

Review of Texas Pharmacy Law for Pharmacists

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Faculty Disclosure

Contributing faculty, Flora Harp, PharmD, has disclosed no relevant financial relationship with any product manufacturer or service provider mentioned.

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The division planner and director have disclosed no relevant financial relationship with any product manufacturer or service provider mentioned.

Audience

This course is designed for pharmacists licensed to practice in Texas.

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Course Objective

The purpose of this course is to review Texas State Board of Pharmacy laws and rules to ensure compliance with the continuing education requirement to complete at least one contact hour on Texas pharmacy laws or rules during each renewal period.

Learning Objectives

Upon completion of this course, you should be able to:

1. Review pharmacist training and continuing education requirements.
2. Identify appropriate prescription dispensing practices.
3. Discuss pharmacy record management and retention requirements.
4. Explain pharmacy technician regulations.
5. Describe controlled substance laws that impact the practice of pharmacy.

INTRODUCTION

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Every state has an agency that functions to protect the health, safety, and welfare of patients. To protect patients, the Texas State Board of Pharmacy has a set of laws and regulations that pharmacy personnel must follow.

There are times when state laws differ from federal laws. When this happens, ALWAYS go with the stricter law. Usually, the stricter law is the state law. So, most of the time, you'll follow the state law.

Think about it this way when considering which law is stricter: if you are complying with the state law, and that automatically makes you compliant with the federal law, then you know the state law is stricter. You will see examples of this throughout this review.

PHARMACIST LICENSURE AND EDUCATION REQUIREMENTS

REFLECTION

What do you need to do to maintain your pharmacist license in Texas? How do you meet these requirements? What special requirements do you have to follow if you are an immunizing pharmacist or a preceptor in Texas?

GENERAL REQUIREMENTS TO MAINTAIN PHARMACIST LICENSURE

Pharmacists who are licensed with the Texas State Board of Pharmacy will need to renew their pharmacist license every two years [1; 2]. Keep in mind that licenses expire on the last day of the assigned expiration month [2].

When you renew, you must report that you've completed **30 hours of continuing education (CE)** [3]. Of those 30 hours, 1 hour must be related to

Texas-specific pharmacy laws and/or rules, which this course is designed to help you meet. The remaining 29 hours can be on any subject and can consist of any special CE requirements, if applicable (e.g., immunization, sterile compounding, preceptorship) [4; 5]. In addition, all pharmacists must complete a Texas Health and Human Services Commission (HHSC)-approved human trafficking prevention training course [4; 6]. Note that while this is a training requirement and not a CE requirement, some courses may offer CE credit. If the course you take provides CE credit, it may count towards your CE hour requirement. You can find HHSC-approved human trafficking courses, including at least one course that is available without charge (a requirement of the statute) on the HHSC Health Care Practitioner Human Trafficking Training website [6].

Newly licensed pharmacists don't need to complete the full 30-hour CE requirement during their initial license period. However, newly licensed pharmacists must complete an HHSC-approved human trafficking training course during their initial renewal period. Additionally, within the first 12 months of licensure, newly licensed pharmacists must obtain at least two CE credit hours related to prescribing and monitoring controlled substances [7].

You'll need to keep copies of the certificates (either hard copy or electronic) for your continuing education activities for at least **three years from the date that you report the hours on a license renewal application** [3]. This means that if you took a course in January 2024, but submitted your renewal application in September 2024, you would need to maintain this record until September 2027 (not January 2027). You must present CE certificates if the Board requests them.

Any program with a primary focus covering the topics specified above that is offered by an Accreditation Council for Pharmacy Education (ACPE)-accredited provider can be used to help meet these continuing education requirements [4].

Pharmacists can receive three credit hours for attending a full, public Texas State Board of Pharmacy Board Meeting in its entirety. A maximum of six credit hours are allowed for attending board meetings during a license period. Proof of attendance will be provided as a certificate from the Texas State Board of Pharmacy, which will serve as the CE certificate [3].

STERILE COMPOUNDING EDUCATION REQUIREMENTS

Pharmacists who prepare sterile compounds or supervise pharmacy technicians that prepare sterile compounds must initially complete a single course on sterile compounding of at least **20 hours of instruction and experience**. This training can be obtained through completion of a recognized course from an accredited college of pharmacy, or a course sponsored by an ACPE-accredited provider. Pharmacists must also complete a structured on-the-job didactic and experiential training program at the pharmacy where the sterile compounding takes place. The training should include the facility's specific sterile compounding processes and procedures. This training cannot be transferred to another pharmacy unless the pharmacies are under the same ownership and use the same training program. After the initial training, moving forward upon license renewal, pharmacists must complete at least **two hours of CE credit** on sterile compounding if the pharmacist is engaged in compounding low- or medium-risk sterile preparations, or **four hours of CE credit** if the pharmacist is engaged in compounding high-risk sterile preparations [8].

Note that with non-sterile compounding, although the Board states that there must be initial training and continuing education "appropriate for the type of compounding done," the type of initial training and number of hours of initial and ongoing training haven't been specified as they have with sterile compounding. Follow your company's policies and procedures around initial and ongoing training for non-sterile compounding [9].

CASE STUDY: ROBERT

Robert has been a Texas licensed pharmacist for the past five years. He just renewed his license last year, so it's due for renewal in another year. He recently moved across the state and started a new job working in a hospital pharmacy that performs high-risk sterile compounding. Even though he was performing sterile compounding at his old job, he knows that he is going to have to get additional training at the new hospital he will be working at. He is also aware that he will have to complete four hours of CE on sterile compounding before renewing his license next year, since he's involved in preparing high-risk sterile compounds.

IMMUNIZATION ADMINISTRATION EDUCATION REQUIREMENTS

Pharmacists may administer immunizations under a written protocol with a physician. Notification of immunization must be provided within 24 hours of administering the vaccine to the protocol physician, and within 14 days to the patient's primary care physician [10].

According to state law, immunizations other than the flu vaccine may be administered to patients 14 years of age and older. The flu vaccine may be administered to patients age 7 and older. Immunizations can be administered to patients under the age of 14 (or under the age of seven for the flu vaccine) upon referral from a physician who has a relationship with the patient [10].

In order to give immunizations, there are several requirements for pharmacists [3; 10]:

- You must have completed an initial course from an ACPE-accredited provider which requires documentation of CPR certification and is a minimum of 20 hours of immunization-related content which includes hands-on training and requires testing with a passing score. You must keep documentation of initial course completion.
- You must complete three hours of continuing education related to immunizations every two years.

- You must maintain current CPR certification. Courses offered by the American Red Cross, American Heart Association, or their equivalent are recognized.
 - CPR courses are recognized as approved CE programs to be counted towards your continuing education requirements. Proof of completion of a CPR course issued by the American Red Cross, American Heart Association, or its equivalent, shall serve as the CE certificate.
 - Pharmacists may receive credit for one contact hour upon completion of a **Basic** CPR course once during a license period.
 - Pharmacists may receive credit for 12 contact hours upon **initial** advanced cardiovascular life support (ACLS) or pediatric advanced life support (PALS) certification once during a license period.
 - Pharmacists may receive credit for four contact hours upon **recertification** in ACLS or PALS once during a license period.

It's also important to be aware that in Texas, it is required by law to cleanse your hands with an alcohol-based waterless antiseptic hand rub or wash your hands with soap and water before preparing to give a vaccine and between each patient contact. Texas law does not require you to wear gloves, but if gloves are worn, you must change them between patients [10].

COVID-19 Considerations

During the COVID-19 public health emergency, the federal government, under the Public Health Readiness and Emergency Preparedness (PREP) Act, authorized qualified pharmacists to order and administer, and pharmacy technicians and pharmacy interns to administer, influenza and COVID-19 vaccines to any patient age 3 and older. Although the

public health emergency has ended, this authority under the PREP Act has been extended through December 2024 [11]. If you are providing immunizations during the public health emergency under the PREP Act, make sure you are following both the federal requirements and your state's requirements for reporting and recordkeeping.

CASE STUDY: KRISTINE

Kristine recently became licensed to practice pharmacy in Texas after moving to the state. She is going to be practicing in a community pharmacy where she will be providing immunizations. She was an immunizer in the state she moved from and has already gone through the 20-hour certificate program. She also has current CPR certification. However, she notes that she is going to have to complete three hours of CE related to immunization every two years, a requirement she didn't have in the state she was previously practicing in.

PRECEPTOR EDUCATION REQUIREMENTS

If you want to become a pharmacist preceptor, you must be approved and certified by the Board of Pharmacy. To become a preceptor, you must meet the following requirements [12]:

- Your Texas pharmacist license must be current and active
- You must have either one year of experience as a licensed pharmacist, OR six months of residency training if the pharmacy resident is completing a residency program
- You must have completed three hours of preceptor training within the previous two years (for initial certification) or within your current license renewal period. This training must be:
 - Developed by a Texas college/school or pharmacy, or
 - Approved by a committee comprised of the Texas college/schools of pharmacy, or
 - Approved by the Board

Once approved by the Texas State Board of Pharmacy, you will be able to print a preceptor certificate from the Board's website [13]. As a preceptor, you are responsible for supervising the activities of pharmacist-interns. Keep in mind that you may only supervise one pharmacist-intern at any given time (1:1 ratio), and the pharmacist-intern is not counted towards the pharmacy technician ratio (discussed later). The exception to the 1:1 ratio is if you are precepting pharmacy students as part of a Texas college/school of pharmacy program (e.g., students on IPPE or APPE rotations); there is no ratio requirement in this scenario [12].

DRUG THERAPY MANAGEMENT EDUCATION REQUIREMENTS

Pharmacists in Texas may engage in drug therapy management as delegated by a supervising physician and authorized through a written protocol. The Texas State Board of Pharmacy defines drug therapy management as [14]:

- The performance of specific acts by pharmacists as authorized by a physician through written protocol. Drug therapy management does not include the selection of drug products not prescribed by the physician, unless the drug product is named in the physician-initiated protocol or the physician initiated record of deviation from a standing protocol. Drug therapy management may include the following:
 - Collecting and reviewing patient drug use histories;
 - Ordering or performing routine drug therapy related patient assessment procedures including temperature, pulse, and respiration;
 - Ordering drug therapy related laboratory tests;
 - Implementing or modifying drug therapy following diagnosis, initial patient assessment, and ordering of drug therapy by a physician as detailed in the protocol; or
 - Any other drug therapy related act delegated by a physician.

In order to initially engage in drug therapy management, pharmacists must have completed at least six hours of CE related to drug therapy offered by an ACPE-accredited provider within the last year (or have been engaging in drug therapy management as allowed under previous laws or rules). This six-hour CE requirement must be met each year if pharmacists want to continue to participate in drug therapy management [14].

PHARMACIST STANDARDS

CASE STUDY: KRISTINE

At Kristine's old pharmacy, she only supervised one to two technicians at a time. Her new pharmacy is much busier, with multiple pharmacists and technicians on duty at any given time.

What rules related to overseeing pharmacy staff should Kristine familiarize herself with? What duties can and cannot be performed by pharmacy technicians in Texas?

IDENTIFICATION

All pharmacy staff (pharmacists, technicians, trainees, and pharmacist-interns) must **wear an ID badge** when working. The badge should include your name and title [15].

The Texas State Board of Pharmacy also requires that you maintain at the pharmacy and make available to the public on request, proof that each pharmacist, pharmacist-intern, pharmacy technician, and pharmacy technician trainee holds the appropriate license or registration [16]. In addition, the pharmacist-in-charge must display their license so that it is visible to the public.

The **license for the pharmacy** must also be posted so that it is visible to the public [16].

Be aware that you'll need to notify the Board **within 10 days of a change in your name, address, or place of employment**. You must also make sure that your name is removed from the pharmacy license of your previous employer and added to the new employer's pharmacy license [17; 18].

PATIENT COUNSELING

REFLECTION

What are the rules in Texas about counseling patients? What information should be discussed during counseling? What type of documentation is needed?

OBRA stands for the Omnibus Budget Reconciliation Act of 1990. This act plays a role in patients receiving counseling on new prescriptions and refills of medications. OBRA '90 required states to establish standards for patient counseling and stated that pharmacists must offer to counsel patients. The Texas State Board of Pharmacy is stricter than OBRA '90 in that it mandates counseling for all patients getting new prescriptions [19].

Keep in mind that requirements for counseling differ based on your practice setting. If you work in a hospital or institution, you do not have to counsel inpatients [19].

If you work in a **community pharmacy**, you must counsel the patient or their agent on **all new prescriptions**. A new prescription is defined as a prescription that hasn't been dispensed by the pharmacy to the patient in the same dosage form and strength within the last year [19].

For new prescriptions, a non-pharmacist staff member (such as a technician) CANNOT ask if a patient requests counseling, because counseling is required. You must also provide counseling if the patient requests it or has questions. Only pharmacists can provide drug information, counsel, or answer questions for patients about their medications [19].

As part of patient counseling, the Texas State Board of Pharmacy states that you should include information that you feel is needed to optimize therapy for the particular prescription drug or device. This might include [19]:

- Name and description of drug
- Dosage form, dose, route of administration, duration of therapy
- Special directions or precautions for use
- Common severe side effects or interactions, including how to avoid these or what to do if they occur
- Techniques for self-monitoring
- Storage requirements
- Refill information
- What to do if a dose is missed

Written information (either in hard-copy or electronic format, such as by email, if requested by the patient) must also be provided at the time of verbal counseling for reinforcement. This info must be in simple language and easy for patients to read (no smaller than 10-point Times New Roman font). For compounded meds, the major active ingredient(s) should determine what written information is provided [19].

If a prescription is delivered to a patient's home, the information that would otherwise be given orally must be given to the patient in writing. Either on the prescription container or on a separate sheet of paper, you must provide the pharmacy's phone number along with this statement (in English and Spanish) [19]:

"Written information about this prescription has been provided for you. Please read this information before you take the medication. If you have questions concerning this prescription, a pharmacist is available during normal business hours to answer these questions at (insert the pharmacy's local and toll-free telephone numbers [if prescriptions are routinely delivered outside the area covered by the pharmacy's local telephone service])."

There is one exception when written information may not need to be provided. If you are dispensing a new drug and written information is not yet available, you are not required to give this info. However, you must inform the patient of this, document that the info was not provided, and if the prescription is refilled you must provide this written information to the patient once it's available [19].

You must also **document the initials or other identification code of the pharmacist who provided counseling**. This documentation may be either on the original hard-copy prescription, in the pharmacy's data processing system, or in an electronic or hard-copy logbook. If a patient refuses counseling, you must document that refusal [19].

Every community pharmacy must have an area which is suitable for patient counseling. The area must be easily accessible to both patients and pharmacists, must not allow patients to have access to prescription drugs, and must be designed to maintain the confidentiality and privacy of the pharmacist/patient communication. Other patients or pharmacy staff should not be able to overhear the conversations occurring at the counseling area. Community pharmacies must also make available to patients, either in hard-copy or electronic format, a drug information reference book or leaflets that are designed for patients [19].

CASE STUDY: KRISTINE

Kristine is excited about getting to know her new patients. She sees that her new pharmacy has a system in place where they specially mark all new prescriptions so that any staff member can easily identify that counseling is needed. For new prescriptions, the technicians immediately direct patients to the counseling window. When Kristine completes the counseling, she documents her initials in the pharmacy's electronic logbook.

PATIENT MEDICATION RECORDS

All pharmacies in Texas must maintain a system for keeping information on patients whenever new or refill prescriptions are dispensed, known as a patient medication record (or patient profile). You and all other pharmacy personnel must make a reasonable effort to obtain, record, and maintain patient information. **All patient records or profiles must be maintained for at least two years from the date of the last entry** [20; 21].

Patient medication records in community settings must include [20; 21]:

- Patient name, address, and phone number
- Patient's age or date of birth
- Patient's gender
- A list of the patient's medications (both Rx and OTC), including all orders dispensed by the pharmacy in the last two years and including any other drugs currently being used by the patient
- Any known drug allergies or drug reactions
- Any known disease states
- Any pharmacist comments relevant to the patient's drug therapy

Patient medication records in hospital settings must include [20; 21]:

- Patient name and room number or identification number
- Gender and date of birth or age
- Weight and height
- Known drug sensitivities and allergies to drugs and/or food
- Primary diagnoses and chronic conditions
- Primary physician
- Other drugs the patient is receiving, in addition to current medication order information (date of distribution; drug name, strength, and dosage form; and directions for use)

PROSPECTIVE DRUG REVIEW

You must review the patient profile before any prescription is dispensed. At a minimum, you must identify any clinically significant [19; 22]:

- Allergies
- Contraindications
- Inappropriate doses or routes of administration
- Inappropriate directions for use
- Duplicate therapy
- Drug-drug, drug-food, or drug-disease interactions
- Adverse drug reactions
- Inappropriate use, including overuse or underuse
- Clinical laboratory or clinical monitoring methods to evaluate drug effectiveness, side effects, toxicity, or adverse effects, and appropriateness to continued use of the drug in its current regimen (hospital setting only)

If you recognize any problem during the review, you must take steps to resolve the problem, such as by consulting with the prescriber. Document your findings by including the date the prescriber was consulted, name of the person you spoke with, any relevant information, and your initials [19; 22].

SUPERVISING PHARMACY STAFF

As a pharmacist, you may be responsible for overseeing **pharmacy technicians** or **pharmacy technician trainees**. Be familiar with the Texas State Board of Pharmacy requirements for these staff members.

Pharmacy Technician Registration

REFLECTION

You are working with a pharmacy technician trainee who is wondering what she needs to do to become registered as a pharmacy technician. What would you tell the technician-in-training? How long can the pharmacy technician trainee work as a technician-in-training before needing to become registered as a pharmacy technician?

Individuals interested in working as a pharmacy technician in Texas must first **register with the Board of Pharmacy** before they begin working in a pharmacy. He or she must meet several requirements to be eligible for pharmacy technician registration [23; 24]:

- Have a high school or equivalent diploma or be working toward one for no more than two years
- Complete the Board application and pay the required fee
- Submit fingerprints in order for the Board to access the individual's criminal history, AND
- Pass the Pharmacy Technician Certification Board (PTCB)'s Pharmacy Technician Certification Exam (PTCE) or the National Healthcareer Association (NHA)'s Exam for the Certification of Pharmacy Technicians (ExCPT)

Technicians who are waiting to take and pass one of the national certification exams can still work in a pharmacy. But they must first apply for registration as a pharmacy technician trainee. This registration as a trainee is only good for two years, and it's NOT renewable. This means that **pharmacy technician trainees can't work as a technician-in-training for more than two years**. To work in the pharmacy after that time, they must have passed one of the Board-approved national certification exams AND have obtained pharmacy technician registration from the Board. Maintaining national certification is completely voluntary. The Texas State Board of Pharmacy only requires that technicians be nationally certified for their initial registration, not to maintain their certification [25]. However, registration with the Board must be maintained at all times that a pharmacy technician will be working in a pharmacy [23].

Pharmacy Technician Training Requirements

Both technicians and technician trainees must complete **initial “on-the-job” training** when they start working at your pharmacy. This training must be outlined in a training manual. The training must include how technicians will be supervised, clarify technician duties, and instruct technicians on basic areas of pharmacy practice. Technicians and trainees must also complete **continuing in-service education and training** to supplement the initial training. Documentation of the training must be kept on file at the pharmacy [26].

A written record of initial and in-service training of pharmacy technicians and pharmacy technician trainees must be maintained at the pharmacy and should include the following information [26]:

- Name of person receiving the training
- Date(s) of training
- General description of topics covered
- Statement certifying that the individual is competent to perform duties assigned
- Name of person supervising the training
- Signatures of person receiving the training and the pharmacist-in-charge, or other pharmacist designated by the pharmacist-in-charge as responsible for training

Additional training, including ongoing continuing education, is required for pharmacy technicians and pharmacy technician trainees engaged in non-sterile or sterile compounding. The pharmacist-in-charge is responsible for determining that all personnel engaged in compounding possess the education, training, and proficiency needed. Training activities should be documented and covered by standard operating procedures [8; 9].

Initial training for pharmacy technicians and pharmacy technician trainees who will be involved in sterile compounding must include either a single 40-hour course offered by an ACPE-accredited provider which provides a combination of instruction and experience, OR a training program accredited by ASHP. Pharmacy technicians and pharmacy

technician trainees must also complete a structured, on-the-job didactic and experiential training program. All pharmacy personnel engaged in sterile compounding, including pharmacy technicians and pharmacy technician trainees, must pass written and skills testing initially and every 12 months for low- and medium-risk level compounding, or every six months for high-risk level compounding [8].

Pharmacy Technician Continuing Education Requirements

Once a pharmacy technician has registered with the Texas State Board of Pharmacy as a pharmacy technician, they will need to renew their pharmacy technician registration **every two years**. In order to renew their license, pharmacy technicians must complete and report 20 contact hours of approved continuing education obtained during the renewal period in pharmacy-related subjects. Up to five hours may be earned during in-service education and training from their employer. One hour must be related to Texas pharmacy laws or rules. Like pharmacists, all pharmacy technicians are also required to complete an HHSC-approved human trafficking prevention training course. Although this is a training requirement and not a CE requirement, if the course taken provides CE credit, it may count towards the technician’s total 20 hours. Even pharmacy technicians in their initial renewal period must complete this human trafficking training requirement [27; 28].

Like pharmacists, for the first renewal, technicians don’t need to complete the required CE hours. Also, like pharmacists, technicians need to keep copies of the certificates (either hard copy or electronic) for CE activities for at least three years from the date of reporting the hours on a renewal application [27].

As mentioned for pharmacists, during each renewal period, pharmacy technicians who are engaged in sterile compounding need to complete at least two hours of CE related to sterile compounding if they are compounding low- or medium-risk sterile compounds, or four hours of CE if they are compounding high-risk compounds [8].

Keep in mind that pharmacy technician trainees do not have any continuing education requirements.

What Pharmacy Technicians May Do

In Texas, pharmacy technicians are allowed to perform many tasks while assisting the pharmacist. But any activities a pharmacy technician performs must be done under the direct supervision of the pharmacist. Ultimately, the pharmacist is the one responsible for all activities that occur inside the pharmacy.

Examples of duties a registered pharmacy technician is allowed to do [15]:

- Access and restock automated medication supply systems after proper training
- Affix labels to prescription containers
- Bulk compound or batch preparation
- Compound non-sterile and sterile preparations
- Distribute routine orders for stock supplies to patient care areas
- Enter prescription data into the pharmacy computer system
- Fill medication carts
- Initiate and receive refill authorization requests
- Load unlabeled drugs into an automated dispensing system
- Prepackage and label prepackaged drugs
- Prepare and package drug orders, including counting pills, measuring liquids, and placing them in containers
- Reconstitute medications
- Remove stock bottles from the shelf to help prepare prescriptions

The type of activities a pharmacy technician assists with will also depend on the practice setting. Depending on the specific activity, there may be additional Board requirements the technician will have to meet.

For example, the Board allows certain technicians who work in a hospital to check the work of another technician. This is often referred to as “tech-check-tech.” But there are a few requirements before a technician can check another technician’s work. The Board must approve the tech-check-tech process for your pharmacy. Then, a technician can only check the work of another technician for orders related to filling floor stock and unit-dose distribution [15].

What Pharmacy Technicians May NOT Do

Tasks that require the professional judgment of a pharmacist must be left to the pharmacist. The Texas Board of Pharmacy recognizes this, and says that pharmacy technicians may NOT [15]:

- Counsel patients
- Interpret prescription drug orders
- Perform a drug regimen review
- Receive oral prescription orders for controlled substances
- Transfer controlled substance prescription orders to and from other pharmacies
- Verify that controlled substances listed on invoices are received

In addition, **only a pharmacist may perform the final check of a completed prescription.**

PHARMACY STANDARDS

There are other rules and regulations that the pharmacy as a whole must follow. Some of these rules will depend on your practice setting.

TECHNICIAN-TO-PHARMACIST RATIO

REFLECTION

If you work in a community pharmacy, what is the pharmacist to pharmacy technician and pharmacy technician trainee ratio? Does a pharmacist-intern count towards this ratio?

Texas limits the number of pharmacy technicians and pharmacy technician trainees that a pharmacist can supervise at one time **in community pharmacies**. This ratio does not apply to institutional pharmacies [15].

A pharmacist is not allowed to supervise more than six pharmacy technicians at any given time. No more than three technicians can be pharmacy technician trainees (in other words, the ratio of pharmacists to pharmacy technician trainees may not exceed 1:3) [15].

As previously mentioned, a **pharmacist may only supervise one pharmacist-intern at any given time.** The pharmacist-intern is not counted as a technician in the ratio of pharmacists to technicians [15].

CASE STUDY: KRISTINE

In her new job, Kristine normally works with one other pharmacist, an intern, and six technicians during the week. On Tuesday, Kristine's partner calls in sick and she's unable to get a covering pharmacist right away.

In this case, as long as the number of pharmacy technician trainees does not exceed three, Kristine would still be operating within the ratios set by the Texas State Board of Pharmacy.

GENERIC SUBSTITUTION

If a prescription is written for a brand-name drug and there is a less expensive generically equivalent or interchangeable biological product available, you may substitute it. This is true unless the patient OR prescriber requests otherwise [29].

For the prescriber to request the brand name to be dispensed, they must write in their own handwriting, **"Brand Medically Necessary"** or **"Brand Necessary"** on the face of written prescriptions. You may get a prescription drug order that has check boxes or other notations that indicate "substitution instructions." This type of method to indicate "no substitution" is not valid in Texas [29].

If the prescription order is called in or electronically transmitted, the prescriber must clearly indicate if the brand is necessary. If a prescription reimbursed by Medicaid is verbally called in to the pharmacy and the prescriber clearly indicates that brand name is necessary, the prescriber must also mail or fax a written prescription to the pharmacy with the appropriate notation within 30 days [29].

Texas recognizes the Food and Drug Administration (FDA)'s Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) and the Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations (Purple Book) to determine which meds can be substituted. This means that if a drug product is therapeutically equivalent and has an "A-rating" in the Orange Book, then a generic can be substituted. And if a biological product is listed as interchangeable, it can be substituted for the reference product. An additional requirement for biological products which have an interchangeable biological product approved by the FDA is that within three business days of dispensing the product, information on the specific product dispensed (including name and manufacturer or NDC number) must be communicated to the prescriber. This communication can be made electronically, or via fax or phone, or via other "prevailing means." It can also be made through documentation into an interoperable electronic medical records system, through electronic prescribing technology, or a pharmacy benefit management system or a pharmacy record that a pharmacist reasonably concludes is electronically accessible by the prescribing practitioner [29].

Keep in mind that in Texas, pharmacists may dispense, without prior approval from the prescribing practitioner, a dosage form of a drug product that's different from that prescribed, such as a tablet instead of a capsule or liquid instead of tablets, provided that the patient consents to the dosage form substitution and that the dosage form dispensed [29]:

- Contains the identical amount of the active ingredients as the dosage form prescribed;
- Is not an enteric-coated or time release product; and
- Does not alter desired clinical outcomes

Patients must be notified when a generic or interchangeable biological product is substituted, and they have the right to request the brand-name drug instead. In addition, if a generically equivalent drug or interchangeable biologic is dispensed, the label must include the statement “Substituted for Brand Prescribed” or “Substituted for [Brand Name]” where [Brand Name] is the actual name of the brand name product prescribed [29].

DISPENSING REQUIREMENTS FOR PRESCRIPTIONS

Earlier in this course, you learned that state law will sometimes be stricter than federal law. This is true in Texas for many of the rules about dispensing prescriptions.

Prescription Expiration Dates/Refills

Texas has limits on how long prescriptions are valid. **Noncontrolled prescriptions cannot be filled or refilled more than one year from the date the original prescription was written.** Keep in mind that this includes prescriptions written by the prescriber, but never filled [15].

If a prescription is written for a smaller quantity of a noncontrolled drug with refills, you may dispense up to a 90-day supply of the prescription. However, you may only do this if the [15]:

- Total amount dispensed does not exceed the total amount prescribed (including refills);
- Patient is at least 18 years old;
- Patient consents and the prescriber is notified electronically or by telephone;
- Prescriber has NOT specified that dispensing the smaller amount with refills is medically necessary; and
- Prescription isn't for a psychotropic drug used to treat mental or psychiatric conditions.

Transferring Prescriptions

Texas requires that the transfer of original prescription information must be completed **within four business hours of the request.**

A patient is allowed to transfer noncontrolled prescriptions that have refills from one pharmacy to another. These can be transferred up to the number of originally authorized refills. Transfers for noncontrolled drugs can be communicated by pharmacists, pharmacist-interns, or pharmacy technicians to another pharmacist, pharmacist-intern, or pharmacy technician [15].

The rules for transferring controlled substances in Schedules III through V are a little stricter. Prescriptions for controlled substances can be transferred between pharmacies, but **only one time, and the remaining refills must be dispensed by the new pharmacy.** Make sure patients who transfer prescriptions for controlled substances realize that they cannot transfer these prescriptions again. The exception is if pharmacies share a real-time, online database. In this case, the prescription can be transferred up to the maximum refills allowed by law and the prescriber's authorization. Also be aware that transfers for controlled substances can be communicated by pharmacists or pharmacy-interns to another pharmacist or pharmacy-intern. Pharmacy technicians cannot transfer controlled substance prescriptions [15].

The person transferring the prescription must [15]:

- Write “void” on the face of the transferred prescription or invalidate it in the electronic record
- Record the following:
 - Name and address of the receiving pharmacy
 - DEA number of the receiving pharmacy for controlled substances
 - Name of the person transferring the information and the name of the person receiving the transfer
 - Date of transfer

The person receiving the transferred prescription must [15]:

- Write “transfer” on the face of the prescription or note this in the electronic record
- Record the following:
 - Original date of issue
 - Date of original dispensing
 - Original Rx number and original number of refills
 - Number of valid refills remaining
 - Dates and locations of previous refills for controlled substances
 - Name and address of transferring pharmacy
 - If transferring pharmacy is different from the pharmacy that originally dispensed the Rx, the name and address of that pharmacy is also needed
 - DEA number of the transferring pharmacy for controlled substances
 - If transferring pharmacy is different from the pharmacy that originally dispensed the controlled substance Rx, the DEA number of that pharmacy is also needed
 - Name of person transferring the Rx

Pharmacies may also perform a one-time transfer of electronically prescribed Schedule II through V controlled substances for initial filling [30; 31]. But this can only be done if both pharmacies are set up to forward and receive electronic controlled substance prescriptions. If this is not the case, the prescriber should be contacted to retract the electronic controlled substance prescription and resend to the pharmacy requested by the patient [15].

Emergency Prescriptions

CASE STUDY: KRISTINE

Kristine is working at the pharmacy on a Saturday when a patient comes in just before closing time. The patient tells Kristine that he is out of refills on his lisinopril and metformin. He thought he had enough pills to get him through the weekend, but he was wrong. What should Kristine do?

There will be times when a patient runs out of refills on a prescription that must be taken with little or no interruption. In most cases, you can dispense a one-time emergency refill when a patient is out of medication AND the prescriber can't be contacted. In these cases, the law says that you can give up to a **72-hour supply of medication**. This includes all medications **except Schedule II controlled substances**. You must notify the patient that prescriber authorization is required and that the emergency refill is being done without prescriber authorization. You must also notify the prescriber of the emergency fill as soon as reasonably possible [15].

If the prescription was originally filled at another pharmacy, you can provide the patient with a 72-hour emergency supply if there are no refills remaining or if the other pharmacy can't be contacted for a transfer. However, the patient must have their prescription bottle (or other documentation that contains enough information to safely fill the prescription). There's one exception to this 72-hour emergency supply and that is if the prescription requiring an emergency supply is for insulin or insulin-related supplies. In this case, the quantity of the emergency refill may not exceed the lesser of a 30-day supply or the smallest available package [15].

Schedule II controlled substances are not included in this 72-hour rule. However, per federal and state law, emergency prescriptions of Schedule II controlled substances are allowed in certain situations. Prescribers can call in an emergency prescription for a Schedule II controlled substance with a quantity needed to cover the emergency period. “Emer-

gency prescription” in this context means that the immediate administration of a drug is necessary for proper treatment of the patient, that no alternative treatment is available, and it’s not possible for the prescriber to provide a written prescription at the time. Prescribers must then, within seven days, send an electronic prescription, or if exempt from the e-prescribing controlled substances mandate (discussed later), deliver a written, signed prescription (either in person or by mail). The written prescription must have written on its face “Authorization for Emergency Dispensing” and the date of the oral order. For electronic prescriptions, the pharmacist must annotate the record with the original authorization and date of the oral order. If a written or electronic prescription isn’t received within seven days, the local DEA diversion field office must be notified [32; 33].

In the event of a disaster, a pharmacist may be able to dispense up to a 30-day supply of a medication (other than a Schedule II prescription) without the authorization of a prescriber under specific circumstances, such as the governor has declared a state of emergency and the executive director of the Board of Pharmacy has notified pharmacies that pharmacists may dispense up to a 30-day supply of prescription drugs [15].

CASE STUDY: KRISTINE

Kristine decides that it is appropriate for her to go ahead and dispense a one-time 72-hour supply of lisinopril and metformin for this patient. Kristine knows that these meds are needed, and that interruption of therapy could result in undesirable health consequences.

Kristine writes out a new prescription for the emergency supply and leaves a voicemail for the patient’s prescriber to let him know an emergency supply has been dispensed. Kristine informs the patient that she is providing this emergency refill without prescriber authorization, and that any additional refills need to be authorized by his prescriber. She recommends that the patient reach out to his prescriber on Monday to find out if he needs to be seen before the prescriber can authorize additional refills.

Handling Prescriptions from Other States and Countries

CASE STUDY: KRISTINE

Kristine gets a prescription for metoprolol tartrate from a prescriber whose office address is in Mexico. What should she do?

Pharmacists can accept prescriptions issued by prescribers licensed in other states, but there are specific rules for controlled substances. For Schedule III through V prescriptions from out-of-state practitioners, the prescription can be filled if it is issued by a physician, dentist, veterinarian, or podiatrist who is legally authorized to prescribe controlled substances in the state they practice (controlled substance prescriptions from out-of-state nurse practitioners or physician assistants may not be filled). However, in order to fill prescriptions from out-of-state prescribers for Schedule II prescriptions, your pharmacy must have a plan approved by and on file with the Board which allows the activity [15; 34].

Prescriptions from prescribers licensed in Canada or Mexico in a health field that is recognized by the state of Texas as one that is legally authorized to prescribe drugs (e.g., physician, dentist, veterinarian, or podiatrist), may also be filled under certain circumstances. The prescription cannot be for a controlled substance, and it must be an original, written prescription with a manual signature [15].

The Texas State Board of Pharmacy provides a helpful quick reference guide for determining if you could dispense out-of-state prescriptions [35].

LABELING REQUIREMENTS FOR PRESCRIPTIONS

According to federal law, certain information must be included on the labels of dispensed prescriptions. Texas has a few additional requirements for the information that must be on the label of dispensed medications.

Community pharmacy prescription labels must include [15]:

- The name, address, and telephone number of the pharmacy
- The prescription number
- The date the prescription was dispensed
- The dispensing pharmacist's initials (not required to be on the label if the identity of the pharmacist is maintained in the dispensing system)
- The name of the patient (or if it's for an animal, the species of the animal and the name of the owner)
- The name of the prescriber
- The directions for use
- The drug name, amount dispensed, and strength
- The generic and brand name of the medication and a note if generic substitution occurred
- Beyond-use date
- Appropriate ancillary instructions, such as storage instructions or cautionary statements
- Disposal statement (explained below)

The beyond-use date should be the expiration date provided by the manufacturer of the drug if the drug is dispensed in its original packaging. If the drug is repackaged, the beyond-use date should be the expiration date provided by the manufacturer, OR the date that is one year from the date the drug is dispensed, whichever comes first. In addition, compounded medications must include a statement that the drug has been compounded (an auxiliary label can meet this requirement). This statement should also be included in the written drug information that is required to be provided to patients in the outpatient setting [15].

The pharmacy must also provide a disposal statement to the patient, either on the prescription label or on the written information accompanying the prescription. The statement must say: "Do not flush unused medications or pour down a sink or drain." But this statement isn't required for drugs that the FDA recommends flushing for disposal, such as some controlled substances. Examples of meds that FDA recommends flushing include fentanyl (*Duragesic*, etc), morphine (*MS Contin*, etc), oxycodone (*OxyContin*, *Percocet*, etc) and others [36].

In the hospital setting, the label must also include a beyond-use date. But many of the other labeling requirements listed above aren't mandated.

CASE STUDY: GEORGE

George works full-time in a hospital pharmacy and part-time in a community pharmacy. What differences should he expect to see in the labeling of drugs in these two settings?

Recordkeeping

Pharmacies in Texas are required to maintain records of all prescriptions and dispensed medications. For prescriptions, the pharmacy must keep the original prescription or an electronic image of it for at least two years from the date it was last filled. Inventory records should also be kept for two years from the date of the inventory or record.

Additionally, in community pharmacies, a daily hard copy printout of all prescriptions dispensed and refilled should be produced within 72 hours and reviewed within seven days. Each individual pharmacist who dispenses or refills a prescription shall verify that the data indicated on the daily hard copy printout is correct, by dating and signing the document. Alternatively, the pharmacy can keep a logbook with each individual pharmacist signing (or electronically signing) a statement each day attesting that the information entered into the dispensing system has been reviewed and is correct. The hard copy printouts or logbook must be maintained for two years from the date of dispensing.

Patient Privacy

Another example of when Texas law is stricter than federal law can be seen with privacy laws. The federal Health Insurance Portability and Accountability Act (HIPAA) was created to protect a patient's health information. The Texas Medical Records Privacy Act (TMRPA) adds additional safeguards on top of HIPAA for protected health information (PHI). For example, TMRPA requires that covered entities, such as pharmacies, provide employee training on both federal and state laws related to the protection of PHI [37]. This training should be specific to the employee's responsibilities and the pharmacy's course of business. Each new employee must complete this training within 90 days after the hire date [37]. Employees must also be trained anytime there is a change in Texas or federal law that affects their duties by no later than the first anniversary of the date the change in law takes effect [37]. Contact your supervisor for more information on where to get this required state/employer-specific training.

Texas law also expands the definition of "covered entities" beyond the HIPAA definition [37]. In addition to healthcare providers, plans, and medical clearinghouses defined in federal law, Texas law broadened this to include any person, business, or organization that touches PHI in any way. Another more stringent state requirement is that patients must be given their electronic health records within 15 business days of their written request [37]. This is shorter than the 30-day federal requirement. Financial penalties related to inappropriate disclosure of PHI in Texas may also be higher compared to federal penalties. Make sure you are familiar with the Texas-specific laws for maintaining patient privacy. You can find more information about the various health information privacy laws that have been passed in Texas on the Attorney General of Texas' website [38].

CONTROLLED SUBSTANCES

Many Texas controlled substance laws are similar to federal law. For example, the number of refills allowed for controlled substance prescriptions in Schedule III or IV is the same as federal law (max of five refills within six months). However, there are some differences to be aware of. For instance, while federal law specifies that prescriptions for Schedule III or IV meds must not be refilled more than five times or more than six months after the date of issue, it doesn't specify this requirement for Schedule V prescriptions, while Texas law does. In other words, Texas law also requires that prescriptions for Schedule V prescriptions not be refilled more than five times and not be refilled beyond six months past the date of issue.

Classifications of Controlled Substances

Texas classifies controlled substances into **five schedules, just like federal law**. Practically all controlled substances are in the same schedules as federal law. For example, fentanyl is a Schedule II product. Buprenorphine is a Schedule III controlled substance. And diazepam is a Schedule IV controlled substance [39].

One difference is that Texas requires a prescription for codeine-containing Schedule V medications. Federal law allows some of these meds to be sold over the counter as long as they don't exceed certain quantities. In Texas, codeine-containing cough meds or any other products containing codeine or dihydrocodeine must have a prescription to be dispensed. Treat these Schedule V products like pregabalin (*Lyrica*), diphenoxylate/atropine (*Lomotil*), and other Schedule V prescription controlled substances [33].

Electronic Prescribing of Controlled Substances

The Texas Health and Safety Code requires prescriptions for controlled substances to be issued electronically [33; 40]. There are some exceptions to this, such as prescriptions issued by veterinarians, prescriptions ordered in an emergency, or cases where a prescriber has applied for a waiver from the Texas Medical Board due to exceptional circumstances prohibiting e-prescribing implementation [41]. Keep in mind

that pharmacists who receive an otherwise valid written, oral, or faxed controlled substance prescription after the implementation date do not have to verify that the prescription is exempt from the requirement of e-prescribing.

Schedule II Prescriptions

CASE STUDY: KRISTINE

Kristine has been working in Texas for about three weeks when she is faced with a partial fill of a Schedule II prescription situation. The patient has requested to fill only a few pills at a time. Is Kristine able to fulfill the patient's request based on Texas state law? Why or why not?

As mentioned above, all controlled substance prescriptions, including Schedule II prescriptions, are required to be sent electronically unless the prescriber is exempted from the requirement. If the prescriber is exempted, the only other acceptable format for a Schedule II prescription outside of an emergency is for it to be written on an "official Texas prescription form" that the prescriber orders from the Texas State Board of Pharmacy [40]. A Schedule II med must be filled within 30 days after the date the prescription was issued [40].

There is generally no days' supply limit set by the Board for a Schedule II prescription. However, for opioids for the treatment of acute pain, a prescriber may not issue a prescription for an opioid in an amount that exceeds a 10-day supply [40]. While pharmacists won't be subject to penalties for dispensing a prescription that exceeds this limit, it's important to remember that pharmacists have a corresponding responsibility to ensure the prescription is for a legitimate medical purpose in the usual course of professional practice [40].

Additionally, there is a days' supply limit when prescribers issue multiple Schedule II prescriptions. Prescribers can issue multiple prescriptions for the same Schedule II drug on the same day, but only up to a 90-day supply (in total for all prescriptions) [40]. The prescriber must include the date each prescription was written AND the earliest date each prescription can be filled. In this case, the prescription must be dispensed within 30 days of the earliest fill date noted on each prescription (not necessarily the date of issue) [40].

Texas allows for partial filling of Schedule II controlled substances in accordance with federal law [33]. According to federal law, partial filling of Schedule II controlled substance prescriptions is allowed at the request of the prescribing practitioner or patient as long as the total quantity dispensed in all partial fillings doesn't exceed the total quantity prescribed. In addition, remaining portions of a partially filled Schedule II prescription cannot be filled beyond 30 days after the date the prescription was written [33; 42]. If a Schedule II prescription is partially filled due to a pharmacy stock issue, DEA regulations specify that the remainder must be dispensed within 72 hours, otherwise the remaining quantity is voided, and the prescriber must be notified [32].

Pharmacists who dispense Schedule II controlled substances must provide patients with a written notice on the safe disposal of controlled substances, unless the pharmacy is able to accept the drugs back for safe disposal (e.g., pharmacies that are authorized collectors or pharmacies that provide at no cost a mail-in pouch for patients to dispose of drugs) [40]. This written notice must include information on locations where Schedule II drugs are accepted for safe disposal or provide a web address of a website specified by the Board, such as the DEA's Drug Disposal information website, that has a searchable database of locations where Schedule II prescriptions can be accepted for safe disposal [40; 43]. The written notice can be provided in an electronic form, but only if the patient or patient's agent requests this and the request is documented [40].

Prescribing Authority

In addition to limits on Schedule II prescriptions, Texas restricts who can write controlled substance prescriptions.

Like most states, Texas allows doctors, dentists, veterinarians, and podiatrists to write controlled substance prescriptions. However, it also allows other prescribers, such as nurse practitioners, optometrists, and physician assistants to order scheduled drugs, but with limits. For example, nurse practitioners and physician assistants can write for Schedule III, IV, and V meds. But the prescription, including refills, cannot exceed a 90-day supply. Nurse practitioners and physician assistants can only write for Schedule II prescriptions in the hospital setting, including for patients receiving services in the emergency department. They may also write Schedule II prescriptions for patients with a terminal illness receiving hospice care [35; 44].

Controlled Substance Inventory

REFLECTION

How often does your pharmacy perform a full inventory of all the medications on the shelves? How does this frequency differ when comparing controlled substances to noncontrolled substances? How does it differ from federal pharmacy law? When must the inventories occur?

Under federal law, controlled substances must be inventoried every two years. This is another area where Texas law is stricter than federal law regarding scheduled medications. **Pharmacies in Texas must inventory controlled substances every year.** This coincides with the annual inventory requirement for noncontrolled drugs as well. However, inventory records for Schedule II drugs must be maintained separately from other controlled substances, and inventory records for Schedule III, IV, and V drugs must be maintained separately from noncontrolled drugs or be readily retrievable [15].

Inventory must occur on May 1st annually, or on the pharmacy's regular general physical inventory date (determined by the pharmacy). Both the person taking the inventory and the pharmacist-in-charge must sign and date the records and have the document notarized within three days of the inventory being completed. This inventory must be filed separately from all other records and be available at the pharmacy for inspection for **at least two years** [15].

Texas Prescription Monitoring Program

Pharmacies must report all outpatient controlled substance prescriptions to the Texas Prescription Monitoring Program no later than the next business day after filling the prescription [45]. Pharmacists may delegate access to the Texas Prescription Monitoring Program to registered pharmacy technicians, but pharmacy technicians must register as a separate user [46]. Additionally, pharmacists dispensing an outpatient prescription for an opioid, benzodiazepine, barbiturate, or carisoprodol will be required to check the patient's Prescription Monitoring Program history before dispensing [47]. Exceptions to this requirement include prescriptions issued by veterinarians or if it's clearly noted on a prescription that the patient has a diagnosis of cancer or sickle cell disease or that the patient is in hospice care [47].

THE BOTTOM LINE

This course covered a few highlights of the Texas pharmacy laws and rules. It is important to keep current on matters that impact you as a pharmacist, and to meet all requirements of the Texas State Board of Pharmacy. Meeting these requirements will help avoid potential violations from the Texas State Board of Pharmacy, the Texas Department of Public Safety, or other regulatory agencies. Staying current on state laws and rules will not only help you and your pharmacy, but your patients as well.

ADDITIONAL INFORMATION

You can find more information from the following websites:

Texas State Board of Pharmacy

<https://www.pharmacy.texas.gov>

Texas Pharmacy Laws & Rules

<https://www.pharmacy.texas.gov/rules>

**Practice Resources for Pharmacists
and Pharmacy Technicians**

[https://www.pharmacy.texas.gov/resources/
practice-resources.asp](https://www.pharmacy.texas.gov/resources/practice-resources.asp)

**Helpful Information Pertaining
to Pharmacy Licensure in Texas**

<https://www.pharmacy.texas.gov/infocies>

Information Regarding Controlled Substances

[https://www.pharmacy.texas.gov/Controlled_Sub-
stance_Info.asp](https://www.pharmacy.texas.gov/Controlled_Substance_Info.asp)

Texas Prescription Monitoring Program

<https://txpmp.org>

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