

Law: Connecticut's Pharmacy Managers Promoting a Constant State of Readiness
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This slide kit was assembled by a team of mainly volunteers.

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- Gabriella Scala, PharmD Candidate, 2022
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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

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The Department of Consumer Protection

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

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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

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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

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Slide 5

JN9

How many pharmacies are there in CT to date?

Joanne Nault, 9/18/2020

Notification Requirements

- The pharmacy owner/supervisor must notify the Commission immediately when a pharmacist is newly appointed as a pharmacy manager
- The owner must report pharmacy manager absences:
 - Of 16 consecutive days
 - After 42 consecutive days, he or she will no longer be recognized as the pharmacy manager

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Operation Responsibilities

- Post the pharmacy manager's name so it is visible to the public
 - The law says, "conspicuously 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

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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

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Responsibilities Vary by Setting

- ENTIRE PREMISES: Devoted primarily to the pharmacy operation?
 - The entire premises is licensed as a pharmacy
 - Pharmacy manager is responsible for the entire premise
 - Includes both front store and prescription department
- ENTIRE PREMISES: Not devoted primarily to the pharmacy?
 - Separate the pharmacy (partial premises) from the rest of the premises with a physical barrier
 - Pharmacy manager is only responsible for the area licensed as the pharmacy
 - Ensure that the pharmacy has a non-legend drug permit (PME)

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What are the Pharmacy Manager's Responsibilities to DCP?

- **Staff Management**
 - Licensing/Registration
 - Scheduling
- **Record keeping**
 - Controlled and noncontrolled prescription records
 - Quality assurance
 - Prescription errors
 - Inventory
 - OBRA regulations
- **Reporting losses, thefts, or unauthorized destruction of controlled substances**

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Supervision of Pharmacists

- Pharmacists licenses valid from February 1 through January 31
 - CT sends renewal notices by e-mail every two years
 - Pharmacists must sign, certify completion of CE, and return the form to DCP with a \$120.00 fee
 - Failure to receive notice or renew license does not exempt licensees from renewal requirements

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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



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Supervision of Pharmacy Technicians

- Each technician must renew his or her registration annually
 - Ongoing training is essential!
 - **Print** your records!!!
- **Technicians must wear name tags that identify them as pharmacy technicians to the public**
- "Pharmacist providing direct supervision of pharmacy technicians shall be responsible for their actions."

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Supervision of Pharmacy Technicians


- Ratio based on setting/certification
 - Outpatient settings allowed 2 technicians per pharmacist
 - Provided one is CPhT, may petition for up to 3 based on need
 - PRO TIP: You cannot add two CPhT and increase your ratio!!! The limit is ONE.
 - Inpatient and satellite settings allowed 3 technicians per pharmacist
 - May petition for up to 5 based on need

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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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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

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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

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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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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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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

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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

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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

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Loss, theft, and unauthorized destruction of controlled substance

- A registrant must
 - Reported loss, theft or unauthorized destruction 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



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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

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OBRA Regulations

- Pharmacist's duties towards Medicaid recipients
 - Obtain, record, and maintain pertinent patient information
 - Always review the drugs previously dispensed to the patient
 - Offer to counsel on the drug being dispensed
 - NEW: Under OBRA, you must offer counseling to EVERYONE

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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

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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

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Record Storage

Just a quick note...

You cannot store pharmacy records outside the pharmacy premises without permission from DCP

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Another note about signage

Post Prominently, Do Not Remove

"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."

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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

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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 obscure the sign behind a promotion or display!



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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

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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>

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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.

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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

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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?

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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

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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!

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Equipment

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

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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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And since January 1, 2019, you must also...

Maintain a perpetual inventory...

- Of Schedule II controlled substances

Reconcile the inventory monthly!

- Report loss, theft, or unauthorized destruction within 72 hours
- Keep the records
 - on the premises
 - separate from other records filed by date
 - for at least three years

Must be readily retrievable

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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

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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

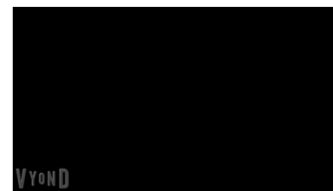
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Computer System and Refill Data

- 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

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VIDEO



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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.

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POST TEST QUESTIONS ARE IN A SEPARATE DOCUMENT

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