on the receipt or in the bag or other similar packaging in which the prescription is contained:
“If you have a concern that an error may have occurred in the dispensing of your prescription you may contact the Department of Consumer Protection, Drug Control Division, by calling (Department of Consumer Protection telephone number authorized pursuant to section 21a-2 of the general statutes).”

The statement shall be printed in a size and style that allows such statement to be read without difficulty by consumers.

You must post this sign prominently in your pharmacy. Do not remove it to promote a product or hide it in an area that nobody can see or behind a magazine rack!

Quality Assurance, continued

- Give a copy of the program to each employed pharmacist
- Notify all pharmacy personnel that must report all prescription errors immediately to a pharmacist on duty
- Inform all pharmacy personnel any changes to the pharmacy policy, procedure, systems, or processes made pursuant to recommendations generated by the QA program

●A critical element in every quality assurance program is to ensure that changes that result from review of errors are communicated to all appropriate people. This means that pharmacy managers need to lay the groundwork for a successful program by making sure that each employed pharmacist (and probably each employed technician, too) has a copy of your organization's quality assurance program as it relates to medication errors.

●Notify all pharmacy personnel – full and part-time employees and even those employees who just come in once a month – that they need to report prescription errors immediately to the pharmacist on duty.

●Once you review quality assurance data and decide to make changes be absolutely certain to communicate those changes and change policies, procedures, or processes appropriately.

Of course, we have another “Pro Tip” for you: Keep a tracking log that shows that you’ve distributed the QA program to staff, noting the date. And, keep simple meeting minutes that document that you’ve reviewed errors with the staff and that you’ve made (and implemented) decisions.

Reporting Prescription Errors

- Display a sign about reporting of prescription errors in a conspicuous location visible to consumers
  - It must be at least 8 inches in height and 10 inches in length

- *Font and size must be easy to read*
- Font and size must be easy to read
- *Font and size must be easy to read*
- Font and size must be easy to read

- Do not obsure the sign behind a promotion or display!

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Again, this is an important reemphasis! Each pharmacy needs to have a sign that's visible to all consumers indicating that they can report concerns to DCP. The specific sign must read:

"If you have a concern that an error may have occurred in the dispensing of your prescription you may contact the Department of Consumer Protection, Drug Control Division, by calling (800) 842-2649."

Notification of Prescription Errors

- Always notify the prescribing physician and patient when errors occur
  - Document the date, time, and person to whom you spoke
  - DO NOT leave this section blank
- Communicate the method of how to correct the error to avoid a negative impact on the patient

As soon as any pharmacist identifies a prescription error, he or she should notify the prescriber immediately. Often, it's the patient who identifies the prescription error, but if someone else identifies the error the pharmacist is also obligated to speak with the patient or the patient's caregiver immediately. If a patient is deceased or cannot fully comprehend the prescription error, the pharmacist or pharmacy manager must inform a family member or caregiver.

While many business have policies on how to handle prescription errors, it is your responsibility to ensure that at a minimum, you meet Connecticut’s legal requirements.

MedWatch Reporting

- FDA's adverse event report program
- Can also report quality control problems, counterfeit products, and therapeutic failures
- Voluntary reports by healthcare professionals and consumers
- Electronic submission on FDA website:
  - https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home

While MedWatch is not a legal requirement, the pharmacy commission encourages pharmacy managers to engage their staff in participating in the MedWatch program This is an opportunity to do surveillance on new drugs and to report information back to the FDA. The web link is provided here.

https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home

Things Pharmacy Managers Should Know

- Inspection of prescriptions, orders, and records
- Pharmacy security and required equipment
- **Annual** inventory
- Child resistant caps
- Hypodermic needles

Please note that the inventory used to be BIENNIAL
In 2019, the law changed.
The inventory is now ANNUAL.

Now let's move onto some miscellaneous areas that will need the pharmacy manager's attention.

Prescription Requirements

- Prescriptions must have labels that comply with federal and state statutes and regulations
- Prescribing practitioners or their agents must communicate oral orders new prescriptions directly to the pharmacist
  - They can communicate refill authorization to the pharmacist or a technician
- The prescription department must receive electronically transmitted prescriptions

●All prescriptions dispensed by pharmacies must have labels that comply with federal and state statutes and regulations. Most pharmacies comply with this requirement well because they use computerized programs to print their labels. These programs ensure that all required elements are on the label.

●Often, prescribers call in prescriptions for patients, either communicating a new prescription or authorizing a refill. Pharmacy managers need to be sure that all staff understand that pharmacists are the only staff members authorized to take a new prescription over the phone. Technicians, however, are allowed to receive oral refill authorizations.

●Currently, all pharmacies in Connecticut must have the capacity to receive prescriptions electronically. With the change in laws regarding Class II controlled substances that went into effect on January 1, 2018, this is more important than ever. [Need to insert information about electronic prescriptions and what happens if you actually print the prescription]

●And a final note here. Pharmacy managers are responsible for monitoring stock (or having a system to monitor stock for misbranded prescription drugs. Misbranded drugs are those that are unlabeled, incompletely labeled or improperly labeled. They must have a system for handling all drug recalls, remove them from sales and storage areas immediately, And they must identify them clearly, storing them in an area where they cannot be inadvertently used.

Busy, Busy, Busy...

It’s busy in the pharmacy and you’re stuck on hold with an insurance company. An agent to Dr. Smith is calling in a refill authorization for one of your patients.

What do you do?

Here, the pharmacist can allow the technician take the oral order for the refill authorization. But, let's note a few points of refinement:

1. The supervising pharmacist must be aware that such an authorization is being requested;
2. The refill for which the authorization is being requested must be identical to the original prescription; the prescriber cannot change the prescribed drug, its strength, form, quantity, dose, route of administration or in any other element of the prescription; and
3. The supervising pharmacist must review all refill authorizations obtained by the pharmacy technician by to insure that there is no change in the prescription

Substitution of a Drug

- Prior to substitution, the pharmacist must notify the patient or the patient's agent
  - Patients may not want the substitution to be made
- Pharmacists must document a substitution on the prescription

●Connecticut's regulations require all pharmacies to post a sign indicating that they may substitute a generic drug for a brand name drug. It must say, "**THIS PHARMACY MAY BE ABLE TO SUBSTITUTE A LESS EXPENSIVE DRUG PRODUCT WHICH IS THERAPEUTICALLY EQUIVALENT TO THE ONE PRESCRIBED BY YOUR DOCTOR UNLESS YOU DO NOT APPROVE."**

●There are various reasons why a pharmacist may need to substitute a generic drug, including third-party or insurance formularies that require substitution, or Medicaid-mandated generic substitution.

●When the pharmacy substitute generics for brand names, the pharmacist is responsible for letting the patient or the patient's agent know that the substitution has occurred. If the patient does not want a generic substitute, the pharmacist needs to explain why the substitution was made, and what will happen if the patient insists on the brand name. So, for example, if the substitution was made because the patient's insurer will not pay for brand name, the patient may have to pay for the prescription if he or she insists upon brand-name drug.

Security

- The pharmacist in charge must restrict or control access to pharmacy stock stored outside of the pharmacy, where it is not under immediate supervision
- Only authorized personnel may have access to the prescription department
- LOCK UP if no pharmacists, interns, or technicians are in the area!

Sometimes, the pharmacy dispensing spaces is small and doesn't have enough space to store excess stock. In this case, the pharmacy may have storage in other areas of the building. When this is the case, the pharmacy manager or pharmacist in charge needs to restrict or control access to that area. All of the rules that apply to regular drug storage apply to that area, so it should be locked at all times unless a pharmacy employee is inside. Unless the area is under a pharmacist's direct visual control, it needs to be locked and access must be limited

As pharmacy manager, you're responsible for the prescription department's security even when it is closed for the day. Earlier, we discussed the point that pharmacies that are located in supermarkets, big-box stores, or other retail locations need to have physical barriers that separate them and are able to be locked during non-business hours. Pharmacy managers need to know Connecticut's laws regarding who is allowed to access the prescription department. They must also know their orghanization's policy and make sure that only authorized individuals have access to the prescription department.

Entry of other people should be limited to activity necessary for legitimate pharmacy business. When sales representatives, delivery people, customers, or anyone else has a legitimate reason to enter the pharmacy, their entry needs to be restricted and well supervised.

Equipment

- To ensure that prescriptions can be dispensed properly, every pharmacy must have
  - Properly working pharmaceutical equipment
  - Appropriate pharmaceutical reference materials

You must make sure policy and procedures are established and followed to ensure all equipment (scales, refrigerators) is working properly. For example, any refrigerator used to store pharmaceuticals needs to be in working order. Using a temperature monitoring log and assigning someone to check the refrigerators temperature daily and record it is a good way to ensure that the refrigerator remains in good working order. Similarly, pharmacy managers need to look at other equipment and determine how often and how pharmacy employees should test the equipment.

Annual Inventory

- Complete and accurate record of all stock of controlled substances
- Prepare annually, initially between May 1 through 4
- Write “opening of business” or “close of business,” who conducted the inventory, and the date conducted

- Keep on file (and readily retrievable) for 3 years
- Have available for the Commissioner and his authorized agents

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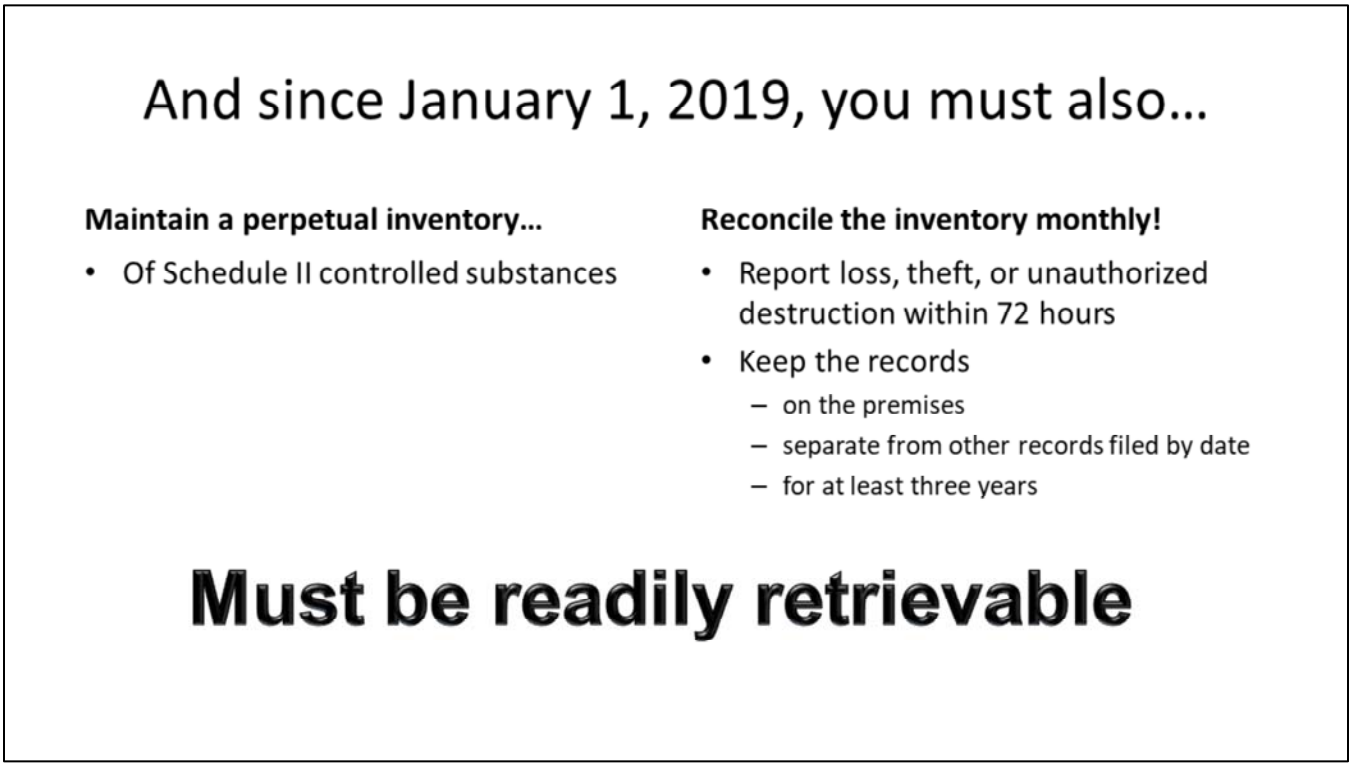
●https://www.canstockphoto.com/pharmacy-chemist-women-in-drugstore-8459038.html

●In Connecticut, state law requires all pharmacies to conduct an annual inventory every year between May 1 and May 4. Often, when drug control agents visit pharmacies and make unannounced visits, they asked to see the annual inventory. Pharmacists may say that they conduct a perpetual inventory or that they conduct the annual inventory in a certain month other than May according to their organization’s policies. This does not fulfill the requirement for an annual inventory in May of every other year.

●You must document whether the inventory was taken at close of business or open of business. You must also indicate who did the inventory, and date it.

●Here's a "Pro Tip" for pharmacy managers: Make sure you create some kind of tickler – a note on your calendar or an electronic reminder – that tells you that your annual inventory is due.



Since January 1, 2019, pharmacies in Connecticut must maintain perpetual inventories of Schedule II controlled substances, and this slide points of the critical elements of the law. Maintaining a perpetual inventory means that you need your entire staff must record all prescriptions for Schedule II controlled substances as they fill them fill them and record the balance. Once a month, you need to conduct a reconciliation. If you find a variation and suspect loss, unauthorized destruction or theft, you must notify the state within 72 hours. Keep your records on the premises. Keep these record separate from other records, and keep them for at least three years.

Child Resistant Caps

- Poison Prevention Packaging Act of 1970
- Requires the use of child resistant packaging for prescription products, over-the-counter drugs, household chemicals, and other hazardous material that is considered dangerous to children
- A patient can request non-child resistant caps
  - Pharmacy staff should document request for future encounters

●Child resistant packaging was developed in the 1970s to reduce the risk of children ingesting dangerous medications. These caps are called child resistant because real childproof packaging is not possible. Children have a remarkable propensity to get into just about anything so pharmacists, pharmacy staff, and patients should not rely on child resistant caps as a first line of defense. All patients need to be aware that they should store medications away from the reach of children.

●In particular it's important for patients to know that two of every 10 medication poisonings in children involve their grandparents' medications. Advise grandparents to store medications away from reach of their grandchildren, and under lock and key if possible.

●During unannounced inspections, drug control agents will look for evidence that you've complied with state laws covering child resistant caps. Patients can request non-child resistant caps, and the pharmacy staff need to document the request on the patient's record.

https://www.cpsc.gov/Business--Manufacturing/Business-Education/Business-Guidance/PPPA

Hypodermic Needles

- Sell 10 or fewer unless
  - The patient has a prescription
  - Purchaser is business or practice with a legitimate industrial or medical use
- Store in location accessible only to authorized personnel
- Destroy all used hypodermic needles and disposable syringes

●Technically, patients do not need prescriptions to purchase insulin syringes. Some states, including Connecticut, have guidelines limiting the number of syringes that can be purchased over the counter. Connecticut limits OTC sales of syringes to 10 or fewer. Several other nearby states also limit the sale of syringes to 10 or fewer unless the patient has a prescription. The states include Maine, New Jersey, New York, and New Hampshire.
●Pharmacy managers need to oversee hypodermic needle storage, and ensure that needles are assessable to authorized personnel only. They also need to have a process available for patients to dispose of needles and syringes.

Computer System and Refill Data

- Automated data processing systems must:
  - Guarantee confidentiality
  - Have safeguards against erasures and unauthorized changes in data after the information has been entered and verified by the pharmacist
  - Be able to be reconstructed

●This slide summarizes requirements for automated data processing systems. Take a moment to review it. [SPEAKER: PAUSE for 5 seconds.]

VIDEO

- Finally, let’s wrap up with a short video that emphasizes a few important points.

A final note…

To be in a constant state of readiness

Be certain to find and read inspection reports from previous years.

DCP's inspectors will know what deficits were discovered in previous inspections. They'll look to see if you have corrected those problems.

How embarrassing for you if you didn't.

●Here's a PRO TIP for you to finish up. When DCP's inspector visit, they leave a copy of their report an their findings. Find and look at reports from previous inspections today or tomorrow. Do all staff members know what the inspectors found? Have those issues been corrected? Were they corrected, but staff is slipping back into bad habits?

●Address the problems until they are fixed and stay fixed. Share the results of previous inspections. Remind staff gently when they are violating state law. It will keep you out of hot water.

POST TEST QUESTIONS ARE IN A SEPARATE DOCUMENT