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The Legal Blueprint: Designing Error-Proof Pharmacy Policies

UCONN

AN ONGOING CE PROGRAM
of the University of Connecticut School of Pharmacy and Pharmaceutical Sciences

EDUCATIONAL OBJECTIVES

After completing the continuing education activity, pharmacists and pharmacy technicians will be able to

- RECALL the key governing bodies and their roles
- RECOGNIZE important details, dates, and timelines for a pharmacy manager
- DESCRIBE the duties of pharmacy technicians and interns
- DETERMINE the roles and responsibilities of a pharmacy manager
- IDENTIFY key pharmacy laws that pharmacy managers should implement in practice

The Uconn School of Pharmacy and Pharmaceutical Sciences is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Pharmacists and pharmacy technicians are eligible to participate in this application-based activity and will receive 0.2 CEU (2 contact hours) for completing the activity, passing the post-test with a grade of 70% or better, and completing an online evaluation. Statements of credit are available via the CPE Monitor online system and your participation will be recorded with CPE Monitor within 72 hours of submission.

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To obtain CPE credit, visit the UConn Online CE Center https://pharmacyce.uconn.edu/login.php. Use your NABP E-profile ID and the **session code 26YC42-DEP75 for pharmacists and 26YC42-PDE57 for pharmacy technicians** to access the online quiz and evaluation. First-time users must pre-register in the Online CE Center. Test results will be displayed immediately and your participation will be recorded with CPE Monitor within 72 hours of completing the requirements.

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TO REGISTER and PAY FOR THIS CE, go to: https://pharmacyce.uconn.edu/program_register.php

TARGET AUDIENCE: Pharmacists and technicians who desire a CONSTANT STATE OF READINESS for inspections.

ABSTRACT: As the retail pharmacist's scope of practice evolves and pharmacies become busier, pharmacy managers' responsibilities grow more and more complex. To understand these complexities, pharmacy managers require a deep understanding of state and federal laws. The most successful pharmacy managers operate in a constant state of readiness, treating compliance as an everyday process rather than a response to an inspection. This continuing education activity will develop pharmacy managers and provide resources for upcoming or unannounced inspections.

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FACULTY DISCLOSURE: The authors have no financial relationships with an ineligible company.

DISCLOSURE OF DISCUSSIONS of OFF-LABEL and INVESTIGATIONAL DRUG USE: This activity may contain discussion of off label/unapproved use of drugs. The content and views presented in this educational program are those of the faculty and do not necessarily represent those of the UConn School of Pharmacy and Pharmaceutical Sciences. Please refer to the official prescribing information for each product for discussion of approved indications, contraindications, and warnings.

INTRODUCTION

Along with pharmacy practice becoming more complex, well-being reports reveal pharmacy staff members experience high rates of burnout and distress. Often, these factors lead to staff turnover, medication errors, inadequate patient education, and increased risk of patient harm. To mitigate these issues and manage staff, pharmacies require highly educated and trained pharmacy managers. For pharmacy managers, companies have high expectations that the candidates they select will know and adhere to company policy, but also state and federal laws.[1,2] The most successful pharmacy managers operate in a constant state of readiness, treating compliance as an everyday process rather than a response to an inspection.

Pharmacy manager responsibilities fall into three main categories: the pharmacy, the personnel, and the prescription. The pharmacy manager's responsibilities are broad because the manager is accountable for anything that occurs in the pharmacy. Let's start with a **PRO TIP:** The best pharmacy managers don't prepare for inspections—they practice in a constant state of readiness every day.

REGULATORY BODIES IN PHARMACY

When they have knowledge of pharmacy governing bodies, pharmacy managers improve efficiency when filing reports, researching pharmacy law updates, and reviewing statutes. The Food and Drug Administration (FDA) and the Drug Enforcement Agency (DEA) are the major players at the federal level. The FDA creates and enforces regulations for all consumer products, including pharmaceuticals. FDA inspectors review each step of the pharmacy supply chain; any issue during this process must be reported to them.

The DEA enforces the U.S. controlled substance laws. Pharmacy managers must report any issue with controlled substance distribution and manufacturing, or general related concerns to the DEA. We discuss some specific DEA Forms during the Legend Drug Inventory section later in this activity.[3]

The Joint Commission (TJC) creates pharmacy practice standards and, similar to the FDA, they enforce these standards. TJC is an independent, non-profit entity that accredits and manages healthcare facilities and services, such as hospitals, home care pharmacies, and point-of-care testing.[4,5]

On the state level, the Board of Pharmacy (BOP) regulates pharmacy practices. Every state has different pharmacy laws. Pharmacy managers must be familiar with their state's BOP to understand changes in laws or pharmacy practice to maintain a CONSTANT STATE OF READINESS. In many states like Connecticut, the BOP acts as a judicial group, approving licenses or registrations and ruling on penalties if anything transpires during inspections.[6] Pharmacists under investigation or at risk of having their license suspended or revoked may need to visit BOP meetings to hear the judgements.[6]

PAUSE AND PONDER: Congrats! Your management promoted you to pharmacy manager. Take a moment and consider your new responsibilities. What have you seen pharmacy managers oversee in the past? Who or what do you supervise?

PHARMACY MANAGER RESPONSIBILITIES

New Pharmacy Managers

Many states have specific regulations for newly promoted pharmacy managers. Regulations for reporting controlled substance inventories, reporting changes in management, and potential interviews with the BOP after promotion often differ between states.

Many states like Alabama, Nevada, New Jersey, and Texas require pharmacy managers to record controlled substance inventories upon promotion.[7] The timeline to report the inventory also differs between states. Alabama requires a full controlled substance inventory within 15 days promotion, whereas Texas and Nevada have stricter reporting laws after the manager changes.[8] Texas requires inventory on the day of management change and Nevada requires inventory within 48 hours.[8,9,10] A **PRO TIP** is that new pharmacy managers should record a full controlled substance inventory, even if state laws do not mandate one. While taking inventory, the pharmacy manager can reconcile old problems that occurred prior to their supervision, preventing future liability issues.

Reporting updates in management also differs between states. A new pharmacy manager should always report a management change to the board. Many states require the out-going pharmacy manager to report their departure as well.[7,11] During state inspections, clarity about the current pharmacy manager can improve the efficiency of the visit.

Upon promotion to pharmacy manager in Connecticut, the state's Department of Consumer Protection requires an in-person interview with the Commission of Pharmacy (COP). The COP, known as the BOP in most states, will discuss new manager responsibilities and assess the pharmacist's character during the interview. The COP meets on the last Wednesday of every month, except for December, January, and February, so each pharmacy manager should plan accordingly and submit requests to appear at the monthly meeting early.[6,12]

Personnel

A pharmacy manager's main responsibility is managing the pharmacy's personnel. Outside of pharmacy law, managers handle staff scheduling and complaints. At first, scheduling may not seem so terrible, but having to schedule an entire staff with no prior experience can quickly become overwhelming. Managers

need to plan and inform the team about deadlines for requesting days off. A **PRO TIP** is to prepare for any eventuality by having staff contact information handy at work and at home. Last minute emergencies or changes will happen sooner than later!

Licenses and registration requirements are ubiquitous in pharmacies. It's the manager's job to ensure that personnel, the premises, and the controlled substance licenses remain active and valid. Inspectors often check license expiration dates, and they may ask the pharmacist in charge to pull all the pharmacy's licenses for staff and the premises. This is where maintaining a CONSTANT STATE OF READINESS is key. The manager needs to guarantee each staff member's license or registration is current and readily available.[13]

In a world plagued with staff burnout, understanding each pharmacy team member and creating a positive environment will prevent errors. According to a 2024 National Pharmacist Workforce Study, 73% of pharmacists rated their workload as high or excessively high.[14] Across different pharmaceutical fields, retail/community pharmacists ranked highest with 91% of employees reporting excessive workloads.[14] Researchers concluded that the pharmacy work environment requires drastic changes. **PRO TIP:** Pharmacy managers should learn each individual staff member's preferences. Some staff members require scheduled one-on-one time to voice their concerns and questions, others prefer more autonomy to make their own decisions. Pharmacy managers should avoid micromanaging their staff.

Let's discuss the details of each pharmacy personnel to understand how to manage them better.

Personnel: Pharmacist

Pharmacists must renew their licenses in keeping with state requirements; The National Association of Boards of Pharmacy (NABP) maintains the CPE Monitor system. Upon upgrading to the Plus Plan, users can receive a state-by-state breakdown of renewal requirements for all 50 states and the District of Columbia (DC).[15] Other Plus Plan features include a dashboard that outlines the states' required hours and develops alerts for upcoming deadlines.[15] Managers need to remind pharmacists as renewal dates approach because, from time to time, states may change the renewal process or period.[16]

Pharmacy managers can purchase pharmacy compliance software to track staff licenses and non-CE training requirements. If managers find themselves inundated with tasks, they can designate a pharmacy technician to monitor overall staff progress. For staff members, federal laws mandate training courses on HIPAA, pseudoephedrine, and Fraud, Waste, and Abuse initially upon hire and/or annually.[17,18,19,20] Pseudoephedrine training is required for any individual who is directly involved in the sale of Scheduled Listed Chemical Products containing ephedrine, pseudoephedrine, or

phenylpropanolamine.[20,21] Fraud, Waste, and Abuse training is required for any facility participating in Medicare Part C or Part D or other federal programs.[18,19]

Compliance software provides courses and tracks each staff member's progress to help the pharmacy meet federal training requirements annually.[22] Some software offers extra management training for pharmacy managers to improve.[22] Larger retail chains have proprietary software for management to use like LearnRX for CVS pharmacy technician training.[23] Many options for compliance tracking are available for independent pharmacies such as COMPLIANCETrack, PRS Pharmacy Services, and AlignRX.[22,24] Independent store pharmacy managers should discuss options with their pharmacy software representatives as they may recommend specific compliance trackers that integrate better with the software.

For license renewal, pharmacy boards generally notify individuals whose licenses are expiring 30 to 45 days before license expiration. Many states, like Connecticut, use fast-track renewal personal identification numbers (PINs) that identify the license or registration, making renewal simple.[25] Renewing the pharmacy license follows the same procedure, which we will discuss later.

During each renewal period, pharmacists need continuing education (CE) credits. Motivating and encouraging pharmacists to keep up with their CE helps prevent license renewal delays.[26] Monitoring each staff member's CEs is difficult, so the pharmacy manager can intermittently remind pharmacists about acquiring CE credits. Many states have different specifications for each CE; Connecticut only requires one annual pharmacy law credit (congrats!).[26] As the pharmacy manager also needs CE credits, finding and sharing CEs with staff from accepted accreditors may ease the process.[26] The most common place to find specific CE is through the Accreditation Council for Pharmacy Education or the state BOP website. Some states allow pharmacists to take Continuing Nursing Education, Continuing Medication Education classes, or other accredited institutions for credits.[26] Although pharmacists do not need to submit CEs when renewing their

license, CE audits can occur up to three years after renewal, so pharmacists should track and record each one in CPE Monitor.[15]

PAUSE AND PONDER: You've completed hundreds of prescriptions, but the list keeps growing! Meanwhile, your pharmacy technicians, Ethan and Matthew, are bickering about renewing their pharmacy technician license. They seem unsure about their requirements after hearing other pharmacists talk about CE credits. Do pharmacy technicians complete CE credits for license registration renewal? What resources can you show them? Why is it necessary to keep staff educated?

Personnel: Pharmacy Technicians and Interns

The Pharmacy Technician Certification Board (PTCB) certifies some pharmacy technicians nationally, designating them Certified Pharmacy Technicians (CPhT). Certain states, such as Texas, North Dakota, and Virginia, require pharmacy technicians to become nationally certified with the PTCB in addition to registering with the state for licensure; all 50 states, DC, and the U.S. territories recognize technician certification.[27] States that do not require this certification often allow higher technician ratios if one technician is a CPhT. If the state authorizes more technicians per pharmacist when the pharmacy employs a CPhT, pharmacy managers can encourage pharmacy technicians to become certified and consider offering a better salary as an incentive.[28] Managers should remember that pharmacists may refuse to supervise extra pharmacy technicians if they are not comfortable directly supervising more staff. How pharmacists handle the refusal depends on state law, employer policy, and professional duty standards.

National certification requires CE credits for technicians.[29] Uncertified pharmacy technicians who register with their states (not nationally) often do not need CE. An advantage to certification is that the PTCB helps pharmacy technicians develop and train continuously. Notifying uncertified technicians and encouraging them to take CE is smart. Complacency causes workplace errors and mistakes, so consistent engagement with CE courses will galvanize development and reaffirm skills to prevent medication errors.[30]

Each pharmacy technician and intern requires direct supervision. In other words, the pharmacist on duty must be physically present to make in-progress and final checks during the prescription filling process. The supervising pharmacist is responsible for any and all actions of the pharmacy technicians and interns. Federal law does not limit the number of pharmacy technicians, but many states dictate a maximum technician to pharmacist ratio.[28,31] **Table 1** shows some state limits to technician ratios.[7,28,32,33,34,35]

In many states, pharmacy interns must accrue at least 1500 hours across the course of their internships, but cannot work more than 40 hours in a week.[31,36] One of few exceptions is Illinois, only requiring students to accumulate 400 hours of training.[37] During this time, interns can perform pharmacist tasks including compounding, dispensing medications, and other services, as long as they have direct supervision from a pharmacist.[38] To oversee interns, pharmacists must become pharmacy intern preceptors.

Compared to pharmacy interns, pharmacy technicians have a limited scope of responsibility. Technicians cannot perform tasks that call for extended clinical knowledge or decision making, such as counseling patients, receiving new verbal prescriptions, or determining therapeutic alternatives. Besides general prescription filling, technicians can receive refill authorizations from practitioners, given the prescription is identical to the previous refill and not a controlled substance.[39] The pharmacist should establish that the prescription remains unchanged from the previous refill by checking the technician's prescription. Pharmacy managers must confirm that staff members practice within their scope.

Sometimes, busy pharmacies use pharmacy interns as extra labor during their rotations. Pharmacy managers should NOT encourage using pharmacy interns this way; all pharmacy managers should remember their time as interns and use that to help promote a safe environment that nurtures learning without overworking them. Because pharmacy managers are knowledgeable in pharmacy practice, they should offer themselves as a resource to pharmacy interns.

Table 1. Pharmacy Personnel in Various States[7,28,32,33,34,35]

Connecticut	Massachusetts	New Jersey	New York
Pharmacy Manager	PIC (resident pharmacy) or Manager of Record (non-resident pharmacy)	PIC	Supervising Pharmacist or PIC
Pharmacy Technician (2:1 or 3:1 ratio)	Pharmacy Technician (3:1 or 4:1 ratio)	Pharmacy Technician (2:1 ratio)	Pharmacy Technician (2:1 ratio)
Pharmacy Intern	Pharmacy Intern	Pharmacy Extern (student)	Pharmacy Intern
		Pharmacy Intern (post-graduation)	

ABBREVIATIONS: PIC = Pharmacist-in-Charge

The same applies to pharmacy technicians. Pharmacy technicians are the pharmacists' most important assets. Without them, the pharmacy would not run smoothly. Pharmacy managers should not delegate menial tasks to them, but rather work alongside them to form a proper team.

To avoid patient confusion (patients sometimes think anyone in a white coat or scrubs is "the pharmacist," when in reality, the person may be a technician or a clerk), pharmacy managers should encourage the use of clearly visible name tags. Name tag laws change among states. New York requires anyone working in a registered pharmacy to wear a name tag that also indicates their position.[40,41] New Jersey instructs all pharmacy personnel to wear name tags, except when actively compounding sterile prescriptions.[42] In Connecticut, state law requires only pharmacy technicians to wear name tags.[39] Every state is different!

Originally, Iowa required pharmacy personnel to wear identification name tags but have since repealed those laws.[43] In April 2024, Iowa legislators developed a new pharmacy practice act to update a 40-year-old law and nurture a modern standard of care. Behind Alaska and Idaho, Iowa became the 3rd state to overhaul their pharmacy laws to push pharmacists toward higher practitioner status.[44] Although not specifically mentioned, some may attribute the name tag repeal to the cut and slash for removing outdated, overly meticulous pharmacy laws.

Maintaining current licenses, required training, and clearly defined staff responsibilities keeps both the team and the pharmacy in a constant state of readiness.

The Pharmacy

Every pharmacy location differs, so each pharmacy manager should identify the exact parts of the premise they control. If the prescription department resides within a regular store, the pharmacy manager will have less to oversee than if the whole store is devoted to pharmacy as its primary operation. The location of the prescription department will also change requirements for personnel, security, signage, and licensing change.

If the pharmacy is entirely devoted to the practice of pharmacy (i.e., not a pharmacy located within a business), the pharmacy manager must supervise all products in the store. Pharmacy managers can delegate clerks or other pharmacy employees to check over-the-counter stock to prevent any safety issues due to misbranded drugs or devices.[45] Staff should remove any improperly labelled, expired, or other damaged products from stock.[45] Independent of normal stock, staff must maintain the pharmacy in clean, sanitary order.[46]

PAUSE AND PONDER: The prescriptions keep piling up, patients are upset, there is simply not enough room or staff to manage the workload. Thankfully, you have notified your pharmacy owner, Frank, and he (finally) determined that the pharmacy needs a new, larger location. As pharmacy manager, what tasks do you perform during the move? Does Frank need your help or can he manage the BOP by himself?

The Pharmacy: Licensure

When applying for pharmacy licensure, state regulations may require the presence of the pharmacy manager. In Connecticut, regardless of whether the application for the pharmacy licensure is for a new pharmacy or a relocating pharmacy, the pharmacy manager must present in person with the licensee to the board.[47] In other states, pharmacy managers are, more often, not required to appear before the board, unless they are the owners. For example, New Jersey and Massachusetts require new owners to disclose their pharmacy manager on the application, but the manager does not always have to interview. Massachusetts indicates any member of the application process, such as the pharmacy manager, applicant, or interest holder, may be required to appear before the board.[48,49] New pharmacy managers should understand their responsibilities in new pharmacy applications.

North Dakota remains the only state that requires the pharmacy owner to be a registered pharmacist in good standing. This law, enacted in 1963, prevents chain pharmacies from opening stores throughout the state. Chains, such as Walgreens and Walmart, attempted to repeal the law in 2009, 2011, and 2014, but were unsuccessful. In 2014, Walmart spent nearly $3 million to campaign pushing to overturn the ownership law, stating that their presence could lower prescription prices. At the time, North Dakota ranked as the 13th lowest state for prescription pricing.[50,51]

Renewing pharmacy licenses follows the same procedure as pharmacists and pharmacy technicians. **PRO TIP:** Pharmacy managers can create charts to help visualize and track deadlines. **Table 2** illustrates how a Connecticut pharmacy manager can display license renewal dates and cost for staff reference.

The Pharmacy: Hours of Operation & Signage

After the board approves the pharmacy's license, the pharmacy manager must supervise the proper placement of signage and

Table 2. CT License Renewal Information [16,25,52]

License	Date Required (Annually)	New License Cost ($)	Renewal License Cost ($)
Pharmacist	January 31st	200	100
Pharmacy Technician	March 31st	50	50
Pharmacy	August 31st	750	190

hours of operation. Each state has specific requirements for minimum hours of operation and sign placement. For Connecticut, the pharmacy must remain open at least 35 hours per week.[53] Unscheduled closings of the prescription department may occur due to emergencies that leave prescription departments without a pharmacist. Unscheduled closings for Connecticut pharmacies must not exceed one day and 18 times in a 365-day period or more than twice in any 39-day period.[54] Within 72 hours of any unscheduled closing, the pharmacy manager must report the closure to the COP.

The pharmacy manager must post helpful details, such as closure duration or any pharmacies in a two-mile radius, so patients can continue to receive therapy.[54] If pharmacy managers find it difficult to keep the business open for lack of staff or other reasons, they can request a change in hours to the prescription department. The pharmacy manager must notify the COP 30 days before making any permanent changes.[55]

Hours of operation in rural states continue to challenge lawmakers. Currently, Maine requires pharmacies to remain open for 40 hours per week.[56] When 10% of Maine pharmacies closed between 2013 and 2024, lawmakers began to push new changes to pharmacy law to prevent more closures and pharmacy deserts.[57,58] A new bill allowing retail pharmacies to operate remote dispensing sites in rural areas is fighting through the Maine legislative system to challenge the current laws.[59]

Without directly changing the hours of operation laws, remote dispensing sites allow pharmacies to employ less staff onsite while increasing access to healthcare. While needing to reach minimum staffing and hours requirements, independent pharmacy gross profit margins plummeted to 21%, the lowest since the National Community Pharmacist Association began recording the data.[60] Rural pharmacy managers must identify ways to reach minimum hours of operation to maximize expenses while providing optimal care to patients. Some rural states, like Montana, do not specify a minimum hours of operation for retail pharmacies.[61]

If the business is devoted to the practice of pharmacy, the pharmacy manager should post its hours at all pharmacy entrances.[62] In addition, pharmacy managers must display their own name within or near the prescription department so patients can identify them.[63] Although signage seems menial, inspectors consistently check during routine visits. For all other signage, pharmacy managers can employ **Table 3** to guarantee signage compliance in future inspections.

The Pharmacy: Equipment & Security

For pharmacy managers in new pharmacies or relocating pharmacies, the BOP must first approve storage conditions for controlled substance and other legend drugs. Facility security requirements will change depending on previous security incidents or vulnerability to theft, number of controlled substances on hand, and other conditions that warrant increased security. Federal law mandates a steel cabinet or approved safe weighing at least 750 pounds or bolted/cemented into the building.[64,65,66]

Other pharmacy equipment subject to inspection include refrigerators, balances, and pharmacy pill counters. The pharmacy manager should maintain equipment in clean, working order.[46] Some states require pharmacies to keep specific equipment on hand, especially if non-sterile compounding occurs on site. Although tedious, New Jersey law instructs pharmacies to keep certain spatulas, volumetric devices, pharmaceutical references, and other materials on hand.[67] Originally, New York instructed every pharmacy to carry the United States Pharmacopoeia Dispensing Information, but recent changes dictate only physical copies of pharmacy law are kept on hand.

Table 3. Key Signage Checklist[46]

Sign	Specifications	
Pharmacy License	Conspicuously posted	☐
Pharmacy manager name	Clearly and readily identifiable to patients and customers	☐
Generic Drug Substitution	"THIS PHARMACY MAY BE ABLE TO SUBSTITUTE A LESS EXPENSIVE DRUG PRODUCT OR INTERCHANGEABLE BIOLOGICAL PRODUCT WHICH IS THERAPEUTICALLY EQUIVALENT TO THE ONE PRESCRIBED BY YOUR DOCTOR UNLESS YOU DO NOT APPROVE"" Block letters not less than one inch in height	☐
Reporting of prescription errors	Lettering in a size and style that allows for consumers to read without difficulty at the prescription department distribution counter "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 1-800-842-2649"	☐

For other current references, New York law permits online access.[68]

Pharmacy managers should delegate refrigerator and freezer temperature tracking twice daily. When logging temperatures, staff should confirm each metric falls within appropriate ranges. Connecticut state law indicates specific safe temperature ranges:

- Refrigerator
  - 2 to 8° C or
  - 36 to 46° F
- Freezer
  - -25 to -10° C OR
  - -13 to 14° F

Staff must notify the pharmacy manager if temperatures stray from the recommended range (called temperature excursions) as inspectors frequently check refrigeration logs.[46] Small details add up during inspections! Routine attention to equipment, security, and environmental requirements prevents last-minute scrambling and reinforces a constant state of readiness.

The Prescription

Document, document, document. If you didn't document it, it did not happen. These phrases should ring in every pharmacist's ears. Whether changing a prescription with practitioner approval, making a generic substitution, or other prescription adjustments, the pharmacy personnel should document everything. Documentation could protect the pharmacy manager and pharmacists from potential liabilities. Always document when dispensing!

PAUSE AND PONDER: What are your state's electronic prescribing laws? How does your staff handle/check written controlled substance prescriptions? Do you accept verbal prescriptions for controlled substances?

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The Prescription: Controlled Substances

Recent pharmaceutical trends show changes between opioid and stimulant prescribing in the United States. The opioid epidemic forced healthcare professionals to adjust prescribing patterns for optimal treatment to ensure minimal opioid use. Meanwhile, stimulant prescribing rates steadily increased between 2012-2022. With the DEA monitoring both situations, pharmacy managers must prepare their pharmacists.[69,70,71]

Electronic prescribing laws can improve the safety, quality, and efficacy of dispensing and prescribing.[72] Most states in the northeast United States have mandatory electronic prescribing laws for controlled substances, except for Vermont and New Jersey. As of 2015, Vermont became the 50th (last) state to *allow* electronic prescribing of controlled substances, without any hopes of electronic prescribing mandates on the horizon.[73] Some New Jersey legislators drafted bills for mandating electronic prescribing for all prescriptions, but none of them passed. The most recent New Jersey mandate bill died January 12, 2026 after two years in the committee.[74]

New York became the first state to mandate electronic prescribing for both controlled and non-controlled substance prescriptions.[75,76] The Center for Medicare and Medicaid Services (CMS) has specific policies for electronic prescribing; currently, CMS requires Part D prescribers to send at least 70% of their prescriptions electronically. States like New York have few worries because their laws align with the CMS mandate.[77,78]

Each state restricts controlled substance prescribing differently. States like North Carolina and New Jersey limit prescribing on initial opioid prescriptions for acute pain to five days. Across the U.S., states often limit initial opioid prescribing to seven days. Filling initial opioid prescriptions outside of these recommendations leave pharmacies open to liabilities.[79] **PRO TIP:** Pharmacy managers can post these recommendations near workstations as a constant reminder.

Prescription drug monitoring programs (PDMP) are state level databases that help track controlled substance habits for each patient. State laws mandate pharmacists use the PDMP to inform clinical decision making. The PDMP verifies that other pharmacies did not dispense the controlled substance in recent history or check to see if the patient has tolerance to opioids to receive more than an initial day supply. Electronic software should transmit all prescription and patient information, including pay code for cash or insurance, to the PDMP. Pharmacists must check the PDMP before filling controlled substance prescriptions and report controlled substance fills to the PDMP.[80,81]

Because controlled substance scheduling changes, each state may require different reporting to the PDMP. For example, gabapentin scheduling varies drastically between states. Kentucky became the first state to reclassify gabapentin to a schedule V controlled substance, so pharmacists must report gabapentin prescriptions to the state's PDMP.[82] Similarly, in 2019, Michigan reclassified gabapentin as a schedule V controlled substance. However, only six years later, Michigan descheduled gabapentin back to non-scheduled; pharmacy laws are always changing![83] Meanwhile, New Jersey does not classify gabapentin as a controlled substance, but still requires pharmacists to report fills to the PDMP.[84] Pharmacy managers should stay up-to-date with their state's reporting regulations to properly submit PDMP information.

The Prescription: Legend Drug Inventory

Pharmacy managers monitor controlled substance inventories. Many states enforce perpetual inventory records for Schedule II controlled substances. Perpetual inventory records allow pharmacies to identify mistakes or stock loss effortlessly during reconciliation periods. Because federal law requires pharmacies to report significant controlled substance loss within one day, perpetual inventory organization bolsters the pharmacy's CONSTANT STATE OF READINESS.

If a significant loss or theft of a controlled substance occurs, the pharmacy manager must report to the DEA in writing within one business day, then file DEA Form 106 within 45 days.[85] The DEA does not specify what constitutes a significant loss, but their Diversion Control Division gives criteria to help pharmacists estimate if a loss is significant[86]:

- Quantity lost in relation to the business
- Type of controlled substance lost
- If a pattern of loss is identified
- The controlled substance lost is a candidate for diversion

The DEA no longer accepts paper DEA form 106, so pharmacy managers should submit electronic forms only. Pharmacy managers will have to report to both federal and state agencies. Although all pharmacies must adhere to federal reporting guidelines, some states allow longer intervals when reporting to state agencies. For example, Connecticut permits 72 hours when reporting loss or theft to the Commissioner of Consumer Protection.[87]

For confirming controlled substance stock, many large retail or inpatient pharmacies use automated dispensing cabinets (ADCs) or pharmacy software equipped with back counting features. Examples of popular ADCs found in hospitals include BD's Pyxis Medflex or Omnicells XT.[88,89] Pharmacies lacking funds for expensive hardware can track similarly with logbooks. In this case, each staff member should write the prescription number,

amount dispensed, date, and their name for each fill. If pharmacy managers implement techniques like these, the risk of medication loss will diminish.

After placing an order for new controlled substances, staff should attach DEA Form 222 (electronic or print) to schedule II invoices. On the invoice, it's necessary to record who received the inventory, when it was received, and how much was received. If the manager discovers a major issue with the inventory, organized records will help pinpoint a date, time, and the person last responsible for that stock.[90]

The DEA enforces a biennial inventory for staff to report and reconcile inventory for all controlled substances. Each inventory record must report if the inventory occurred before opening of business or after close of business, the date, and the staff member responsible.[91]

If a patient does not pick up prescribed medication, staff must return those medications to stock. Before relocating the bottle to the shelf, staff must credit the insurance by reversing the claim.[92] To prevent misbranded drugs in the pharmacy stock, staff must take precautions to properly label returned medications. Return to stock medications should display the drugs name, strength, lot number, manufacturer, and expiration date.[93] Managers should encourage staff to use this advice for other legend drugs as well. Pharmacies should not shelve medication with damaged labels; tears that obstruct small information could lead to fines during inspection.

Well-organized records do more than satisfy inspectors—they allow pharmacy managers to demonstrate a constant state of readiness every day of the year.

The Prescription: Record Keeping

In many pharmacy basements, anyone can find boxes and boxes of prescription records as old as time. Maybe they do not have to stay there forever! Connecticut state law deems three years as satisfactory for documentation[87,94,95,96,97,98]:

- Prescription records (regular and controlled)
- Medication error documentation
- Controlled substance inventories (annual and perpetual)
- Pharmacist prescribing screening

Every pharmacy manager should understand that record keeping regulations change between states. Other states, such as Colorado and Virginia, require pharmacies to keep prescription records on file and retrievable for only two years.[99,100]

State pharmacy inspections often allow 48 hours to retrieve these documents, except for controlled substance inventory records. Pharmacy managers must produce controlled substance inventory data immediately upon inspection. The DCP permits electronic records, but if staff print the electronic copy, then they must add them to regular prescription records in chronological order.[96] Outside of pharmacy records, pharmacists should keep their continuing education certificates for three years for potential CE audits.[26] Connecticut's three-year record keeping requirement generally satisfies federal regulations. For electronic controlled substance ordering system (CSOS) records and prescriptions, federal law mandates pharmacies keep records for two years.[101,102]

Note that, despite state law, many pharmacies keep prescription records longer. CMS dictates retaining prescription records for at least 10 years, a requirement for all Part D sponsors and their downstream entities, like pharmacies, to receive Medicare reimbursement.[103] A **PRO TIP** is to mark boxes headed to storage with the content by date and prescription number range, and also include the date on which the contents can be destroyed.

PAUSE AND PONDER: A patient calls you over for consultation. She received someone else's prescription! As a newly promoted pharmacy manager, what steps do you need to take? Who is responsible?

The Prescription: Quality Assurance and Reporting

Quality improvement, a major task delegated to the pharmacy manager, ensures that the pharmacy and its staff members monitor prescription errors. The strongest programs identify potential oversight and correct them before a medication error occurs. Every staff member in the pharmacy should receive a copy of the quality improvement policies and procedures from the pharmacy manager. When pharmacy managers create strong quality assurance programs, they reduce liabilities. **PRO TIP:** Pharmacy managers with interest in learning new quality improvement techniques can visit the National Coordinating Council for Medication Error Reporting and Prevention (https://www.nccmerp.org/).[104]

When an error occurs, the pharmacy manager or staff should notify all involved parties: the prescriber, the patient, and the person who made the error (if applicable). Any error ideally initiates a policy review. The person closest to the error must document the date of the review, the name and title of the reviewer, and any information related to the prescription error. Every medication error should be documented on a separate incident report. Organization is key for prescription error reports. Clear and concise notes allow future inspectors or pharmacy managers to determine potential areas of vulnerability.[105] **Supplement 1** is an example of a prescription error reporting form that pharmacy managers can use in practice.

Pharmacy managers should update procedures after identifying problem areas to prevent future errors. If a change in the procedure occurs, the pharmacy manager should properly educate all staff. Some staff members take longer to learn, so pharmacy managers should allow time to learn and adjust.

Discovering medication errors will test pharmacy managers' ability to lead their teams. Many times, managers discipline staff after finding medication errors, but, instead of scolding staff, pharmacy managers should learn more progressive alternatives. The more a manager scolds staff, the less the staff will bring issues to the manager. Healthier work environments create stronger error prevention systems.[106]

Some managers use monthly staff meetings to identify potential problems. Pharmacy managers cannot observe at all times. When pharmacists speak at monthly meetings, they create conversations about topics that went unnoticed. Multiple staff recognizing the same issue means discovering a trend. At

meetings, pharmacists can brainstorm alternatives, refurbish policies, and improve communication between staff!

Apart from onsite medication error reporting, the Food and Drug Administration (FDA) hosts a post-marketing surveillance system called MedWatch (https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program). If patients experience adverse events, quality issues, medication errors, or other therapeutic failures, they can visit the FDA website to submit the event. After receiving the information, the FDA will monitor other patient reports. If additional patients note the same dilemma, a team of experts may trigger a recall or further investigation to amend the issue.[107]

The FDA MedWatch helps advance public health initiatives. Pharmacy managers should encourage staff to use and recommend patients report to MedWatch to prevent future harm.

The Prescription: Child Resistant Caps

A major federal law change in pharmacy history was the Poison Prevention Act of 1970. This law mandates manufacturers and pharmacies to have child resistant packaging on any over-the-counter or prescription medication. Pharmacy managers must instruct all staff to default child resistant caps for prescription bottles.[108]

If patients cannot open the child resistant cap due to disability, preference, or other limitations, they can ask the pharmacy to provide them only non-child resistant caps. The pharmacy manager should teach staff to document the patient's request and date on their file for future fills.

Pharmacists must inform patients on proper storage of prescription medications in homes where children frequent. Children are resilient and always find ways into places they should not access. Using all precautions, such as keeping medication out of reach or locking medication away, avoids accidental poisoning.

The Prescription: Hypodermic Needles

Pharmacy managers should teach staff about over-the-counter needle sales. Pharmacy managers should teach staff about over-the-counter needle sales. States like New Jersey and Connecticut permit over-the-counter needle sales, but an individual may only receive 10 needles or fewer per over-the-counter purchase. New Jersey limits over-the-counter needle sales to patients 18 years and older. Any quantity that exceeds that amount needs a prescription. The NJ Harm Reduction and CT Syringe Services programs do not specify any weekly or monthly limit on over-the-counter purchases of hypodermic needles. Meanwhile, the California Department of Public Health NO limit on the number of syringes sold at a single time. New York's Expanded Syringe Access Program permits daily purchases.[109,110,111,112,113,114]

Expanding access to hypodermic needles prevents the spread of bloodborne diseases. Pharmacy managers should work with staff to create a stigma free environment for patients seeking cleaner methods.[110,111]

The Prescription: Omnibus Budget Reconciliation Act of 1990 (OBRA)

The Omnibus Budget Reconciliation Act of 1990 (OBRA) was designed to improve dispensing laws for Medicaid beneficiaries; any pharmacy wanting to receive funding from Medicaid programs must comply. The federal government made pharmacies responsible for obtaining, recording, and maintaining patient information. Furthermore, OBRA requires pharmacies to review previously received medications to assess the risk for starting or continuing therapy. This practice, called drug utilization review (DUR), became a staple in current pharmacy practice. OBRA also requires pharmacies to offer counseling to every patient.[115,116]

Originally intended for only Medicaid beneficiaries, many states adopted OBRA policies to improve pharmacy practice. For example, the Connecticut Medical Assistance DUR Board retroactively reviews HUSKY Health medication claims.[117] Each state has similar programs to identify fraud or take corrective action on improperly filled prescriptions.

Pharmacist Prescribing

Pharmacist prescribing is a fresh topic for pharmacy managers. Because of the risk associated with prescribing, pharmacy managers must create proper policies and procedures for staff to adhere. All pharmacy staff must document, document, document! Every pharmacy manager should review state record

keeping regulations for prescribing; the time for retaining records changes across states.

As of January 2026, pharmacists can prescribe contraceptives to patients in 30 states and DC. Each state has specific prescribing laws, but all require pharmacists to take extra training for prescribing.[118] Notably, these courses review the United States Medical Eligibility Criteria for Contraceptive Use published by the Centers for Disease Control and Prevention (CDC). The training provides a certificate for the pharmacy's records. The eligibility criteria from the CDC discusses the leading guidelines for prescribing contraceptives, so any pharmacist who prescribes outside of its recommendation should document their thought process.[119]

After completing the training program, all states require pharmacists to screen any patient who requests a contraceptive prescription.[118] Generally, the screening process consists of documenting medical history, recording blood pressure, and completing intake forms.[120] Patients are only eligible if they meet the criteria set by the U.S. Medical Eligibility Criteria for Contraceptive Use.[120] Most states limit each prescription for 12-months, like normal, non-controlled prescriptions, however, Indiana limits each pharmacist prescribed contraceptive to a maximum of 6-month supply.

CONCLUSION

Consistently changing pharmacy laws create a complex environment for pharmacy managers. Controlling the pharmacy, the personnel, and the prescription handling means pharmacy managers must develop a strong understanding of these changing laws. A strong foundation in pharmacy law and organization improve the pharmacy's likelihood of success and help prevent future liabilities and fines during inspections. Ultimately, a constant state of readiness is not simply preparation for an inspection. It is a leadership philosophy that integrates legal compliance, staff development, patient safety, and continuous quality improvement into daily pharmacy practice.

PAUSE AND PONDER: The stack of prescriptions is falling over. Matt and Ethan have not stopped arguing about nonsense in three hours. The line of patients stretches out the door, and they are tired of waiting. But wait… What is that? Through the glass doors a figure appears with sunlight glimmering around her. The light is bright, but you recognize her. Is it your savior? A floater pharmacist? A technician returning from vacation?

Nope. The state inspector. She expects you to move fast despite the 30 barking patients. Have you developed your CONSTANT STATE OF READINESS?

Figure 1. Concentrating on Maintaining a Constant State or Readiness

Best

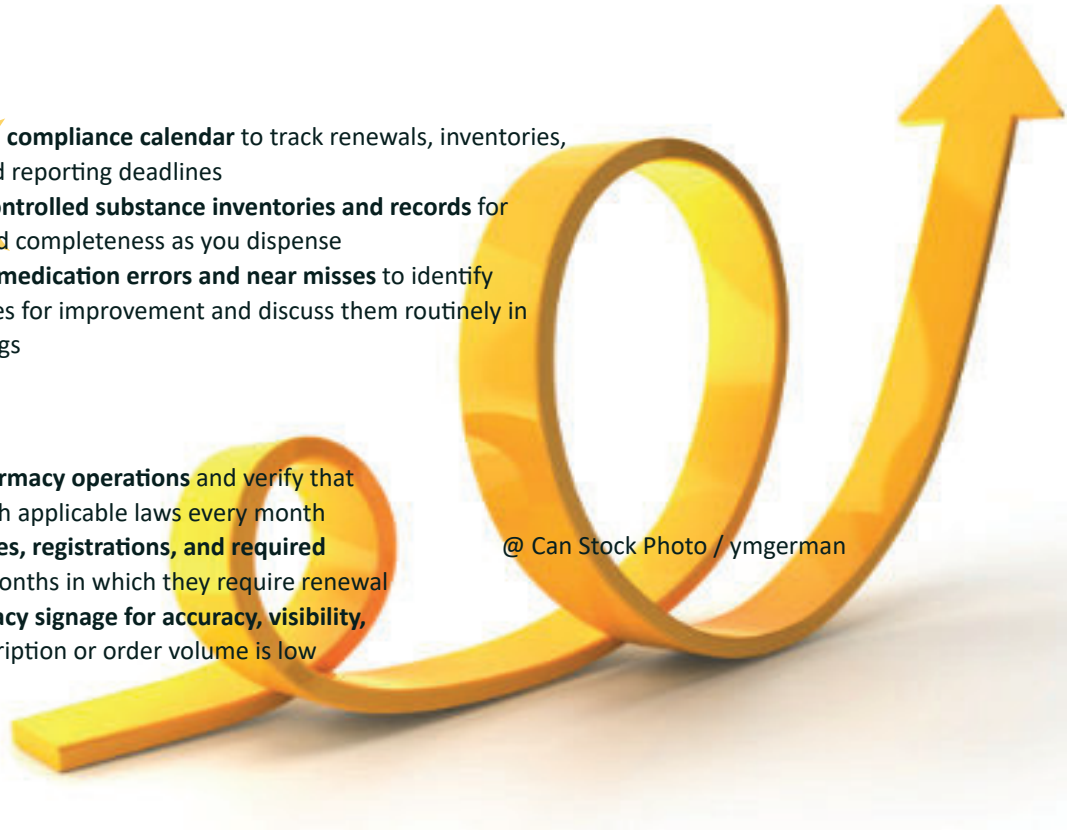
1. **Be COMMUNITY CHAMPIONS** and whenever possible, Assign compliance responsibilities to various staff members and routinely verify that required tasks are completed
2. **Update pharmacy policies promptly** when laws, regulations, or practice requirements change
3. **Conduct periodic mock inspections u**sing applicable state and federal requirements and review the results with staff and managers in your chain of command

Better

1. **Create a compliance calendar** to track renewals, inventories, training, and reporting deadlines
2. **Audit controlled substance inventories and records** for accuracy and completeness as you dispense
3. **Review medication errors and near misses** to identify opportunities for improvement and discuss them routinely in staff meetings

Good

1. **Identify one area of pharmacy operations** and verify that current practices comply with applicable laws every month
2. **Confirm that staff licenses, registrations, and required training** are current in the months in which they require renewal
3. **Review required pharmacy signage for accuracy, visibility, and compliance** when prescription or order volume is low



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