This supplement updates the Texas and Federal Pharmacy and Drug Law 10th Edition to include rule changes adopted by the Texas State Board of Pharmacy in January 2016 through January 2017. It also includes corrections, clarifications, and significant changes to federal laws and rules to keep the book current until the next edition is printed in January 2018.

New language is shown as underlined. Deleted language is shown as strikethrough.

We have included bolded references to the affected pages in the book. So that you do not inadvertently rely on material in the book that has been changed by this supplement, we recommend that you highlight or mark each page number in the book that is referenced in this supplement. By doing so, you will be reminded that some of the text on that page has been changed and that you should refer to this supplement for those pages. While some of the changes are minor corrections or clarifications, some are substantive changes in the law and rules.

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b. Class II – Controls and Performance Standards
   Class II devices are those intended for human use and those for which controls alone (such as Class I) are insufficient to provide reasonable assurance of safety and efficacy. There is sufficient information about Class II devices to establish performance standards that provide such assurance (i.e., controls alone will not assure safety and efficacy, but controls in addition to a performance standard will).
   Examples: insulin syringes, thermometers, diagnostic reagents, tampons, blood pressure gauges, and electric heating pads.

c. Class III – Controls, Performance Standards, and Premarket Approval
   Class III devices are those intended for human use that are purported to be supportive or sustaining of human life or of substantial importance in preventing impairment of human health. Class III devices present a potential unreasonable risk of illness or injury and are subject to premarket approval to provide reasonable assurance of safety and efficacy.
   Examples: pacemakers, intraocular lenses, replacement heart valves, insulin pumps, and breast implants.
d. **Restricted Devices**

Under the provisions of Section 520(e) of the Act, the FDA is authorized to restrict the sale, distribution, or use of a device if there cannot otherwise be reasonable assurance of its safety and effectiveness. A restricted device can only be sold on oral or written authorization by a licensed practitioner or under conditions specified by regulation. Devices such as cardiac pacemakers and heart valves, for example, require a practitioner’s authorization. Hearing aids are restricted by a regulation which limits their sale to persons who have obtained a medical evaluation of their hearing loss by a physician within six months prior to the sale of the hearing aid. Adult purchasers can sign a waiver declining the medical evaluation, however. The labeling of hearing aids must provide information on their use and maintenance. See 21 CFR 801.420.

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d.e. **Sale of Certain Devices**

Certain devices may be sold only to or on the prescription or other order of a practitioner. The label of the device, other than surgical instruments, bears the statement “Caution: Federal law restricts this device to sale by or on the order of a __________,” with the blank to be filled with the word “physician,” “dentist,” or “veterinarian.” Although prescription drug products have been able to use the “Rx only” designation on labels, this was not formally available on prescription medical devices. However, since 2000, FDA has informally allowed it by exercising enforcement discretion. In April 2013, FDA proposed a new rule to formally allow medical device manufacturers to utilize the symbol statement “Rx only” on these products.

e.f. **Medical devices** are subject to the **Current Good Manufacturing Practice (CGMP)** requirements set forth in the Quality System (QS) regulation (21 CFR 820). They require that domestic or foreign manufacturers have a quality system for the design, manufacture, packaging, labeling, storage, installation, and servicing of finished medical devices intended for commercial distribution in the United States. The regulation requires that various specifications and controls be established for devices; that devices be designed under a quality system to meet these specifications; that devices be manufactured under a quality system; that finished devices meet these specifications; that devices be correctly installed, checked and serviced; that quality data be analyzed to identify and correct quality problems; and that complaints be processed.
In September 2013, FDA finalized a rule requiring a unique device Identifier (UDI) on medical device labels and packaging unless a specific exemption is met. The UDI requirement is intended to reduce medical errors, simplify the integration of device use information into data systems, provide for more rapid adverse event information for medical devices, and for more rapid and more efficient recalls. The UDI requirements are being phased in over several years, starting September 24, 2013 through September 24, 2020, depending on the device classification. For more information, see the FDA’s UDI webpage.

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IV. Federal Hazardous Substances Act of 1966
(Administered and enforced by Consumer Product Safety Commission)

A. Intent and Purpose
The intent was that all hazardous substances be regulated regardless of their packaging and wrapping. The purpose was to protect the consumer, especially children, from household and non-household substances.
1. Hazardous items that could not be labeled safely for household use were banned from interstate commerce.
2. The sale of toys and other children’s articles containing hazardous substances was banned.

B. Definitions
1. Hazardous Substance – Substance or a mixture of substances that can cause injury or illness through handling and that can cause potential danger, especially to children, if misused.
2. Toxic Substance – Any substance (other than radioactive substances) which has the capacity to produce personal injury or illness to man through ingestion, inhalation, or absorption through any body surface.
3. Highly toxic – One in which a single oral dose of 50 mg or less per kilogram body weight would kill half or more of the white rats to which it is fed.

C. Labeling requirements
1. Name and address of manufacturer.
2. Common name.
3. The signal word “danger.”
4. The signal word(s) “warning” or “caution.”
5. Statement of the hazardous properties.
6. Precautionary statements.
7. First aid instructions followed by “call a physician immediately.”
8. The signal word “poison” and the skull and crossbones symbol on highly toxic substances when required by the regulation.

The label on the immediate package of a hazardous product and any outer wrapping or container that might cover up the label on the package, must have the following information in English:
1. The name and business address of the manufacturer, packer, distributor, or seller;
2. The common or usual or chemical name of each hazardous ingredient;
3. The signal word “Danger” for products that are corrosive, extremely flammable, or highly toxic;
4. The signal word “Caution” or “Warning” for all other hazardous products;
5. An affirmative statement of the principal hazard or hazards that the product presents, for example, “Flammable”, “Harmful if Swallowed”, “Causes Burns”, “Vapor Harmful”, etc.;
6. Precautionary statements telling users what they must do or what actions they must avoid to protect themselves;
7. Where it is appropriate, instructions for first aid treatment to perform in the event that the product injures someone;
8. The word “Poison” for a product that is highly toxic, in addition to the signal word “Danger”;
9. If a product requires special care in handling or storage, instructions for consumers to follow to protect themselves; and
10. The statement “Keep out of the reach of children”. If a hazardous product such as a plant does not have a package, it still must have a hang tag that contains the required precautionary information. That information must also be printed in any literature that accompanies the product and that contains instructions for use.

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D. Act deals primarily with household items such as bleach, cleaning fluids, antifreeze, drainpipe cleaners, and muriatic acid.
E. Sale of items in pharmacies
   The pharmacist should sell the products in the original manufacturer’s container or label properly.

V. **Federal Hazard Communication Standard**
   (Administered and enforced by the Occupational and Safety Health Administration (OSHA))
   A. OSHA requires all employers (including pharmacies) that deal with hazardous materials to meet the Hazardous Communications Standard. See 29 CFR 1910.1200.
   B. The standard requires chemical manufacturers and importers to classify the hazards of chemicals they produce or import and to prepare appropriate labels and Safety Data Sheets (SDS), which were formerly known as Material Safety Data Sheets (MSDS).
   C. Pharmacies are required to have a written Hazardous Communication Plan.
   D. The plan must include a list of hazardous chemicals in the workplace, must ensure all such products are appropriately labeled and have a Safety Data Sheet, and must include training for all workers on the hazards of chemicals, appropriate protective measures, and where and how to obtain additional information. Note: Additional details can be found in OSHA’s publication “Small Entity Compliance Guide for Employers that Use Hazardous Chemicals.”
   E. Drugs in solid, final dosage form for administration to patients are exempt from these requirements, but hazardous chemicals or products not in solid, final dosage form for administration (such as liquid products used in compounding) may be covered. Generally, a pharmacy may rely on the manufacturer to determine if a product is considered hazardous.
VI.V. Poison Prevention Packaging Act of 1970 (PPPA)
(Administered and enforced by the Consumer Product Safety Commission (CPSC))

A. Purpose – The primary purpose of the Act was to extend to prescription and nonprescription drugs special packaging requirements known as “child resistant containers.” Other household substances are also included (those under the Federal Hazard Substances Act - labeling).

B. Requirements – Packaging must meet a test by children. A package fails if more than 20% of the child test group can open the package AFTER DEMONSTRATION and/or if more than 10% of the ADULTS tested cannot open the package. Usually a time period of 10 minutes is used for the children and 5 minutes for adults. Regulations effective in 1998 require that packaging also meets new senior testing requirements to ensure that the packaging is not too difficult for senior citizens to open. Unit-dose packaging also must meet PPPA standards but is evaluated somewhat differently. A test failure is defined as the ability of one child to open more than eight individual units or the number of units representing a toxic amount, whichever is less.

A child-resistant container (CRC) made of plastic or any component made of plastic CANNOT be reused according to the Act, since wear of the components may limit the package’s ability to be child resistant. If you reuse a prescription container (i.e., when refilling prescription), you violate PPPA (and TSBP rules). Unless specifically exempted, ALL drugs (over-the-counter or prescription) produced by a manufacturer must be sold in child-resistant containers meeting the requirements if the containers will be sold or dispensed to the consumer.

*Note: These are child-resistant standards and are required and enforced by CPSC. The standards for tamper-evidence packaging for OTC drugs are required and enforced by FDA. See OTC Drug Regulation Section of this Chapter.*

C. Exemptions to child-resistant containers requirement

1. Patient/physician request.
   a. You can use non-child resistant containers at the request of the physician or patient.
   b. You can get a blanket request for all prescriptions from the patient BUT NOT FROM THE DOCTOR. It is good practice to verify this with the patient yearly.
   c. The law doesn’t require a written request, but all requests should be documented.
   d. The pharmacist may initiate the request for a non-CRC container, but it must be the patient’s decision.

2. Bulk containers shipped to manufacturers, wholesalers, pharmacies (not intended for household use).

3. Drugs distributed to institutionalized patients, provided the drugs are administered to patients by institutional (hospital or nursing home) employees.

4. One package size designed for elderly patients of an over-the-counter as long as it is labeled: “THIS PACKAGE IS FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN.”
D. Drugs covered under the Federal Poison Prevention Packaging Act and Exemptions from the Act

Editorial Note: Items 1.-4. below are not being deleted. They are being moved to items 2.-4. for better clarity.


Exemptions: Aspirin-containing effervescent tablets, other than those intended for pediatric use, provided that the tablet contains less than 10% aspirin, the tablet has an oral median lethal dose greater than 5 g/kg of body weight, and the tablet, when placed in water, releases at least 85 ml of carbon dioxide per grain of aspirin. Unflavored aspirin-containing preparations in powder form that are packaged in unit doses, providing that these are intended for uses other than pediatric. They must contain no other substance subject to special packaging requirements and not more than 13 grains of aspirin per unit dose.

2. Methyl salicylate (oil of wintergreen): Liquid preparations containing more than 5% by weight of methyl salicylate unless packaged in pressurized spray containers.

3. Controlled drugs: Any preparation for human use in a dosage form intended for oral administration that consists in whole or in part of any substance subject to control under the Federal Controlled Substance Act.

4. Methyl alcohol (methanol): Household substances in liquid form containing 4% or more by weight of methyl alcohol unless packaged in a pressurized spray container.

1.5. Prescription drugs: Any drug for human use that is in a dosage form for oral administration and that is required by federal law to be dispensed only by or upon an oral or written prescription of a practitioner licensed by law to administer such drugs. The following prescription drugs are exempt from the child-resistant container requirements:

Exemptions:

a. Sublingual dosage forms of nitroglycerin.

b. Sublingual and chewable forms of isosorbide dinitrate in dosage strengths of 10 mg or less.

c. Erythromycin ethylsuccinate granules for oral suspension and oral suspensions in packages containing not more than 8 g or the equivalent of erythromycin.

d. Erythromycin ethylsuccinate tablets in packages containing no more than the equivalent of 16 g erythromycin.

e. Anhydrous cholestyramine in powder form.

f. Potassium supplements in unit dose forms, including individually wrapped effervescent tablets, unit dose vials of liquid potassium and powdered potassium in unit dose packets, containing not more than 50 mEq per unit dose.

g. Sodium fluoride drug preparations, including liquid and tablet forms, containing no more than 264 mg of sodium fluoride per package.
h. Betamethasone tablets packaged in manufacturers’ dispenser packages containing no more than 12.6 mg betamethasone.

i. Mebendazole in tablet form in packages containing not more than 600 mg of the drug.

j. Methylprednisolone in tablet form in packages containing not more than 84 mg of the drug.

k. Colestipol in powder form in packages containing not more than 5 g of the drug.

l. Pancrelipase preparations in tablet, capsule, or powder form.

m. Medically administered oral contraceptives in manufacturers’ mnemonic (memory-aid) dispenser packages which rely solely upon the activity of one or more progestogen or estrogen substances.

n. Prednisone in tablet form when dispensed in packages containing no more than 105 mg of the drug.

o. Conjugated estrogen tablets when dispensed in mnemonic dispenser packages containing not more than 26.5 mg of the drug.

p. Norethindrone acetate tablets in mnemonic dispenser packages containing not more than 50 mg of the drug.

q. Medroxyprogesterone acetate tablets.

r. Sacrosidase (sucrose) preparations in a solution of glycerol and water.

s. Hormone Replacement Therapy products that rely solely upon the activity of one or more progestogen or estrogen substances.


Exemptions: Aspirin-containing effervescent tablets, other than those intended for pediatric use, provided that the tablet contains less than 10% aspirin, the tablet has an oral median lethal dose greater than 5 g/kg of body weight, and the tablet, when placed in water, releases at least 85 ml of carbon dioxide per grain of aspirin. Unflavored aspirin-containing preparations in powder form that are packaged in unit doses, providing that these are intended for uses other than pediatric. They must contain no other substance subject to special packaging requirements and not more than 13 grains of aspirin per unit dose.

3. Methyl salicylate (oil of wintergreen): Liquid preparations containing more than 5% by weight of methyl salicylate unless packaged in pressurized spray containers.

4. Controlled drugs: Any preparation for human use in a dosage form intended for oral administration that consists in whole or in part of any substance subject to control under the Federal Controlled Substance Act.

5. Methyl alcohol (methanol): Household substances in liquid form containing 4% or more by weight of methyl alcohol unless packaged in a pressurized spray container.
6. Iron-containing drugs
With the exception of animal feeds used as vehicles for the administration of drugs, noninjectable animal and human drugs providing iron for therapeutic or prophylactic purposes, which contain a total amount of elemental iron equivalent to 250 mg.

7. Dietary supplements containing iron
With the exception of those preparations in which iron is present solely as a colorant, dietary supplements that contain an equivalent of 250 mg or more of elemental iron in a single package.

8. Acetaminophen
Preparations for human use in a dosage form intended for oral administration and containing more than 1 g of acetaminophen in a single package.
   **Exemptions:**
   a. Acetaminophen-containing effervescent tablets or granules containing less than 10% acetaminophen, with a median lethal dose greater than 5 g/kg of body weight and that release at least 85 ml of carbon dioxide per grain of acetaminophen when placed in water.
   b. Unflavored acetaminophen-containing preparations in powder form, other than those intended for pediatric use, that are packaged in unit doses with no more than 13 grains of acetaminophen per unit dose and that contain no other substance subject to the special packaging requirements.

9. Diphenhydramine HCl: Preparations for human use in oral dosage forms containing more than the equivalent of 66 mg of diphenhydramine base in a single package.

10. Ibuprofen: Preparations for human use in oral dosage forms containing 1 gram or more of ibuprofen in a single package.

11. Loperamide: Preparations for human use in oral dosage forms containing more than 0.045 mg of loperamide in a single package.

12. Lidocaine: Products containing more than 5 mg of lidocaine in a single package (includes all dosage forms including creams, sprays, and transdermal patches).

13. Dibucaine: Products containing more than 0.5 mg of dibucaine in a single package (includes all dosage forms including creams, sprays, and transdermal patches).

14. Naproxen: Preparations for human use in oral dosage forms containing 250mg or more of naproxen in a single package.

15. Ketoprofen: Preparations for human use in oral dosage forms containing more than 50mg of ketoprofen in a single package.

16. Fluoride: Products containing more than 50 mg of elemental fluoride and more than 0.5% fluoride in a single package.

17. Minoxidil: Preparations for human use containing more than 14 mg of minoxidil in a single package (includes topical products and they must continue to meet requirements once applicator is installed by consumer).
18. Imidazolines: Products containing 0.08 mg or more in a single package. Imidazoline is a drug class that includes tetrahydrozoline, naphazoline, oxymetazoline, and xylometazoline often found in ophthalmic and nasal products.

19. Any drug switched from Rx to OTC status.

**VII.4. Omnibus Budget Reconciliation Act of 1990 (OBRA-90)**

*Editorial Note: renumber remaining sections as VIII. – XII.*

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F. Exempted Prescription Products

1. Manufacturers may apply to DEA to exempt a product or chemical from certain provisions of the Controlled Substances Act (labeling and inventory) if the product or chemical is not likely to be abused. These products may still be considered to be controlled substances for certain criminal violations even though they are not labeled as controlled substances.

2. Exempted prescription preparations include non-narcotic products containing small amounts of phenobarbital, butalbital, chlordiazepoxide, or meprobamate.

3. The DEA Exempt Prescription Product List Exemption lists can be found at:
   - http://www.deadiversion.usdoj.gov/schedules/exempt/exempt_list.htm

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V. Enforcement of TCSA and Rules

A. Primary responsibility for enforcement of the TCSA is with the Texas Department of Public Safety (DPS); however, the DPS state controlled substance registration requirement was eliminated on September 1, 2016. While DPS still has the authority to enforce the act since pharmacies and practitioners no longer have a DPS registration, DPS will likely only be involved in criminal matters. Violations of the TCSA may be enforced by the Texas State Board of Pharmacy (TSBP) in taking disciplinary action against the license of a pharmacist, pharmacy, or registration of a pharmacy technician or trainee. TSBP has the authority under the Texas Pharmacy Act to enforce all laws relating to the practice of pharmacy as they relate to pharmacists and pharmacies, e.g., Federal Controlled Substances Act, Texas Controlled Substances Act, U.S. Food, Drug, and Cosmetic Act, and Texas Food, Drug, and Cosmetic Act.

B. Both the DPS and TSBP have authority to promulgate rules under specific sections of the TCSA. Legislation passed in 2015 transferred operation of the Prescription Access Texas (PAT) program from DPS to the Board of Pharmacy, effective September 1, 2016, and gave the Board of Pharmacy authority to adopt rules to administer Sections 481.073, 481.074, 481.075, 481.076, and 481.0761 of the TCSA.
VI. Registration – How Entities and Persons are Regulated under the CSA

A. Who must register
   Every person or firm who manufactures, distributes, or dispenses any controlled substances or who proposes to engage in same must register with DEA. Effective September 1, 2016, Texas will no longer have a state controlled substance registration. Until that date, state controlled substance registrations will be issued by the Texas Department of Public Safety (DPS).

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4. Officials of the U.S. Army, Navy, Marine Corps, Air Force, Coast Guard, Public Health Service, or Bureau of Prisons acting in course of official duties. (See 21 CFR §1301.23) In Texas, these practitioners can’t write C-IIIs for patients to fill off base if practitioners are not registered in Texas. An official prescription form is required. All other prescriptions can be filled off base. The prescription will have:
   a. The Branch of Service (i.e., “U.S. Army”) and service identification number; or
   b. The name of the agency (i.e., “U.S. Public Health Service”) and social security number of the practitioner.

Note: Because these military practitioners are exempt from DEA registration requirements, their Schedule III-V prescriptions can be filled off base. However, any Schedule II prescriptions they write can only be filled on base unless they have obtained official prescription forms from the Texas State Board of Pharmacy. The Board requires a valid DEA number from the practitioner to order official prescription forms.

Note: This exemption does not apply to military contractors who are practitioners.

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J. Summary
   A prescription calling for compounding a Schedule V narcotic-containing product and adding more narcotic to it will be in Schedule III or Schedule II depending on the amount of narcotic added.

REMEMBER – The narcotic substances listed must be compounded in combination with one or more therapeutic ingredients in recognized therapeutic amounts. Cherry syrup, simple syrup, etc. are not therapeutic ingredients. To place a narcotic substance in one of these vehicles is like placing the drug in water. The law views this as having a prescription for a straight narcotic (codeine, morphine, etc.), which is classified as a Schedule II drug.
B. Theft or Significant Loss of Controlled Substances.

DEA regulation 21 CFR 1301.74(e) and 21 CFR 1301.76(b) require registrants to report a theft or significant loss of controlled substances. (Note: Any theft must be reported, but only “significant” losses. See section 6. below)

1. DEA requires the initial notification to be in writing and within one business day of discovery. See section 5 below. TSBP rules require notification immediately upon discovery. Notify the appropriate divisional office of DEA, DPS, local police, and TSBP immediately upon discovery of the theft/loss. (Note: DEA requires initial notification to be within one business day. See section 5. below.)

2. Complete DEA Form 106 – Provide a copy to:
   a. Drug Enforcement Administration (DEA);
   b. Texas Department of Public Safety (DPS requirement);
   c. Texas State Board of Pharmacy (TSBP requirement); and
   d. Local police (recommended by DEA)

3. Although a paper version is still available, DEA recommends the DEA Form 106 be filled out online at the Office of Diversion Control’s website (www.deadiversion.usdoj.gov).

4. The DEA 106 Form must include:
   a. Name and address of the registrant (pharmacy)
   b. DEA registration number
   c. Date of theft
   d. Name and telephone number of local police department notified
   e. Type of theft (break-in, employee, etc.)
   f. Listing of symbols or cost code used by pharmacy in marking containers (if any)
   g. Listing of controlled substances missing from theft or significant loss.
   h. The NDC number of the missing products is required when using the online version of the DEA 106 Form. Using the NDC number allows the online system to auto-populate the information for name of product, dosage form, strength, and quantity per container.

5. While filing a DEA Form 106 is not immediately necessary if the registrant needs time to investigate the facts surrounding a theft or significant loss, a registrant must provide, in writing, initial notification of the event within one business day of discovery. This notification may be a short statement provided by FAX or other means, but must be in writing. If the investigation of a theft or significant loss lasts longer than two months, registrants should provide updates to DEA. This initial notification should also be sent to DPS and TSBP.

6. Factors to Consider in Determining if a Loss is Significant
   a. The actual quantity of controlled substances lost in relation to the type of business;
   b. The specific controlled substance lost;
c. Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;
d. A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and if known,
e. Whether the specific controlled substances are likely candidates for diversion;

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XIV. Inspections
A. Controlled Premises
   1. Places where original or other records or documents required under FCSA are kept.
   2. Places where persons registered under FCSA dispense controlled substances, i.e., pharmacies.
B. DEA can inspect and copy any record, report, or other document required under the FCSA.
C. DEA can inspect the pharmacy with regard to controlled substances.
D. DEA can inspect the inventory of controlled substances and obtain samples.
E. DEA may not inspect the following records without consent of the registrant: Records not allowed to be inspected without the consent of the registrant:
   1. Financial data
   2. Sales data
   3. Pricing data

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XVI. Controlled Substance Prescriptions
A. Persons entitled to prescribe controlled substances or communicate controlled substance prescriptions
   1. Practitioners – Must be registered with DEA (and Texas DPS until September 1, 2016).
      a. Physicians (MD or DO)
      b. Dentists
      c. Podiatrists
      d. Veterinarians
   2. Mid-level practitioners – Must be registered with DEA (and Texas DPS until September 1, 2016).
      a. Practitioners other than a physician, dentist, veterinarian, or podiatrist who are authorized by state law to prescribe controlled substances.
      b. Examples may include nurse practitioners, nurse midwives, clinical nurse specialists, physician assistants, ambulance services, and veterinary euthanasia technicians.
c. Texas law allows in-state advanced practice nurses and physician assistants to prescribe controlled substances in Schedules III–V (and in certain practice settings, Schedule II controlled substances) with some restrictions. [See Chapter C in this book]

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e. Controlled substance prescriptions generally cannot be post-dated; however, the DEA FCSA and Texas DPS TCSA allow practitioners to issue multiple prescriptions for Schedule II drugs at one time under certain conditions [See Section XVI in this Chapter].

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E. Pharmacist Responsibilities – The “Corresponding Responsibility”
1. For a prescription for a controlled substance to be valid, it must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his/her professional practice.
2. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, and a corresponding responsibility rests with the pharmacist who fills the prescription.
3. Under the “corresponding responsibility” doctrine a pharmacist that fills an invalid controlled substance prescription that the pharmacist knows to be invalid has violated the FCSA and TCSA. The knowledge requirement has been interpreted in case law to mean that a pharmacist either knew or should have known that the prescription was invalid. Thus, a pharmacist cannot simply claim that he/she had no knowledge that a prescription was invalid if a reasonable and prudent pharmacist would have known the prescription was invalid.

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Texas law. Pharmacists should use professional judgment when dispensing controlled substances to ensure that the prescriptions are being dispensed for legitimate medical purposes and to the correct patient.
2. Prescriptions from out-of-state practitioners (not practitioners in Mexico/Canada)
   a. Schedule IIs – Texas pharmacies can only fill Schedule II controlled substances from a practitioner in another state if:
      (1) A share of the pharmacy’s business involves the dispensing and delivery or mailing of controlled substances;
      (2) The prescription is issued by a prescribing practitioner in the ordinary course of practice; and
      (3) The prescription is filled in compliance with a written plan providing the manner in which the pharmacy may fill a Schedule II prescription issued by an out-of-state practitioner. The plan must be approved by DPS and TSBP. until August 31, 2016. Starting September 1, 2016 only TSBP will approve such plans.
F. Partial filling of Schedule II Prescriptions

   a. This act amended the FCSA to allow a schedule II controlled substance prescription to be partially filled if it is not prohibited by state law, the prescription is written and filled in accordance with DEA regulations and state law, the partial fill is requested by the patient or the practitioner who wrote the prescription, and the total quantity dispensed in all partial refills does not exceed the total quantity prescribed.
   b. For written and electronic prescriptions, all partial fills must be completed 30 days after the date the prescription is issued.
   c. For emergency verbal prescriptions of a Schedule II controlled substance, any partial refills must be completed no later than 72 hours after the prescription was issued.
   Note: Although this federal law has passed, DEA has yet to rewrite their current rules on partial fills that require the remaining quantity to be dispensed within 72 hours for non-long term care or terminally ill patients. Existing rules for long term care and terminally ill patients (see section 3. below) that allow for 60 days of partial fills were not changed by this law.
   d. Despite this new federal law, the Texas Controlled Substances Act still requires that partial filling of controlled substances be filled within 72 hours (except for long term care or terminally ill patients). Until the Texas law is amended, it must be followed since it is stricter than the new 30-day time limit under federal law.

2. Under current Texas law, if a pharmacy is unable to supply the full quantity ordered on a Schedule II prescription, partial filling is allowed under the following conditions:
   a. The balance must be dispensed within 72 hours of the first partial dispensing.
   b. The pharmacist notes on the face of the prescription (or the electronic record for an electronic prescription) the quantity supplied.
   c. If the balance can’t be dispensed within 72 hours, no further quantity may be dispensed, and the pharmacist must contact the practitioner to get a new prescription.

3. Patients in LTCFs (Long-Term Care Facilities) and terminally ill patients
   a. A prescription for a Schedule II controlled substance written for a patient in a Long-Term Care Facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities for up to 60 days from the date the prescription was issued.
b. How does the partial fill rule for LTCF or terminally ill patients work with the Texas requirement that schedule II controlled substance prescriptions be filled within 21 days after the date issued? In this situation, the initial partial filling must occur within 21 days after the date the prescription was issued. Subsequently, the pharmacist would have 60 days to fill the remaining quantity of the prescription with partial fills. However, the partial fills must be completed within 60 days of the date when the prescription was issued, not the date of the initial partial fill.

c. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist must contact the practitioner prior to partially filling the prescription. Both the pharmacist and the practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient.

d. The pharmacist must record on the prescription (or electronic record if an electronic prescription) whether the patient is “terminally ill” or an “LTCF patient.” A prescription that is partially filled and does not contain the notation “terminally ill” or “LTCF patient” shall be deemed to have been filled in violation of the Federal Controlled Substances Act.

e. For each partial filling, the dispensing pharmacist shall record on the back of the prescription or electronic record (or on another appropriate record uniformly maintained and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. Prior to any subsequent partial filling, the pharmacist is to determine that the additional partial filling is necessary.

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G. Time limit for filling Schedule II Prescriptions
1. FCSA – There is no time limit for filling a Schedule II prescription under the FCSA.
2. TCSA – The time limit in Texas for filling a Schedule II prescription is as follows:
   a. A Schedule II prescription has to be filled within 21 days after the date issued. Note: The date issued is the date written or the date electronically prescribed. The day after a prescription is issued is considered Day 1 (i.e., a prescription issued on Feb. 1 must be filled by Feb. 22).
   b. A Schedule II prescription issued to be filled at a later date must be filled within 21 days after from the first date authorized to be filled rather than 21 days from the date issued. For example, if a Schedule II prescription is issued on May 5th, with instructions not to fill until June 5th, it must be filled by June 26th. The day after June 5 (June 6) is considered day one.

H. Quantity Limits and Treatment of Pain
1. Neither the FCSA nor the TCSA have quantity limits for Schedule II (or any other schedule) controlled substance prescriptions. However, advance practice nurses and physician assistants in Texas may only prescribe a total 90-day supply (including refills) of a CIII-CV controlled substance. See Chapter C. in this book.
2. It is a pharmacist’s responsibility to determine that a controlled substance prescription is legitimate, and it is also a pharmacist’s responsibility to ensure that patients obtain appropriate pain medication for their condition. Just because a prescription for a narcotic medication contains a large quantity or exceeds recommended doses, it does not necessarily mean the prescription is not legitimate.

3. Texas State Board of Pharmacy Position Statement on Treatment of Pain can be found at http://www.tsbp.state.tx.us/files_pdf/Pain_Policy.PDF

4. DEA Policy Statement on Dispensing Controlled Substances for the Treatment of Pain can be found at http://www.deadiversion.usdoj.gov/fed_regs/notices/2006/fr09062.htm

5. Pain management clinics in Texas must be certified by the Texas Medical Board.
   a. The names of certified Pain Management Clinics are posted on the Texas Medical Board’s website. The website also lists Pain Management Clinics whose certificates have been revoked.
   b. Individual physicians do not need to be certified to prescribe controlled substances and just because a prescription is written from a certified Pain Management Clinic does not mean a pharmacist would not need to confirm its authenticity and that it was issued in the usual course of professional practice and for a legitimate medical purpose.

I. Texas Official Prescription Form

   Note: 2015 legislation transferred the Official Prescription and Prescription Access Texas (PAT) programs from the Department of Public Safety (DPS) to the Texas State Board of Pharmacy (TSBP). Forms will show the DPS seal until new forms are issued by TSBP. Existing DPS forms will include a DPS registration number, but DPS registration will be eliminated effective September 1, 2016 and the Official Prescription Program will be transferred to TSBP.

   1. Unless a specific exemption applies, all Schedule II controlled substance prescriptions in Texas must be written on an official prescription form
   1-a. The original “official” prescription form was a triplicate prescription issued by the Texas Department of Public Safety (DPS).
   2-b. In 2000, the official prescription forms became single copies with security features to prevent fraud. Since transitioning to an electronic reporting system in 2000, official prescription forms are just single copies, but have security features.
   c. On September 1, 2016, the official prescription program and the prescription monitoring program were transferred from DPS to the Texas State Board of Pharmacy. The forms are still single forms but have been modified slightly by TSBP.
   d. If a practitioner still has the older DPS issued triplicate forms, or the DPS issued single forms, these are still valid. Schedule II prescriptions are only valid if written on these specially issued forms or prescribed electronically.
4. Ordering Official Prescription Forms
   a. Official Prescription Forms can be obtained from TSBP, DPS until August 31, 2016 and will remain valid after that date. Starting September 1, 2016 the forms will be available from TSBP. Each official prescription has a unique control number which is tied to the prescriber’s name.
   b. Preprinted information on forms
      (1) Full name and address of prescriber.
      (2) Prescriber’s DEA number.

5. Prescriber’s Information to Complete Official Prescription Form
   a. Date prescription is issued and date to be filled by if applicable
   b. Name of patient (or animal owner)
   c. Address of patient (or animal owner)
   d. Species, if it’s an animal
   e. Age of patient
   f. Drug prescribed
   g. Quantity - numerically and written as a word (not required to be written as a word if electronic prescription)
   h. Drug dosage
   i. Instructions for use
   j. Intended use of the drug unless the practitioner determines the information is not in the best interest of the patient
   k. Legibly printed or stamped the name, address, DEA number, and telephone number of the practitioner
   l. Signature of prescriber or in the case of an electronic prescription, an electronic signature or validation as required by federal law to transmit the prescription

6. Official Prescriptions Filled by a Pharmacist
   a. If written on a non-triplicate official form, the practitioner will give the prescription to the patient, and the patient will present the form to the pharmacy.
   b. If written on a triplicate form, the practitioner keeps copy 3 and provides the patient with copy 1 or copy 1 and 2. If the pharmacist receives copies 1 and 2, the pharmacist should attach copy 2 to copy 1 since copy 2 is no longer required to be sent in.
   c. It is important to remember that copy 2 of the triplicate form by itself is not a valid prescription, and, if it is presented without the original (copy 1), it cannot be legally filled.

7. Pharmacist’s Responsibilities (Board Rule 315.5)
   a. The pharmacist must sign, date, and enter the prescription number on the form.
   b. The pharmacist may make informational changes or additions such as changing or adding the patient’s address upon verification. Most other changes require contacting the prescribing practitioner.
   c. Prescription information must be transmitted electronically to the Board of Pharmacy within 7 days of the date the prescription was completely filled.
d.— Dispensing time limit. The prescription must be filled within 21 days after the date of issued or first date authorized to be filled, e.g., if issued on 5/1, must be filled by 5/22.

e.— Information that must be added in “pharmacy use only” section:
(1) Pharmacy name, street address, city, state, and zip code.
(2) Pharmacy telephone number with area code.
(3) Pharmacy DEA number.
    Information may be printed, typed, stamped, or on a label which is affixed to the prescription.

a. Upon receipt of a properly completed prescription form, a dispensing pharmacist must:
(1) If the prescription is for a Schedule II controlled substance, ensure the date the prescription is presented is not later than 21 days after the date of issuance;
(2) If multiple prescriptions are issued by the prescribing practitioner allowing up to a 90-day supply of Schedule II controlled substances, ensure each prescription is neither dispensed prior to the earliest date intended by the practitioner nor dispensed beyond 21 days from the earliest date the prescription may be dispensed;
(3) Enter the date dispensed and the pharmacy prescription number;
(4) Indicate whether the pharmacy dispensed to the patient a quantity less than the quantity prescribed; and
(5) If issued on an official prescription form, enter the following information, if different from the prescribing practitioner’s information:
    (a) The brand name or, if none, the generic name of the controlled substance dispensed; or
    (b) The strength, quantity, and dosage form of the Schedule II controlled substance used to prepare the mixture or compound.

b. The prescription presented for dispensing is void, and a new prescription is required if:
(1) The prescription is for a Schedule II controlled substance and is presented 21 days after issuance or 21 days after any earliest dispense date; or
(2) The prescription is for a Schedule III, IV, or V controlled substance and is presented more than six months after the date of issuance or has been dispensed five times during the six months after issuance.

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8. Only one prescription per form
a. Official Prescription Forms are valid for prescriptions for all controlled substances. However, they are only required for Schedule II controlled substances.

b. If a physician has written for a Schedule II drug and another lower schedule (Schedule III, IV or V) drug or a dangerous drug, the pharmacist can cross out the non-Schedule II and transfer it to a pharmacy prescription pad as follows.
(1) Dispense and file the Schedule II prescription and make sure that the non-Schedule II drug is marked out.

(2) Fill the non-Schedule II prescription as a verbal prescription and transfer it to a pharmacy prescription pad and file it with Schedule III-V prescriptions.

9. Electronically transmitting controlled substance prescription information from the pharmacy to TSBP DPS (TSBP effective September 1, 2016). – Schedule II prescription information must be transmitted to TSBP DPS (TSBP effective September 1, 2016) within 7 days of the date the prescription is completely filled. See Section XIX C. XVIII. B. below.

10. Exceptions to the Use of an Official Prescription Form (When an official prescription form is NOT required)
   a. Hospital inpatient medication orders that include patients admitted to a hospital, hospital clinic, hospital emergency room, licensed ambulatory surgical center, surgical suite in a dental office, or veterinary medical school.
   b. Hospital inpatients requiring an emergency quantity of a Schedule II drug upon release from the hospital.
      (1) Limited to a seven-day supply or minimum amount needed until patient can obtain access to a pharmacy whichever is less.
      (2) Must be in an appropriately-labeled container.
      (3) Must be dispensed by the hospital pharmacy while the patient is still admitted.
   c. Persons receiving treatment with a Schedule II drug from a member of a life flight helicopter medical team or emergency medical ambulance crew or a paramedic-emergency medical technician.
   d. Persons receiving treatment with a Schedule II drug while an inmate in a correctional facility operated by the Texas Department of Criminal Justice.
   e. Animals admitted to an animal hospital including animals that are residents of zoos, wildlife parks, exotic game ranches, wildlife management programs, or state or federal research facilities.
   f. Administration of a Schedule II drug from a long term care facility’s emergency kit.
   g. Therapeutic optometrists administering topical ocular cocaine as permitted under the Texas Optometry Act [See Chapter C in this book].
   h. Prescriptions from out-of-state practitioners but only if the pharmacy has submitted a plan which has been approved by DPS and TSBP until August, 31, 2016. Effective September 1, 2016, only TSBP will approve such plans.

11. Official Prescription Forms
   a. Triplicate Form
      (1) Prescription control number is preprinted and is unique to individual prescriptions.
      (2) Prescriber keeps copy 3 and patient presents copies 1 and 2 or just copy 1 to the pharmacy.
      (3) Copy 2 by itself is not a valid prescription.
   b. Official Prescription Form
      (1) Single copy with security features, a green background.
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(2) Prescription control number is preprinted and is unique to individual prescriptions.

(3) VOID pantograph – If the prescription is copied the word “VOID” appears.

(4) Heat sensitive “thumbprint” disappears and reveals the word “SAFE” when rubbed or heated.

(5) Watermark – A gray scale State of Texas seal appears in the middle of the prescription. Note: Effective September 1, 2016, the Official Prescription and Prescription Access Texas (PAT) programs will transfer from the Department of Public Safety (DPS) to the Texas State Board of Pharmacy (TSBP). Forms issued prior to September 31, 2016 will show the DPS seal. Until new forms are issued by TSBP, these forms remain valid after September 1, 2016 and will include a DPS registration number even though the registration system has been eliminated and the DPS number is no longer required.

Editorial Note: Delete the sample official prescription form (front and back).

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XIX. Texas Prescription Program for Controlled Substances (Prescription Drug Monitoring Program)

A. Overview and Background

1. As part of Ross Perot’s “Texans’ War on Drugs” legislative package, the Texas Prescription Program was created by the Texas Legislature in 1982 to monitor Schedule II controlled substance prescriptions. It included:
   a. A required triplicate prescription form for all Schedule II prescriptions, and
   b. Reporting to DPS (TSBP effective September 1, 2016) of all Schedule II prescriptions dispensed by pharmacies.

2. The intent of the original legislation was to reduce drug diversion of Schedule II controlled substances from four sources:
   a. Patient; “shopping” different prescribers
   b. Physician; non-therapeutic prescribing patterns
   c. Pharmacy; non-therapeutic dispensing patterns
   d. Forged prescriptions

3. The program was expanded in 2008, to include monitoring of Schedule III-V controlled substances. Although no special prescription forms are required for Schedule III-V drugs, pharmacies are required to electronically report dispensing of all controlled substance prescriptions, including refills, to DPS (now TSBP) within seven days of the prescription being completely filled.

B. Prescription Monitoring Program (PMP) Access Texas (PAT) program
1. The Texas PMP collects prescription dispensing data on all Schedule II, III, IV, and V controlled substances dispensed by a pharmacy in Texas or to a Texas resident from an out-of-state pharmacy. Texas’ Prescription Monitoring Program is called the Prescription Access Texas (PAT) program and is administered by the Texas Department of Public Safety (DPS) until August 31, 2016. Effective September 1, 2016 the program will be administered by Texas State Board of Pharmacy (TSBP).

2. The PMP PAT is designed to assist pharmacists and physicians in identifying patients who may be getting prescriptions for controlled substances from multiple physicians or having prescriptions filled by multiple pharmacies.

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3. The Texas State Board of Pharmacy’s contracted vendor for the PMP program is Appriss, Inc. and access is through the PMP AWARxE portal which can be found at the TSBP website or at https://texas.pmpaware.net/login. Authorized users, including pharmacists and pharmacy technicians acting at the direction of a pharmacist may access the PAT at https://texaspatx.com and can search the last 365 days worth of prescription dispensing history for Schedule II – V controlled substances.

4. Access to the PMP is restricted. The information is available to practitioners (and their delegates) and pharmacies inquiring about their own patients. State regulatory Boards also have access. A pharmacist may delegate no more than four access to PMP data to pharmacy technicians to access the PAT for the pharmacist and the technicians must be employed at the same pharmacy and acting under the direction of the pharmacist as the pharmacist. A person who knowingly gives access or obtains unauthorized access to the PMP is subject to administrative, civil, or criminal penalties.

5. The Texas PMP program is also part of the National Association of Boards of Pharmacy’s PMP Interconnect® program which facilitates the transfer of PMP data across state lines. With over 40 states participating, this program provides the means for physicians and pharmacists to more easily identify patients with prescription drug abuse and misuse problems, especially if those patients are crossing state lines to obtain drugs.

C. Electronically transmitting controlled substance prescription information from the pharmacy to TSBP DPS (TSBP effective September 1, 2016).

1. Dispensing information must be transmitted to TSBP through the PMP Clearinghouse. Detailed information on how this is done through the AWARxE PMP Clearinghouse can be found at the TSBP’s PMP website https://www.pharmacy.texas.gov/PMP/ DPS/TSBP no later than the 7th day after the date the prescription was completely filled.

a. For a Schedule II prescription issued to a patient who is terminally ill or a resident of a LTCF this could be the 7th day after the last partial fill.

b. For a Schedule III-V prescription this would be the 7th day after the filling of the original quantity prescribed and for each full refill thereafter.

2. Pharmacies may transmit more frequently, but are required to transmit controlled substance dispensing information to TSBP no later than the 7th day after the date the prescription was completely filled.
a. For a Schedule II prescription issued to a patient who is terminally ill or a
resident of a LTCF this could be the 7th day after the last partial fill.
b. For a Schedule III-V prescription this would be the 7th day after the filling
of the original quantity prescribed and for each full refill thereafter.

The pharmacist is responsible for making sure that the following prescription
information is transmitted to DPS/TSBP:
a. The official prescription control number;
b. The patient’s (or the animal owner’s) name, age (or date of birth), and
   address (including city, state, and zip code);
c. The date the prescription was issued and filled;
d. The NDC number of the controlled substance dispensed;
e. The quantity of controlled substance dispensed;
f. The pharmacy’s prescription number; and

g. The pharmacy’s DEA registration number.

3. Although it is normally done automatically by a pharmacy’s software program,
it is still the pharmacist’s responsibility to make sure that the following
prescription information is transmitted to TSBP for all controlled substance
prescriptions dispensed:
a. The official prescription control number;
b. The patient’s (or the animal owner’s) name, age (or date of birth), and
   address (including city, state, and zip code);
c. The date the prescription was issued and filled;
d. The NDC number of the controlled substance dispensed;
e. The quantity of controlled substance dispensed;
f. The pharmacy’s prescription number; and

g. The pharmacy’s DEA registration number.

Waiver from electronic reporting—DPS rules allowed pharmacies filling a
small number of reportable prescriptions to request a waiver from electronic
reporting. TSBP does not plan to offer this option when the program transfers
to TSBP on September 1, 2016.

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C. Office-based Treatment of Opiate Dependence

1. The Drug Addiction Treatment Act of 2000 allows for the treatment of opiate
dependence from a physician’s office with less restrictive controls than for
Schedule II drugs. The law allows specially trained physicians to prescribe
certain narcotic Schedule III-V drugs to treat opiate dependence through a risk
management program which includes close monitoring of drug distribution
channels.

2. A practitioner authorized to issue prescriptions to treat opiate dependence under
the Act is given a Drug Addiction Treatment Act of 2000 (DATA 2000) waiver
identification code or “X” number. The “X” number of the practitioner must be
on the prescription in addition to the practitioner’s DEA registration number.
3. Authorized practitioners (sometimes called DATA waived physicians) may treat 30 or 100 patients at any one time, dependent on individual authorization from the Center for Substance Abuse Treatment (CSAT). Physicians who submitted the notification for initial authorization at least one year prior may submit a second notification of the need and intent to increase the patient limit from 30 patients up to 100 patients. Upon authorization by CSAT, DEA will issue a new DEA certificate of registration with a business activity code to identify whether the physician is authorized to treat 30 or 100 patients. To increase access to treatment, rules adopted on August 8, 2016 allow physicians who have authorization to treat 100 patients to apply for authorization to treat 275 patients if specific eligibility criteria are met.

4. Drugs approved under the act are Subutex® (buprenorphine) and Suboxone® (buprenorphine/naloxone combination). Subutex® is used for treatment while Suboxone® is used for maintenance therapy. These drugs, both Schedule III controlled substances, are available in sublingual form and may be dispensed by a pharmacy upon a prescription from a qualified physician. For more information, see [http://buprenorphine.samhsa.gov/](http://buprenorphine.samhsa.gov/) and [http://www.deadiversion.usdoj.gov/pubs/docs/dwp_buprenorphine.htm](http://www.deadiversion.usdoj.gov/pubs/docs/dwp_buprenorphine.htm)

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#### III. Schedule II Controlled Substances

A. Special official prescription form required in Texas.

B. Time limit for filling Schedule II prescriptions
   1. FCSA – No time limit
   2. TCSA – 21 days after from the date issued or the first date authorized to be filled if multiple prescriptions are issued on the same day with instructions not to fill until a later date.

C. Partial fills for regular patients (not long term care or terminally ill patients)
   1. FCSA – partial fills may be provided for up to 30 days
   2. TCSA – partial fills may be provided for up to 72 hours

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5. Every person or firm who manufactures, distributes, dispenses, or performs various other functions with controlled substances must register with DEA. Texas previously had a similar registration requirement with the Texas Department of Public Safety (DPS); however, effective September 1, 2016 the state controlled substance registration was eliminated.

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13. A theft or significant loss of controlled substances must be reported to the DEA, DPS, and TSBP. DEA also recommends reporting to local police. DEA requires initial notification to be within one business day, but the Report of Theft or Loss (DEA 106 Form) may be sent later after a determination of the extent of the theft or loss.
22. Schedule II Prescriptions  
   a. May not be refilled, however DEA and Texas rules allow multiple prescriptions for Schedule II drugs to be issued the same day with instructions that they be filled at a later date under certain conditions including that the total quantity is not more than a 90-day supply.  
   b. Must be written on a Texas Official Prescription form and may not be taken verbally unless it is an emergency.  
   c. A fax of the Texas Official Prescription form may serve as the original Schedule II prescription only for  
      (1) narcotic controlled substances to be administered by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion,  
      (2) any Schedule II controlled substance for residents of a long-term care facility, or  
      (3) narcotic controlled substances for a patient enrolled in a hospice care program  
   d. Must be filled within 21 days after from the date issued or the first date authorized to be filled.  

   e. May be sent electronically if both the prescriber and pharmacy’s computers systems meet all DEA security requirements.  
   f. If a pharmacy is unable to supply the full quantity ordered on a Schedule II prescription, a partial filling may be given as long as the remaining quantity is dispensed within 72 hours (may be up to 60 days for long term care and terminally ill patients). Note: federal law now allows partial fills for up to 30 days, but Texas law is more restrictive and is still 72 hours.  

23. Schedule III-V Prescriptions  
   a. May be written, verbal, fax or electronic.  
   b. May be refilled up to five times in six months.  
   c. May be transferred to another pharmacy one time only unless the pharmacies share a common database.  
   d. From out-of-state advanced practice nurses or physician assistants are not valid in Texas even if they are registered with DEA and have prescriptive authority in their state. [See Chapter C.]  

24. Although federal law allows some Schedule V products to be sold without a prescription, all codeine products require a prescription under Texas law and there are no other commercially available Schedule V products available that can be sold without a prescription in Texas.  

25. Texas’ Prescription Monitoring Program (PMP) is called the Prescription Access Texas (PAT) program is administered by the Texas State Board of Pharmacy (TSBP) and requires data regarding dispensing of controlled substances to be transmitted to TSBP no later than 7 days after a prescription is completely filled, effective September 1, 2016.  

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26. A prescription written for methadone or any other controlled substance to treat addiction is not a valid prescription. The only exceptions are prescriptions written for Subutex® (buprenorphine) and Suboxone® (buprenorphine/naloxone combination) by specially trained physicians under the Drug Addiction Treatment Act of 2000.

27. Non-prescription products containing certain List Chemicals such as pseudoephedrine must be placed behind a counter or in a locked cabinet and are subject to retail sales limits.

28. Records of electronic controlled substance prescriptions must be maintained electronically.

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Section 483.103 Dispensing of Opioid Antagonist

A. A pharmacist may dispense an opioid antagonist under a valid prescription to:
   1. a person at risk of experiencing an opioid-related drug overdose; or
   2. a family member, friend, or other person in a position to assist a person described by Subdivision (1).

B. A prescription filled under this section is considered as filled for a legitimate medical purpose in the usual course of professional practice.

C. A pharmacist who, acting in good faith and with reasonable care, dispenses or does not dispense an opioid antagonist under a valid prescription is not subject to any criminal or civil liability or any professional disciplinary action for:
   1. dispensing or failing to dispense the opioid antagonist; or
   2. if the pharmacist chooses to dispense an opioid antagonist, any outcome resulting from the eventual administration of the opioid antagonist.

Board of Pharmacy Rule §295.14 Dispensing of Opioid Antagonist by Pharmacist

(a) Purpose. The purpose of this section is to provide standards for pharmacists engaged in the dispensing of opioid antagonists as authorized in Chapter 483 of the Health and Safety Code.

(b) Definitions.

(1) Opioid antagonist - Any drug that binds to opioid receptors and blocks or otherwise inhibits the effects of opioids acting on those receptors.

(2) Opioid-related drug overdose - A condition evidenced by symptoms such as extreme physical illness, decreased level of consciousness, constriction of the pupils, respiratory depression, or coma that a layperson would reasonably believe to be the result of the consumption or use of an opioid.

(3) Prescriber - A person authorized by law to prescribe an opioid antagonist.

(c) Dispensing.

(1) A pharmacist may dispense an opioid antagonist under a valid prescription, including a prescription issued by a standing order, to:
   (A) A person at risk of experiencing an opioid-related drug overdose or
   (B) A family member, friend, or other person in a position to assist a person described by subparagraph (A) of this paragraph.

(2) A prescription dispensed under this section is considered as dispensed for a legitimate medical purpose in the usual course of professional practice.
(3) A pharmacist who, acting in good faith and with reasonable care, dispenses or does not dispense an opioid antagonist under a valid prescription is not subject to any criminal or civil liability or any professional disciplinary action for:

(A) Dispensing or failing to dispense the opioid antagonist or

(B) If the pharmacist chooses to dispense an opioid antagonist, any outcome resulting from the eventual administration of the opioid antagonist.

Section 483.104 Distribution of Opioid Antagonist; Standing Order

A person or organization acting under a standing order issued by a prescriber may store an opioid antagonist and may distribute an opioid antagonist, provided the person or organization does not request or receive compensation for storage or distribution.

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E. Controlled Substances. A PA/APRN may prescribe controlled substances under the following conditions:

1. The PA/APRN must be registered with the DEA (and Texas DPS until September 1, 2016).
2. Schedule III, IV, and V Prescriptions

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E. Must be registered with DEA (and DPS until September 1, 2016) to prescribe and administer controlled substances.

Page C.12 (bottom of chart)

If properly registered with DPS and DEA, Therapeutic Optometrists may possess for administration no more than 2 vials of prepackaged cocaine 10% eye drops.

Optometric Glaucoma Specialists (identified by a license number ending in the letters TG) may prescribe everything a Therapeutic Optometrist may prescribe and the following drugs:

1. Appropriate oral pharmaceutical agents used for diagnosing and treating visual defects, abnormal conditions, and diseases of the human visual system, including the eye and adnexa, which are included in the following classification or are combinations of agents in the classifications:
   A. One 10-day supply of oral antibiotics;
   B. One 72-hour supply of oral antihistamines;
   C. One seven-day supply of oral nonsteroidal anti-inflammatories;
   D. One three-day supply of any analgesic in controlled substance Schedules III, IV, and V (if properly registered with DPS and DEA); and
2. Antiglaucoma drugs.
V. Cocaine Eye Drops for Diagnostic Purposes
   A. Therapeutic Optometrists and Optometric Glaucoma Specialists can administer (but not prescribe or dispense) cocaine eye drops not greater than a 10% solution in prepackaged liquid form for diagnostic purposes.
   B. To do so, Therapeutic Optometrists and Optometric Glaucoma Specialists must have a controlled substance registration certificate from DEA (and DPS until September 1, 2016).
   C. Pharmacist’s Information
      1. A pharmacist may only distribute cocaine to Therapeutic Optometrists or Optometric Glaucoma Specialists pursuant to a DEA order form (DEA 222).
      2. A pharmacist may not distribute a controlled substance (other than a 10% solution of cocaine in prepackaged liquid form) to a Therapeutic Optometrist.
      3. The 10% cocaine solution may not be compounded.

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CII CONTROLLED SUBSTANCE RX: CII RXs may be dispensed only if written on an “official form” provided by the Texas State Board of Pharmacy (TSBP) and the Department of Public Safety (DPS). Authorized Texas APRNs and PAs can prescribe CII prescriptions only if working in a hospital-based practice for patients admitted to the hospital or seen in the emergency room or for terminally ill/hospice patients. CII prescriptions from out-of-state prescribers may only be filled by Texas pharmacies who have submitted a plan to the TSBP, DPS which has been approved by TSBP, the DPS and the Texas State Board of Pharmacy.

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Section 552.008 Grounds for Removal
   A. It is a ground for removal from the Board that a member:
      1. Does not have at the time of appointment the qualifications required for appointment to the Board;
      2. Does not maintain during service on the Board the qualifications required for appointment to the Board;
      3. Violates a prohibition established by Section 552.004 (related to being a lobbyist or an officer, employee or paid consultant of a trade association in a health care field);
      4. Cannot, because of illness or disability, discharge the member’s duties for a substantial part of the member’s term; or
      5. Is absent from more than half of the regularly scheduled Board meetings that the member is eligible to attend during a calendar year unless the absence is excused by majority vote of the Board.

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C. College/School-based Internship Programs.
   1. Internship experience acquired by student-interns.
a. An individual may be designated a student-intern provided he/she meets all of the following requirements:
   (1) submits an application to the Board with required information;
   (2) is enrolled in the professional sequence of a college/school of pharmacy whose professional degree program has been accredited by ACPE and approved by the Board;
   (3) has successfully completed the first professional year and obtained a minimum of 30 credit hours of work towards a professional degree in pharmacy; and
   (4) has met all requirements necessary in order for the Board to access the criminal history records information, including submitting fingerprint information and being responsible for all associated costs.

b. The terms of the student internship shall be as follows.
   (1) The student internship shall be gained concurrent with college attendance, which may include:
      (a) partial semester breaks such as spring breaks;
      (b) between semester breaks; and
      (c) whole semester breaks provided the student-intern attended the college/school in the immediate preceding semester and is scheduled with the college/school to attend in the immediate subsequent semester.
   (2) The student internship shall be obtained in pharmacies licensed by the Board, federal government pharmacies, or in a Board-approved program.
   (3) The student internship shall be in the presence of and under the supervision of a healthcare professional preceptor or a pharmacist preceptor.

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B. Alternative licensing procedure. For the purpose of §55.004, Occupations Code, an applicant for a pharmacist’s license who is a military service member, military veteran, or military spouse may complete the following alternative procedures for licensing as a pharmacist.

1. Requirements for licensing by reciprocity. An applicant for licensing by reciprocity who meets all of the following requirements may be granted a temporary license as specified in subsection (b) of this section prior to completing the NABP application for pharmacist license by reciprocity, and taking and passing the Texas Pharmacy Jurisprudence Examination. The applicant shall:
   a. complete the Texas application for pharmacist license by reciprocity that includes the following:
      i. name;
      ii. addresses, phone numbers, date of birth, and social security number; however, if an individual is unable to obtain a social security number, an individual taxpayer identification number
may be provided in lieu of a social security number along with documentation indicating why the individual is unable to obtain a social security number; and

iii. any other information requested on the application;

b. meet the educational and age requirements as set forth in §283.3 (relating to Educational and Age Requirements);

c. present to the Board proof of initial licensing by examination and proof that any current licenses and any other licenses granted to the applicant by any other state have not been suspended, revoked, canceled, surrendered, or otherwise restricted for any reason;

d. meet all requirements necessary for the Board to access the criminal history records information, including submitting fingerprint information and such criminal history check does not reveal any disposition for a crime specified in §281.64 (relating to Sanctions for Criminal Offenses) indicates a sanction of denial, revocation, or suspension; and

e. be exempt from the application and examination fees paid to the Board set forth in 61 §283.9(a)(2)(A) and (b); and

f. provide documentation to include:

i. military identification indicating that the applicant is a military service member, military veteran, or military dependent if a military spouse; and

ii. marriage certificate, if a military spouse.

2. Requirements for an applicant whose Texas pharmacist’s license has expired. An applicant whose Texas pharmacist’s license has expired within five years preceding the application:

a. shall complete the Texas application for licensing that includes the following:

i. name;

ii. addresses, phone numbers, dates of birth, and social security numbers; however, if an individual is unable to obtain a social security number, an individual taxpayer identification number may be provided in lieu of a social security number along with documentation indicating why the individual is unable to obtain a social security number; and

iii. any other information requested on the application;

b. shall provide documentation to include:

i. military identification indicating that the applicant is a military service member, military veteran, or military dependent if a military spouse; and

ii. marriage certificate, if a military spouse.

C. For the purpose of §55.005, Occupations Code, an applicant for a pharmacist license who is a military service member, military veteran, or military spouse and who holds a current license as a pharmacist issued by another state may complete the following expedited procedures for licensing as a pharmacist. The applicant shall:

1. meet the educational and age requirements specified in §283.3 of this title (relating to Educational and Age Requirements);
2. meet all requirements necessary in order for the Board to access the criminal history record information, including submitting fingerprint information and being responsible for all associated costs;
3. complete the Texas and NABP applications for reciprocity. Any fraudulent statement made in the application for reciprocity is grounds for denial of the application; if such application is granted, any fraudulent statement is grounds for suspension, revocation, and/or cancellation of any license so granted by the Board. The Texas application includes the following information:
   a. name;
   b. addresses, phone numbers, date of birth, and social security number; however, if an individual is unable to obtain a social security number, an individual taxpayer identification number may be provided in lieu of a social security number along with documentation indicating why the individual is unable to obtain a social security number; and
   c. any other information requested on the application.

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Section 558.154 Issuance of License to Provisional License Holder

These sections authorize and set forth the requirements for the Board to grant a provisional or temporary license to individuals licensed in another state and applying for licensure in Texas. Except for military spouses, the Board does not offer provisional or temporary licenses.

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3. Dates
   If you attend a live CE program, the completion date and the credit date for the course is the day that you attended the program. If you participated in correspondence courses, these courses are not considered complete until you receive a certificate of completion from the provider with a dated, certifying signature. Credit for the correspondence course is awarded on the date specified on the certificate, not the date you completed the CE. This can be important when reporting hours to the Board for your specified renewal period.
   Note: All pharmacists should register with CPE Monitor Service, a collaborative effort of the National Association of Boards of Pharmacy (NABP), and the Accreditation Council for Pharmacy Education (ACPE) that allow pharmacists to electronically keep track of continuing pharmacy education (CPE) credits from ACPE-accredited providers. More information is available at https://nabp.pharmacy/cpe-monitor-service/

SUBCHAPTER C. Inactive Status (Inactive License)
Board of Pharmacy Rule §291.1 Pharmacy License Application

A. Application shall state:
   1. Name and address of pharmacy;
   2. Type of ownership;
   3. Names, addresses, dates of birth, phone numbers, copies of social security cards, copies of current driver’s licenses, state-issued photo identification cards, or passports of all owners or of all managing officers if the pharmacy is owned by a partnership or corporation. If an individual is unable to obtain a social security number, an individual taxpayer identification number may be provided in lieu of a social security number along with documentation indicating why the individual is unable to obtain a social security number;
   4. Name and license number of pharmacist-in-charge;

SUBCHAPTER C. Restrictions on Pharmacy License

Section 560.101 License Not Transferable

A pharmacy license issued under this chapter is not transferable or assignable. Note: Although a pharmacy license is not transferable, TSBP does have rules requiring notification to the Board of a change in location or name. See TSBP Rule 291.3(a) or Chapter E. in this book.

Board of Pharmacy Rule §291.2 Change of Location and/or Name

A. File a new application with the information required in §291.1 within ten days of the change.
B. Return the previous license with the application.
C. Board issues an amended license reflecting the change; the previous license number is not changed.
D. Fee will be required as specified in Rule §291.6.
E. (Note: You must also notify DEA and DPS of the change.)

Board of Pharmacy Rule §291.14 Pharmacy License Renewal

A. Renewal requirements
   1. A license to operate a pharmacy expires on the last day of the assigned expiration month.
   2. “Timely receipt of the completed application and renewal fee” means the receipt in the Board’s office of such application and renewal fee on or before the last day of the assigned expiration month; the postmark date is not relevant.
   3. The provisions of §561.005 (Relating to Suspension of License) shall apply if the completed application and a renewal fee is not received on or before the last day of the assigned expiration month.
   4. An expired license may be renewed according to the following schedule:
a. If the license has been expired for 90 days or less, the license may be renewed by paying to the Board a renewal fee that is equal to one and one-half times the required renewal fee as specified in §291.6 of this title (relating to Pharmacy License Fees).

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b. If the license has been expired for 91 days one year or more, the license may not be renewed. The pharmacy may apply for a new license as specified in §291.1 of this title (relating to Pharmacy License Application).

B. If the Board determines on inspection at the pharmacy’s address on or after the expiration date of the license that no pharmacy is located or exists at the pharmacy’s address (e.g., the building is vacated or for sale or lease, or another business is operating at the location), the Board shall not renew the license.

C.B—Additional renewal requirements for Class E pharmacies. See Chapter J. on Class E pharmacies.

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Board of Pharmacy Rule §309.3 Generic Substitution Requirements

A. General requirements. In accordance with Chapter 562 of the Act, a pharmacist may dispense a generically equivalent drug product or interchangeable biological if:
1. The generic drug or interchangeable biological product costs the patient less than the prescribed drug product;
2. The patient does not refuse the substitution; and
3. The practitioner does not certify on the prescription form that a specific prescribed brand is medically necessary as specified in a dispensing directive described in subsection C. (c) of this section.

B. Prescription format for written prescription drug orders.
1. A written prescription drug order issued in Texas may:
   a. Be on a form containing a single signature line for the practitioner; and
   b. Contain the following reminder statement on the face of the prescription: “A generically equivalent drug product may be dispensed unless the practitioner hand writes the words ‘Brand Necessary’ or ‘Brand Medically Necessary’ on the face of the prescription.”

2. A pharmacist may dispense a prescription that is not issued on the form specified in paragraph 1.(4) of this subsection. However, the pharmacist may dispense a generically equivalent drug or interchangeable biological product unless the practitioner has prohibited substitution through a dispensing directive in compliance with subsection C. 1. (6)(I) of this section.

3. The prescription format specified in paragraph 1.(4) of this subsection does not apply to the following types of prescription drug orders:
   a. Prescription drug orders issued by a practitioner in a state other than Texas;
   b. Prescriptions for dangerous drugs issued by a practitioner in the United Mexican States or the Dominion of Canada; or
c. Prescription drug orders issued by practitioners practicing in a federal facility provided they are acting in the scope of their employment.

4. In the event of multiple prescription orders appearing on one prescription form, the practitioner shall clearly identify to which prescription(s) the dispensing directive(s) apply. If the practitioner does not clearly indicate to which prescription(s) the dispensing directive(s) apply, the pharmacist may substitute on all prescriptions on the form.

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   a. If a prescription drug order is transmitted to a pharmacist orally, the practitioner or practitioner’s agent shall prohibit substitution by specifying “Brand Necessary” or “Brand Medically Necessary.” The pharmacist shall note any substitution instructions by the practitioner or practitioner’s agent on the file copy of the prescription drug order. Such file copy may follow the one-line format indicated in subsection B.1. (b)(1) of this section or any other format that clearly indicates the substitution instructions.
   b. If the practitioner’s or practitioner’s agent does not clearly indicate that the brand name is medically necessary, the pharmacist may substitute a generically equivalent drug or interchangeable biological product.
   c. To prohibit substitution on a verbal prescription reimbursed through the medical assistance program specified in 42 C.F.R., Section 447.331 (Medicaid):
      (1) The practitioner or the practitioner’s agent shall verbally indicate that the brand is medically necessary; and
      (2) The practitioner shall mail or fax a written prescription to the pharmacy which complies with the dispensing directive for written prescriptions specified in paragraph 1. (f) of this subsection within 30 days.

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D. Refills.
   All refills shall follow the original substitution instructions unless otherwise indicated by the practitioner or practitioner’s agent.
   1. Original substitution instructions. All refills shall follow the original substitution instructions unless otherwise indicated by the practitioner or practitioner’s agent.
   2. Narrow therapeutic index drugs – This rule is not in effect. See rule under Section 560.014. 
C. **Notification by pharmacies delivering prescriptions by mail.**
   1. A pharmacy that supplies a prescription by mail is considered to have complied with the provision of subsection A. of this section if the pharmacy includes on the prescription order form completed by the patient or the patient’s agent language that clearly and conspicuously:
      a. States that if a less expensive generically equivalent drug or interchangeable biological is available for the brand prescribed, the patient or the patient’s agent may choose between the generically equivalent drug or interchangeable biological and the brand prescribed; and
      b. Allows the patient or the patient’s agent to indicate the choice of the generically equivalent drug or interchangeable biological and the brand prescribed.
   2. If the patient or patient’s agent fails to indicate otherwise to a pharmacy on the prescription order form under paragraph 1.(1) of this subsection, the pharmacy may dispense a generically equivalent drug or interchangeable biological.

D. **Inpatient notification exemption.** Institutional pharmacies shall be exempt from the labeling provisions and patient notification requirements of §562.006 and §562.009 of the Act with respect to drugs distributed pursuant to medication orders.

**Board of Pharmacy Rule §309.5 Communication with prescriber (biological products)**

A. Not later than the third business day after the date of dispensing a biological product, the dispensing pharmacist or the pharmacist’s designee shall communicate to the prescribing practitioner the specific product provided to the patient, including the name of the product and the manufacturer or national drug code number.

**Board of Pharmacy Rule §309.6 Records**

A. When the pharmacist dispenses a generically equivalent drug or interchangeable biological product pursuant to Subchapter A, Chapter 562 of the Act, the following information shall be noted on the original written or hard copy of the oral prescription drug order: (Note: TSBP rules also allow these records to be maintained in the pharmacy’s computer system).
   1. Any substitution instructions communicated orally to the pharmacist by the practitioner or practitioner’s agent or a notation that no substitution instructions were given; and
   2. The name and strength of the actual drug product dispensed shall be noted on the original or hard-copy prescription drug order. The name shall be either:
      a. The brand name and strength; or
b. The generic name or name of the interchangeable biological, strength, and name of the manufacturer or distributor of such generic drug or interchangeable biological product. (The name of the manufacturer or distributor may be reduced to an abbreviation or initials, provided the abbreviation or initials are sufficient to identify the manufacturer or distributor. For combination drug products having no brand name, the principal active ingredients shall be indicated on the prescription.)

B. If a pharmacist refills a prescription drug order with a generically equivalent product or interchangeable biological product from a different manufacturer or distributor than previously dispensed, the pharmacist shall record on the prescription drug order the information required in subsection A.(a) of this section for the product dispensed on the refill.

C. If a pharmacy utilizes patient medication records for recording prescription information, the information required in subsection A.(a) and B.(b) of this section shall be recorded on the patient medication records.

D. The National Drug Code (NDC) of a drug or any other code may be indicated on the prescription drug order at the discretion of the pharmacist, but such code shall not be used in place of the requirements of subsections A.(a) and B.(b) of this section.

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3. The quantity of a prescription drug dispensed does not exceed a 72-hour supply (or 30-day supply if authorized by the Governor and allowed by TSBP). Note: By policy, TSBP permits dispensing the entire supply for unit-of-use products such as oral contraceptives, inhalers, and ophthalmic solutions.

4. The pharmacist informs the patient or the patient’s agent at the time of dispensing that the refill is being provided without such authorization and that authorization of the practitioner is required for future refills;

5. The pharmacist informs the practitioner of the emergency refill at the earliest reasonable time;

6. The pharmacist maintains a record of the emergency refill containing the information required to be maintained on a prescription as specified in this subsection;

7. The pharmacist affixes a label to the dispensing container as specified in §291.33(c)(4) of this title (Operational Standards); and

8. If the prescription was initially filled at another pharmacy, the pharmacist may exercise his/her professional judgment in refilling the prescription provided:
   a. The patient has the prescription container, label, receipt or other documentation from the other pharmacy which contains the essential information;
   b. After a reasonable effort, the pharmacist is unable to contact the other pharmacy to transfer the remaining prescription refills or there are no refills remaining on the prescription;
   c. The pharmacist, in his/her professional judgment, determines that such a request for an emergency refill is appropriate and meets the requirements of clauses 1. and 2. (1)(2) above; and
   d. The pharmacist complies with the requirements of clauses 3.-5. (3)-(5) above.
4. **Epinephrine auto-injector** – a disposable drug delivery system with a spring-activated needle that contains a premeasured single dose of epinephrine that is used to treat anaphylaxis in an emergency situation. It is designed for emergency administration of epinephrine to provide rapid, convenient first aid for persons suffering a potentially fatal reaction to anaphylaxis.

C. **Administration requirements.**
   1. Pharmacists may administer epinephrine through an auto-injector to a patient in an emergency situation.
   2. The authority of a pharmacist to epinephrine through an auto-injector may not be delegated.
   3. Epinephrine administered by a pharmacist under the provisions of this section shall be in the legal possession of a pharmacist or legal possession of a pharmacy, which shall be the pharmacy responsible for drug accountability, including the maintenance of records of administration of the epinephrine.

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**SUBCHAPTER C. Practice By Pharmacy (Pharmacies)**

**Section 562.101 Supervision of Pharmacy**

A. A pharmacy is required to be under the supervision of a pharmacist as provided by this section.

B. A Class A or Class B pharmacy is required to be under the continuous on-site supervision of a pharmacist during the time the pharmacy is open for pharmacy services.

C. A Class C pharmacy that is in an institution with more than 100 beds is required to be under the continuous on-site supervision of a pharmacist during the time the pharmacy is open for pharmacy services.

D. A Class C pharmacy that is in an institution with 100 beds or fewer is required to have the services of a pharmacist on a part-time or consulting basis according to the needs of the institution.

E. A Class D pharmacy is required to be under the continuous supervision of a pharmacist whose services are required according to the needs of the pharmacy. *NOTE: On-site supervision not required.*

F. A Class E pharmacy is required to be under the continuous on-site supervision of a pharmacist and shall designate one pharmacist licensed to practice pharmacy by the regulatory or licensing agency of the state in which the Class E pharmacy is located to serve as the pharmacist-in-charge of the Class E pharmacy. *Note: Section 560.052 requires that the pharmacist-in-charge be a Texas licensed pharmacist. See Chapter J.*

G. For a pharmacy license classification established under Section 560.053 (petition to Board), the Board shall adopt rules that provide for the supervision of the pharmacy by a pharmacist. Supervision under the Board rules must require at least continuous supervision by a pharmacist according to the needs of the pharmacy.
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3. A Texas DPS registration for the facility is required (until September 1, 2016) to store controlled substances in an emergency kit regardless if the emergency kit is a non-automated system such as a tackle box or an automated dispensing system being used as an emergency kit. According to Appendix H of the DEA Pharmacist’s Manual, a DEA registration is not required for a non-automated emergency kit such as a tackle box at a long term care facility, however DEA does require a pharmacy using an automated dispensing system as an emergency kit with controlled substances in it to obtain a separate DEA registration at the address of the facility. See 21 CFR 1301.27(b).

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3. If controlled substances are to be stored at the remote location using an automated pharmacy system, a DEA registration (and DPS registration until September 1, 2016) must be obtained for the remote location in the name of the pharmacy providing the remote pharmacy services.

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3. If controlled substances are to be stored at the remote location, a DEA registration (and DPS registration until September 1, 2016) must be obtained for the remote location.

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§297.3 Registration Requirements
A. General.
   1. Individuals who are not registered with the Board may not be employed as or perform the duties of a pharmacy technician or a pharmacy technician trainee.
   2. Individuals who have previously applied and registered as a pharmacy technician, regardless of the pharmacy technician’s current registration status, may not register as a pharmacy technician trainee.
   3. Individuals who apply and are qualified for both a pharmacy technician trainee registration and a pharmacy technician registration concurrently will not be considered for a pharmacy technician trainee registration.
B. Registration for pharmacy technician trainees. An individual may register as a pharmacy technician trainee only once and the registration may not be renewed.
   1. Each applicant for pharmacy technician trainee registration shall:
      a. have a high school or equivalent diploma (e.g. GED), or be working to achieve a high school or equivalent diploma. For the purpose of this clause, an applicant for registration may be working to achieve a high school or equivalent diploma for not more than two years; and
      b. complete the Texas application for registration that includes the following information:
         (1) name;
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C. Initial registration for pharmacy technicians.
   1. Each applicant for pharmacy technician registration shall:
      a. Have a high school or equivalent diploma (e.g. GED), or be working to achieve a high school or equivalent diploma. For the purpose of this clause, an applicant for registration may be working to achieve a high school or equivalent diploma for not more than two years; and
      b. Either have:
         (1) Taken and passed the Pharmacy Technician Certification Board’s National Pharmacy Technician Certification Examination or other examination approved by the Board and have a current certification certificate; or
         (2) Been granted an exemption from certification by the Board as specified in §297.7 of this title (relating to Exemption from Pharmacy Technician Certification Requirements); and
      c. Complete the Texas application for registration that includes the following information:
         (1) name;
         (2) addresses, phone numbers, date of birth, and social security number; however, if an individual is unable to obtain a social security number, an individual taxpayer identification number may be provided in lieu of a social security number along with documentation indicating why the individual is unable to obtain a social security number; and
         (3) any other information requested on the application; and
      d. Pay the registration fee specified in §297.4 of this title (relating to Fees).

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C. Initial registration for pharmacy technicians.
   1. Each applicant for pharmacy technician registration shall:
      a. Have a high school or equivalent diploma (e.g. GED), or be working to achieve a high school or equivalent diploma. For the purpose of this clause, an applicant for registration may be working to achieve a high school or equivalent diploma for not more than two years; and
      b. Either have:
         (1) Taken and passed the Pharmacy Technician Certification Board’s National Pharmacy Technician Certification Examination or other examination approved by the Board and have a current certification certificate; or
         (2) Been granted an exemption from certification by the Board as specified in §297.7 of this title (relating to Exemption from Pharmacy Technician Certification Requirements); and
      c. Complete the Texas application for registration that includes the following information:
         (1) name;
         (2) addresses, phone numbers, date of birth, and social security number; however, if an individual is unable to obtain a social security number, an individual taxpayer identification number may be provided in lieu of a social security number along with documentation indicating why the individual is unable to obtain a social security number; and
         (3) any other information requested on the application; and
      d. Pay the registration fee specified in §297.4 of this title (relating to Fees).
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E. Notification of Theft or Loss of a Controlled Substance or a Dangerous Drug.
   1. Controlled substances. For the purposes of the Act, §562.106, the theft or significant loss of any controlled substance by a pharmacy shall be reported in writing to the Board immediately on discovery of such theft or loss. A pharmacy shall be in compliance with this subsection by submitting to the Board a copy of the Drug Enforcement Administration (DEA) report of theft or loss of controlled substances, DEA Form 106, or by submitting a list of all controlled substances stolen or lost.

   *Note: Although the language in the Board rule states you can comply by sending a copy of DEA Form 106, this may not be feasible. Remember, you don’t have to actually submit DEA Form 106 immediately. You must notify DEA in writing within one business day of discovery, but DEA Form106 may be provided later once you have investigated the extent of the theft or loss. It may be best to notify TSBP at the same time the initial notification is made to DEA and then follow up with DEA Form 106 when it is complete and sent to DEA.*

   2. Dangerous drugs. A pharmacy shall report in writing to the Board immediately on discovering the theft or significant loss of any dangerous drug by submitting a list of the name and quantity of all dangerous drugs stolen or lost.

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F. Fire or Other Disaster. If a pharmacy experiences a fire or other disaster, the following requirements are applicable.
   1. Responsibilities of the pharmacist-in-charge.
      a. The pharmacist-in-charge shall be responsible for reporting the date of the fire or other disaster which may affect the strength, purity, or labeling of drugs, medications, devices, or other materials used in the diagnosis or the treatment of the injury, illness, and disease; such notification shall be immediately reported to the Board, but in no event shall exceed 10 days from the date of the disaster.
      b. The pharmacist-in-charge or designated agent shall comply with the following procedures.
         (1) If controlled substances, dangerous drugs, or Drug Enforcement Administration (DEA) order forms are lost or destroyed in the disaster, the pharmacy shall:
            (a) notify the DEA, Department of Public Safety (DPS), and Texas State Board of Pharmacy (Board) of the loss of the controlled substances or order forms. A pharmacy shall be in compliance with this section by submitting to each of these agencies a copy of the DEA’s report of theft or loss of controlled substances, DEA Form 106, immediately on discovery of the loss (*Note: Again, this may not be feasible. See Section E. 1 above.*); and
(b) notify the Texas State Board of Pharmacy in writing of the loss of the dangerous drugs by submitting a list of the dangerous drugs lost.

(2) If the extent of the loss of controlled substances or dangerous drugs is not able to be determined, the pharmacy shall:

(a) take a new, complete inventory of all remaining drugs specified in §291.17(c) of this title (relating to Inventory Requirements);

(b) submit to DEA and DPS a statement attesting that the loss of controlled substances is indeterminable and that a new, complete inventory of all remaining controlled substances was conducted and state the date of such inventory; and

(c) submit to the Board a statement attesting that the loss of controlled substances and dangerous drugs is indeterminable and that a new, complete inventory of the drugs specified in §291.17(c) of this title was conducted and state the date of such inventory.

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§291.5 Closing a Pharmacy (TSBP Rule)

Note: These rules apply when closing a pharmacy and no further pharmacy activities will take place at the location. If a pharmacy is being sold and pharmacy activities will continue at the location, the rules for change of ownership should be followed. These rules include applying for a new pharmacy license and providing notification to TSBP at least 10 days in advance as required under TSBP Rule 291.3, as well as DEA notification, inventory, and transfer requirements (see Termination of Registration and Transfer of Controlled Substances Upon Sale of a Pharmacy in Chapter B).

A. Prior to closing.

At least 14 days prior to the closing of a pharmacy that dispenses prescription drugs, the pharmacist-in-charge shall comply with the following: post a closing notice sign in a conspicuous place in the front of the prescription department and at all public entrance doors to the pharmacy. Such closing notice sign shall contain the following information:

1. The date of the closing; and

2. The name, address, and telephone number of the pharmacy acquiring the prescription drug orders, including refill information and patient medication records of the pharmacy.

If the pharmacy is registered to possess controlled substances, send a written notification to the appropriate divisional office of the Drug Enforcement Administration (DEA) containing the following information:

a. The name, address, and DEA registration number of the pharmacy;

b. The anticipated date of closing;

c. The name, address, and DEA registration number of the pharmacy acquiring the controlled substances; and

d. The date on which the transfer of controlled substances will occur.
2. If the pharmacy dispenses prescription drug orders, post a closing notice sign in a conspicuous place in the front of the prescription department and at all public entrance doors to the pharmacy. Such closing notice sign shall contain the following information:
   a. The date of closing; and
   b. The name, address, and telephone number of the pharmacy acquiring the prescription drug orders, including refill information and patient medication records of the pharmacy.

B. Closing day.
   On the date of closing, the pharmacist-in-charge shall comply with the following:
   1. Take an inventory as specified in §291.17 (Inventory Requirements).
   2. Remove all prescription drugs from the pharmacy by one or a combination of the following methods:
      a. Return prescription drugs to manufacturer or supplier (for credit/disposal);
      b. Transfer (sell or give away) prescription drugs to a person who is legally entitled to possess drugs, such as a hospital, or another pharmacy; and
      c. Destroy the prescription drugs following procedures specified in §303.2 of this title (relating to Disposal of Stock Prescription Drugs).

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3. If the pharmacy dispenses prescription drug orders:
   a. Transfer the prescription drug order files, including refill information and patient medication records, to a licensed pharmacy within a reasonable distance of the closing pharmacy; and
   b. Remove all signs or notify the landlord or owner of the property that it is unlawful to use the word “pharmacy” either in English or any other language, or any other word or combination of words of the same or similar meaning, or any graphic representation that would mislead or tend to mislead the public that a pharmacy is located at the address.

C. After closing.
   1. Within 10 days after the closing of the pharmacy, the pharmacist-in-charge shall forward to the Board a written notice of the closing which includes the following information:
      a. The actual date of closing;
      b. The license issued to the pharmacy;
      c. A statement attesting:
         (1) That an inventory as specified in §291.17 (Inventory Requirements) has been conducted; and
         (2) The manner by which the dangerous drugs and controlled substances possessed by the pharmacy were transferred or disposed; and
      d. If the pharmacy dispenses prescription drug orders, the name and address of the pharmacy to which the prescription drug orders, including refill information, and patient medication records were transferred.
   2. If the pharmacy is registered to possess controlled substances, a notification must be sent to:
a. Appropriate DEA divisional office explaining that the pharmacy has closed and include the following items: closed. Include the following items with the letter:
(1) a. DEA registration certificate; and
(2) b. All unused DEA order forms (222) with the word “VOID” written on the face of each order form; and
(3) c. Copy 2 of any DEA order forms (222) used to transfer Schedule II controlled from the closed pharmacy.
b. The Texas Department of Public Safety (DPS) explaining that the pharmacy has closed and include the DPS registration certificate. Note: No longer required starting September 1, 2016.
3. Once the pharmacy has notified the Board that the pharmacy is closed, the license may not be renewed. The pharmacy may apply for a new license as specified in §291.1 (Pharmacy License Application).

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§291.123 Centralized Prescription Drug or Medication Order Processing
A. Allows Class A (community), Class C (institutional) and Class E (non-resident pharmacies to provide central prescription drug order or medication order processing if they meet specific standards outlined in the rule. Note: If a pharmacy is only providing these services, they may be licensed as a Class G pharmacy. See Chapter J.

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SUBCHAPTER B. Inspections

Section 556.051 Authorization to Enter and Inspect
A. The Board or a representative of the Board may enter and inspect a facility relative to the following:
1. Drug storage and security
2. Equipment
3. Components used in compounding, finished and unfinished products, containers, and labeling of any item;
4. Sanitary conditions
5. Records, reports, or other documents required to be kept or made under this subtitle, Chapter 481 (TCSA) or 483 (TDAA), Health and Safety Code, or the Comprehensive Drug Abuse Prevention and Control Act of 1970 (FCSA).
6. Subject to Subsection B., financial records relating to the operation of the facility.
B. The Board or a representative of the Board may inspect financial records under Subsection A only in the course of the investigation of a specific complaint. The Board or representative may inspect only records related to the specific complaint. The inspection is subject to Section 565.055. Note: This inspection of financial records is different from DEA which does not have the authority to inspect financial records without the consent of the registrant.
2. The pharmacy possesses or engages in the sale, purchase, or trade or the offer to sell, purchase, or trade prescription drug samples (Does not apply to prescription drugs provided by manufacturer as starter prescriptions, to samples possessed by health care entities providing indigent care provided pharmacy is owned by a charitable organization and samples are dispensed at no charge)

3. The pharmacy possesses or engages in the sale, purchase, or trade or the offer to sell, purchase, or trade prescription drugs in violation of the Prescription Drug Marketing Act (i.e. drugs sold for export only, drugs purchased by a public or private hospital or other health care entity, or drugs donated or supplied at a reduced price to charitable organizations.)

4. The pharmacy engages in the sale, purchase, or trade or the offer to sell, purchase, or trade of misbranded products or prescription drugs beyond the manufacturer’s expiration date.

5. The owner or managing officer has previously been disciplined by the Board.

6. A non-resident pharmacy fails to reimburse the Board or its designee for all expenses, including travel, incurred by the Board in inspecting the non-resident pharmacy as specified in §556.0551 of the Texas Pharmacy Act.

7. The owner, managing officer(s), or other pharmacy employee(s) displays abusive, intimidating, or threatening behavior toward a Board member or employee during the performance of such member’s or employee’s lawful duties.

8. The pharmacy waived, discounted, or reduced, or offered to waive, discount, or reduce, a patient copayment or deductible for a compounded drug in the absence of:
   a. A legitimate, documented financial hardship of the patient; or
   b. Evidence of a good faith effort to collect the copayment or deductible from the patient.

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**Board of Pharmacy Rule §281.31 Burden Of Proof**

A. In a contested case hearing at the State Office of Administrative Hearings involving grounds for disciplinary action, the Board has the burden to prove that grounds to discipline respondent exist. However, the party that claims any exemption or exception, including mitigating factors as specified in §281.62 of this chapter, has the burden to prove that the exemption or exception should be applied.

B. In a contested case hearing at the State Office of Administrative Hearings involving a petition for reinstatement or removal of restriction, the petitioner has the burden to prove that the license should be reinstated or that a restriction on the license should be removed in accordance with §281.66 of the chapter.

C. In a show cause order hearing before a panel of the Board at the State Office of Administrative Hearings involving an applicant, licensee, or registrant who has been previously ordered by the Board to submit to a mental or physical examination under §565.052 or §568.0036 of the Act, the applicant, licensee, or registrant has the
burden to prove that the applicant, licensee, or registrant should not be required to submit to the examination.

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12. Length of time since license or registration was sanctioned and whether the time period has been sufficient for rehabilitation to occur;
13. Competency to engage in the practice of pharmacy; and
14. Other rehabilitation actions taken by the applicant.
C. If a reinstatement case involves cases involving criminal offenses, the sanctions specified in §281.64 apply.

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SUBCHAPTER D. Criminal Offenses

Section 566.151 Offenses; Criminal Penalty
A. A person commits an offense if the person violates this subtitle or any rule adopted under this subtitle relating to unlawfully engaging in the practice of pharmacy or unlawfully operating a pharmacy.
B. A person commits an offense if the person knowingly violates the licensing requirements of this subtitle or Section 558.001, 558.002, or 560.002.
C. A person commits an offense if the person violates Section 560.001 or 560.003.
D. Each day of violation under Subsection B. or Subsection C. is a separate offense.
E. An offense under this section is a Class A misdemeanor. The penalty is up to one year in a county jail and/or a fine of up to $4000.

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§291.33 Operational Standards
A. Licensing requirements. The pharmacy shall:
1. Be licensed annually or biennially in compliance with §291.1 (Pharmacy License Application).
2. A Class A pharmacy which changes ownership shall notify the Board within ten days of the change of ownership and apply for a new and separate license as specified in §291.3 (relating to Required Notifications).
3. A Class A pharmacy which changes location and/or name shall notify the Board within ten days of the change and file for an amended license as specified in §291.3 (relating to Required Notifications). Note: Requires notification not later than 30 days prior to the date of change.
4. A Class A pharmacy owned by a partnership or corporation which changes managing officers shall notify the Board in writing of the names of the new managing officers within ten days of the change, following the procedures in §291.3 (relating to Required Notifications).
5. A Class A pharmacy shall notify the Board in writing within ten days of closing, following the procedures as specified in §291.5.
6. A separate license is required for each principal place of business and only one pharmacy license may be issued to a specific location.

7. A fee as specified in §291.6 will be charged for the issuance and renewal of a license and the issuance of an amended license.

8. Need for other class of license: A Class A pharmacy, which also operates another type of pharmacy which would otherwise be required to be licensed as a Class B pharmacy, is NOT required to secure a Class B pharmacy license, but the Class A pharmacy shall comply with the provisions of Chapter 291 Subsection C (Nuclear Pharmacy rules) to the extent such rules are applicable to the operation of the pharmacy.

9. A Class A pharmacy engaged in the compounding of non-sterile preparations shall comply with the provisions of §291.131

10. Prior to August 31, 2014, a Class A pharmacy engaged in the compounding of sterile preparations shall comply with the provisions of §291.133

10.1 Effective August 31, 2014, a Class A pharmacy shall not compound sterile preparations. **Note:** Must be licensed as a Class A-S pharmacy to compound sterile preparations, unless the pharmacy has applied for and obtained a Class A-S pharmacy license.

11. A Class A pharmacy engaged in the provision of remote pharmacy services, including storage and dispensing of prescription drugs, shall comply with the provisions of §291.121. **(Note: This includes remote pharmacy services using automated systems, provision of emergency medication kits, and provision of telepharmacy services.)**

12. A Class A pharmacy engaged in centralized prescription dispensing and/or prescription drug or medication order processing shall comply with the provisions of §291.125 (relating to centralized prescription dispensing) and/or §291.123 (relating to centralized prescription drug or medication order processing).

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c. Documentation of consultation. When a pharmacist consults a prescriber as described in subparagraph b. of this paragraph the pharmacist shall document on the prescription hard copy or in the pharmacy’s data processing system associated with the prescription such occurrences and shall include the following information:

(1) Date the prescriber was consulted;

(2) Name of the person communicating the prescriber’s instructions;

(3) Any applicable information pertaining to the consultation; and

(4) Initials or identification code of the pharmacist performing the consultation clearly recorded for the purpose of identifying the pharmacist who performed the consultation.
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l. If the pharmacist has selected a generically equivalent drug pursuant to the provisions of Chapter 562, the statement “Substituted for Brand Prescribed” or “Substituted for ‘Brand Name’” where “Brand Name” is the actual name of the brand name product prescribed;

m. Name and strength of the actual drug product dispensed that is printed in an easily readable font-size comparable to but no smaller than ten-point Times Roman, unless otherwise directed by the prescribing practitioner.

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e. The dispensing container bears a label that adequately:

(1) Identifies the:
(a) Pharmacy name and address;
(b) Unique identification number of the prescription;
(b)(e) Name and strength of each drug product dispensed;
(c)(d) Name of the patient;
(d)(e) Name of the prescribing practitioner of each drug product or the pharmacist who signed the prescription drug order; and

(2) Sets forth a beyond-use date

(3) For each drug product sets forth the directions for use and cautionary statements, if any contained on the prescription drug order or required by law.

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3. Automated storage and distribution device. A pharmacy may use an automated storage and distribution device to deliver a previously verified prescription to a patient or patient’s agent when the pharmacy is open or when it is closed provided:

a. the device is used to deliver refills of prescription drug orders and shall not be used to deliver new prescriptions as defined by §291.31(28) of the title (Relating to Definitions);

b. the automated storage and distribution device may not be used to deliver a controlled substance;

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(3) C-II prescriptions may not be dispensed unless:

(a) The prescription is filled in compliance with Board Rule 315.9 including having with a written plan approved by the Texas State Board of Pharmacy, Director of the Texas Department of Public Safety.
in consultation with the Board, which provides for the manner in which the dispensing pharmacy may fill a Schedule II controlled substance. Note: Starting September 1, 2016, any such plan will be approved by only by TSBP.

(b) An original written prescription is required; and
(c) Issued by a physician, dentist, veterinarian or podiatrist having a current DEA registration.

(c. Prescription drug orders written by practitioners in Mexico or Canada.
(1) Controlled substance prescriptions may not be dispensed.
(2) Prescriptions issued for dangerous drugs by a person licensed in Canada or Mexico as a physician, dentist, veterinarian, or podiatrist may be dispensed provided:
(a) The prescription is an original written prescription; and
(b) If there are no refill instructions on the original written prescription or if all refills authorized on the original written prescription drug order have been dispensed, a new written prescription drug order shall be obtained.

d. Prescription drug orders issued by an advanced practice registered nurse (APRN), physician assistant (PA), or signed by pharmacist.
(1) A pharmacist may dispense a prescription drug order issued by an APRN or PA if the APRN or PA is practicing in accordance with the Subtitle B, Chapter 157, Occupations Code (Texas Medical Practice Act) and a prescription drug order for a dangerous drug signed by a pharmacist under delegated authority in accordance with the Texas Medical Practice Act.
(2) Each practitioner must designate in writing the name of each APRN or PA authorized to prescribe or order a prescription, maintain the list in the physician’s usual place of business, and furnish the list to a pharmacist upon request.

e. Prescriptions for Schedule II controlled substances.
Except in “emergency situations” written Schedule II prescriptions may not be dispensed without an official prescription form as required by the Texas Controlled Substances Act.

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(i) The confidential prescription information is not altered during transmission; and
(ii) Confidential patient information is not accessed or maintained by the operator of the data communication device other than for legal purposes under federal and state law.

b. Controlled substance prescription orders
A pharmacist may only dispense an electronic prescription drug order for a Schedule II, III, IV, or V controlled substance in compliance with the
federal and state laws and the rules of the Drug Enforcement Administration, Texas Department of Public Safety, and starting September 1, 2016, the Texas State Board of Pharmacy.

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b. At the time of dispensing, a pharmacist is responsible for documenting the following information on either the original hard-copy prescription or in the pharmacy’s data processing system:
   (1) Unique identification number of the prescription;
   (2) Initials or identification code of the dispensing pharmacist;
   (3) Initials or identification code of the pharmacy technician or pharmacy technician trainee performing data entry of the prescription if applicable;
   (4) Quantity dispensed, if different from the quantity prescribed;
   (5) Date of dispensing, if different from the date of issuance; and
   (6) Brand name or manufacturer of the drug or biological product actually dispensed, if the drug was prescribed by generic name or interchangeable biological name or if a generically equivalent or interchangeable biological product was dispensed.

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f. In lieu of the printout described in paragraph 2.c., above, the pharmacy shall maintain a log book in which each individual pharmacists using the system shall sign a statement each day that the information entered into the data processing system has been reviewed and is correct. Log book shall be maintained at the pharmacy for two years after the date of dispensing.
   (1) Even if using a log book, the computer system must be able to produce the printout described above on demand by an agent of the Board or DEA, DEA or DPS.
   (2) If the printer is not on site, the printout must be available within 72 hours with a certification by the individual providing the printout stating it is correct as of the date of entry and that the information has not been changed.

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7. Both the individual transferring the prescription and the individual receiving the prescription must engage in confirmation of the prescription information by means such as:
   a. The transferring of individual faxes of the hard copy prescription to the receiving individual; or
   b. The receiving individual repeats the verbal information from the transferring individual and the transferring individual verbally confirms the repeated information is correct.
9. An individual may not refuse to transfer original prescription information to another pharmacist or pharmacist intern who is acting on behalf of a patient and who is making a request for this information as specified in this subsection. Transfer of original prescription information must be completed within four business hours of the request.

When transferring a compounded prescription, a pharmacy is required to provide all of the information regarding the compounded preparation including the formula unless the formula is patented or otherwise protected, in which case, the transferring pharmacy shall, at a minimum, provide the quantity or strength of all of the active ingredients of the compounded preparation.

10. When transferring a compounded prescription, a pharmacy is required to provide all of the information regarding the compounded preparation including the formula unless the formula is patented or otherwise protected, in which case, the transferring pharmacy shall, at a minimum, provide the quantity or strength of all of the active ingredients of the compounded preparation.

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I. Other Records.

Other records to be maintained by a pharmacy:

1. A permanent log of the unique initials or identification codes which will identify each pharmacist, pharmacy technician, and pharmacy technician trainee, who is involved in the dispensing process, in the pharmacy's data processing system, by name performing data entry of prescription information (the initials or identification code shall be unique to ensure that each individual can be identified, i.e., identical initials or identification code shall not be used). Such log shall be maintained at the pharmacy for at least seven years from the date of the transaction;

2. Copy 3 of completed DEA order form (DEA 222) that has been properly dated, initialed, and filed, and all copies of each unaccepted or defective order form and any attached statements or other documents and/or for each order filled using the DEA Controlled Substance Ordering System (CSOS), the original signed order and all linked orders for that order;

3. A hard copy of the power of attorney to sign DEA 222 order forms (if applicable);

4. Suppliers’ invoices of dangerous drugs and controlled substances on which are recorded the actual date of receipt of controlled substances and the initials of the pharmacist who verified that the controlled substances listed on the invoices were actually received;

5. Suppliers’ credit memos;

6. A hard copy of controlled substances inventories required by §291.17 (relating to the Controlled Substances Inventory Requirements);

7. Hard copy reports Reports of surrender or destruction of controlled substances (DEA Form-41) and/or dangerous drugs;
8. A hard copy of The Schedule V nonprescription register book. Note: Likely not required since there are no commercially available Schedule V products available that may be sold without a prescription in Texas. See Chapter B in this book.

9. Records of distribution of drugs to other pharmacies, practitioners or registrants; and

10. A hard copy of any notification required by the Pharmacy Act or Rules, including but not limited to:
   a. Reports of theft or significant loss of controlled substances (DEA Form 106);

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**Records Pharmacists Should be Able to Locate in a Class A Pharmacy**

Even if you are not the pharmacist-in-charge of a pharmacy, if you are the pharmacist on duty during a compliance inspection or investigation audit of a Class A pharmacy, you should be able to locate the following records for the previous two years:

1. Annual inventories
2. Executed DEA 222 forms
3. Controlled substance invoices
4. Theft and loss reports
5. Drug destruction reports
6. All prescriptions
7. DEA registration certificate, if it is not posted
8. DPS registration (until September 1, 2016)
9. Daily dispensing printouts or dispensing logs
10. Prepackaging records if applicable
11. Technician training manual and documentation of technician training.

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4. The ratio of onsite pharmacists to pharmacy technicians and pharmacy technician trainees in a Class A pharmacy may be 1:4 provided that at least one of the four technicians is a pharmacy technician and not a pharmacy technician trainee. The ratio of pharmacists to pharmacy technician trainees may not exceed 1:3.

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7. Temporary Absence of Pharmacist
   a. A pharmacist may leave the prescription department to take breaks and the prescription department may remain open. Pharmacy technicians, trainees, and other personnel may remain in the pharmacy and perform specific functions as long as at least one pharmacy technician (not a technician trainee) remains in the prescription department.
b. If a pharmacist leaves the premises, the prescription department must be secured and closed. Pharmacy technicians may not remain in the prescription department but patients may pick up previously filled and verified prescriptions using an automated storage and distribution device or the pharmacist may designate an agent to deliver a previously verified prescription to a patient or patient’s agent during short periods of not exceed two consecutive hours in a 24-hour period.

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and practical tests, and media-fill challenge testing, and such evaluation documented. Compounding personnel shall not evaluate their own aseptic technique or results of their own media-fill challenge testing.

(F) Media-fill tests must be conducted at each pharmacy where an individual compounds low and medium risk sterile preparations. If pharmacies are under common ownership and control, the media-fill testing may be conducted at only one of the pharmacies provided each of the pharmacies is operated under equivalent policies and procedures and the testing is conducted under the most challenging or stressful conditions. In addition, each pharmacy must maintain documentation of the media-fill test. No preparation intended for patient use shall be compounded by an individual until the on-site media-fill tests test indicates that the individual can competently perform aseptic procedures, except that a pharmacist may temporarily compound sterile preparations and supervise pharmacy technicians compounding sterile preparations without media-fill tests provided the pharmacist completes the on-site media-fill tests within seven days of commencing work at the pharmacy.

(G) Media-fill tests must be conducted at each pharmacy where an individual compounds high risk sterile preparations. No preparation intended for patient use shall be compounded by an individual until the on-site media-fill tests indicate that the individual can competently perform aseptic procedures, except that a pharmacist may temporarily compound sterile preparations and supervise pharmacy technicians compounding sterile preparations without media-fill tests provided the pharmacist completes the on-site media-fill tests within seven days of commencing work at the pharmacy.

(H) Media-fill tests procedures for assessing the preparation of specific types of sterile preparations shall be representative of the most challenging or stressful conditions encountered by the pharmacy personnel being evaluated and, if applicable, for sterilizing high-risk level compounded sterile preparations.

(I) Media-fill challenge tests simulating high-risk level compounding shall be used to verify the capability of the compounding environment and process to produce a sterile preparation.
Commercially available sterile fluid culture media, such as Soybean-Casein Digest Medium shall be able to promote exponential colonization of bacteria that are most likely to be transmitted to compounding sterile preparations from the compounding personnel and environment. Media-filled vials are generally incubated at 20 to 25 degrees Celsius or at 30 to 35 degrees Celsius for a minimum of 14 days. If two temperatures are used for incubation of media-filled samples, then these filled containers should be incubated for at least 7 days at each temperature. Failure is indicated by visible turbidity in the medium on or before 14 days.

The pharmacist-in-charge shall ensure continuing competency of pharmacy personnel through in-service education, training, and media-fill tests to supplement initial training. Personnel competency shall be evaluated:

(i) During orientation and training prior to the regular performance of those tasks;
(ii) Whenever the quality assurance program yields an unacceptable result;
(iii) Whenever unacceptable techniques are observed; and
(iv) At least on an annual basis for low- and medium-risk level compounding, and every six months for high-risk level compounding.

The pharmacist-in-charge shall ensure that proper hand hygiene and garbing practices of compounding personnel are evaluated prior to compounding, supervising, or verifying sterile preparations intended for patient use and whenever an aseptic media fill is performed.

(i) Sampling of compounding personnel glove fingertips shall be performed for all risk level compounding.
(ii) All compounding personnel shall demonstrate competency in proper hand hygiene and garbing procedures and in aseptic work practices (e.g., disinfection of component surfaces, routine disinfection of gloved hands).
(iii) Sterile contact agar plates shall be used to sample the gloved fingertips of compounding personnel after garbing in order to assess garbing competency and after completing the media-fill preparation (without applying sterile 70% IPA).
(iv) The visual observation shall be documented and maintained to provide a permanent record and long-term assessment of personnel competency.

The pharmacist-in-charge shall ensure surface sampling shall be conducted in all ISO classified areas on a periodic basis. Sampling shall be accomplished using contact plates at the conclusion of compounding. The sample area shall be gently touched with the agar surface by rolling the plate across the surface to be sampled.
(IV) For a low-risk preparation, in the absence of passing a direct sterility test testing results or appropriate information sources that justify different limits, the storage periods cannot may not exceed the following periods:

(V) For a medium-risk preparation, in the absence of passing a direct sterility test testing results the storage periods beyond use dates may not cannot exceed the following time periods: before administration, the compounded sterile preparations are properly stored and are exposed for not more than 30 hours at controlled room temperature, for not more than 9 days at a cold temperature, and for 45 days in solid frozen state between minus 25 degrees Celsius and minus 10 degrees Celsius.

(i) be clean, well lit, and of sufficient size to support sterile compounding activities;
(ii) be maintained at a temperature of 20 degrees Celsius or cooler and at a humidity below 60% a comfortable temperature (e.g., 20 degrees Celsius or cooler) allowing compounding personnel to perform flawlessly when attired in the required aseptic compounding garb;

(B) Biological Safety Cabinet (BSC) safety cabinet
(i) If the pharmacy is using a biological safety cabinet as its PEC for the preparation of hazardous sterile compounded preparations, the biological safety cabinet shall be a Class II or III vertical flow biological safety cabinet located in an ISO Class 7 area that is physically separated from other preparation areas. The area for preparation of sterile chemotherapeutic preparations shall:
(I) Have not less than 0.01 inches water column negative pressure to the adjacent positive pressure ISO Class 7 or better anteroom; and

(II) Have a pressure indicator that can be readily monitored for correct room pressurization.

(ii) Pharmacies that prepare a low volume of hazardous drugs, are not required to comply with the provisions of clause (i) of this subparagraph if the pharmacy uses a device that provides two tiers of containment (e.g., closed-system vial transfer device within a BSC or CACI that is located in a non-negative pressure room).

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(ii) If the CACI meets all conditions specified in clause (i) of this subparagraph, the CACI shall not be located in the same room as a CAI, but shall be located in a separate room in the pharmacy, that is not required to maintain ISO classified air. The room in which the CACI is located shall provide a minimum of 0.01 inches water column negative pressure compared with the other areas of the pharmacy and shall meet the following requirements:

(I) Be clean, well lit, and of sufficient size;

(II) Be maintained at a temperature of 20 degrees Celsius or cooler and a humidity below 60% comfortable temperature (e.g., 20 degrees Celsius or cooler) allowing compounding personnel to perform flawlessly when attired in the required aseptic compounding garb;

(III) Be used only for the compounding of hazardous sterile preparations;

(IV) Be located in an area of the pharmacy with walls, ceilings, floors, fixtures, shelving, counters, and cabinets that are smooth, impervious, free from cracks and crevices, non-shedding and resistant to damage by disinfectant agents; and

(V) Have non-porous and washable floors or floor covering to enable regular disinfection.

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(iii) If the CACI is used in the compounding of high-risk hazardous preparations, the CACI shall be placed in an area or room with at least ISO 8 quality air so that high-risk powders, weighed in at least ISO-8 air quality conditions, are not exposed to lesser air quality prior to the completion of compounding and packaging of the high-risk preparation.

(iv) Pharmacies that prepare a low volume of hazardous drugs are not required to comply with the provisions of clauses (i) and (iii) of this subparagraph if the pharmacy uses a device that provides two tiers of
containment (e.g., CACI that is located in a non-negative pressure room).

(8) Additional Equipment and Supplies. Pharmacies compounding sterile preparations shall have the following equipment and supplies:

be performed at locations inside the ISO Class 5 environment and other areas that are in close proximity to the ISO Class 5 environment during the certification of the primary engineering control.

(vi) Air sampling frequency and process. Air sampling shall be performed at least every 6 months as a part of the re-certification of facilities and equipment. A sufficient volume of air shall be sampled and the manufacturer’s guidelines for use of the electronic air sampling equipment followed. At the end of the designated sampling or exposure period for air sampling activities, the microbial growth media plates are recovered and their covers secured and they are inverted and incubated at a temperature and for a time period conducive to multiplication of microorganisms. Sampling data shall be collected and reviewed on a periodic basis as a means of evaluating the overall control of the compounding environment. If an activity consistently shows elevated levels of microbial growth, competent microbiology or infection control personnel shall be consulted. A colony forming unit (cfu) count greater than 1 cfu per cubic meter of air for ISO Class 5, greater than 10 cfu per cubic meter of air for ISO Class 7, and greater than 100 cfu per 422 cubic meter of air for ISO Class 8 or worse should prompt a re-evaluation of the adequacy of personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency within the aseptic compounding location. An investigation into the source of the contamination shall be conducted. The source of the problem shall be eliminated, the affected area cleaned, and resampling performed. Counts of cfu are to be used as an approximate measure of the environmental microbial bioburden. Action levels are determined on the basis of cfu data gathered at each sampling location and trended over time. Regardless of the number of cfu identified in the pharmacy, further corrective actions will be dictated by the identification of microorganisms recovered by an appropriate credentialed laboratory of any microbial bioburden captured as a cfu using an impaction air sampler. Highly pathogenic microorganisms (e.g., gram-negative rods, coagulase positive staphylococcus, molds and yeasts) can be potentially fatal to patients receiving compounded sterile preparations and must be immediately remedied, regardless of colony forming unit count, with the assistance, if needed, of a competent microbiologist, infection control professional, or industrial hygienist.
(vii) Compounding accuracy checks. Written procedures for double-checking compounding accuracy shall be followed for every compounded sterile preparation during preparation and immediately prior to release, including label accuracy and the accuracy of the addition of all drug products or ingredients used to prepare the finished preparation and their volumes or quantities. At each step of the compounding process, the pharmacist shall ensure that components used in compounding are accurately weighed, measured, or subdivided as appropriate to conform to the formula being prepared.

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(2) Compounding records.

(A) Compounding pursuant to patient specific prescription drug orders or medication orders. Compounding records for all compounded preparations shall be maintained by the pharmacy electronically or manually as part of the prescription drug or medication order, formula record, formula book, or compounding log and shall include:

(i) the date and time of preparation;

(ii) a complete formula, including methodology and necessary equipment which includes the brand name(s) of the raw materials, or if no brand name, the generic name(s) or official name and name(s) of the manufacturer(s) or distributor of the raw materials and the quantities of each; however, if the sterile preparation is compounded according to the manufacturer’s labeling instructions, then documentation of the formula is not required;

(iii) written or electronic signature or initials of the pharmacist or pharmacy technician or pharmacy technician trainee performing the compounding;

(iv) written or electronic signature or initials of the pharmacist responsible for supervising pharmacy technicians or pharmacy technician trainees and conducting in-process and finals checks of compounded pharmaceuticals if pharmacy technicians or pharmacy technician trainees perform the compounding function;

(v) the quantity in units of finished preparation or amount of raw materials;

(vi) the container used and the number of units of finished preparations prepared; and

(vi) a reference to the location of the following documentation which may be maintained with other records, such as quality control records:

(I) the criteria used to determine the beyond-use date; and

(II) documentation of performance of quality control procedures.
§291.74 Operational Standards

A. Licensing Requirements.
   1. The pharmacy shall be licensed as indicated by the procedures specified in §291.1 (relating to Pharmacy License Application). A Class C pharmacy which changes ownership shall notify the Board within 10 days of the change of ownership and apply for a new and separate license as specified in Board rule §291.3 (relating to Required Notifications).
   2. If the pharmacy is owned or operated by a hospital management or consulting firm (TSBP has generally interpreted this to mean the management or consulting company owns the drug inventory):
      a. The license application must list the hospital management or consulting firm as the owner or operator.
      b. Management or consulting firm shall obtain DEA and (DPS until September 1, 2016) controlled substance registrations issued in its name, unless the following occurs:
         (1) The management or consulting firm and facility cosign a contractual pharmacy service agreement which assigns overall responsibility for controlled substances to the facility; and
         (2) The management or consulting firm maintains dual responsibility for controlled substances.

2. A Class C (Institutional) pharmacy engaged in the provision of remote pharmacy services, including storage and dispensing of prescription drugs, shall comply with the provisions of §291.121. (Note: This includes remote pharmacy services using automated systems, provision of emergency medication kits, and provision of telepharmacy services.)

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4. A Class C (Institutional) pharmacy engaged in centralized prescription dispensing or medication order processing shall comply with the provisions of §291.125 (relating to centralized prescription dispensing) and/or §291.123 (relating to centralized prescription drug or medication order processing).

5. Class C pharmacies must comply with all notification requirements of Board rule §291.3.

3. A Class C pharmacy that changes location and/or name shall notify the Board of the change as specified by Board Rule 291.3. Note: Requires notification not later than 30 days prior to the date of change.

4. A Class C pharmacy owned by a partnership or corporation which changes managing officers shall notify the Board in writing of the names of the new managing officers within 10 days of the change following the procedures in Board Rule §291.3.

5. A Class C pharmacy shall notify the Board in writing within 10 days of closing, following the procedures in Board Rule §291.5 (relating to Closing a Pharmacy).
6. A fee as specified in Board Rule §291.6 (relating to Pharmacy License Fees) will be charged for the issuance and renewal of a license and the issuance of an amended license.

7. A separate license is required for each principal place of business and only one pharmacy license may be issued to a specific location.

8. Need for other class(es) of license(s).
   A Class C pharmacy, which also operates as another type of pharmacy which would otherwise be required to be licensed as:
   a. A Class A pharmacy is not required to secure a Class A license; however, the Class C pharmacy shall comply with §291.31 (Definitions), §291.32 (Personnel), §291.33 (Operational Standards), §291.34 (Records), and §291.35 (Official Prescription Records), contained in Class A rules to the extent such rules are applicable to the operation of the pharmacy.
   b. A Class B pharmacy is not required to secure a Class B license; however, the Class C pharmacy shall comply with §291.51 (Definitions), §291.52 (Personnel), §291.53 (Operational Standards), and §291.54 (Records), contained in Class B pharmacy rules, to the extent such rules are applicable to the operation of the pharmacy.

9. A Class C pharmacy engaged in non-sterile compounding shall comply with the provisions of §291.131 (non-sterile compounding).

10. Prior to August 31, 2014, a Class C pharmacy engaged in sterile compounding shall comply with the provisions of §291.133 (sterile compounding).

11. Effective August 31, 2014, a Class C pharmacy personnel shall not compound sterile preparations unless the pharmacy has applied for and obtained a Class C-S pharmacy.

12. A Class C pharmacy engaged in the provision of remote pharmacy services, including the storage and dispensing of prescription drugs, shall comply with the provisions of §291.121 (remote pharmacy services).

13. A Class C pharmacy engaged in the provision of centralized prescription dispensing and/or centralized prescription drug or medication order processing shall comply with the provisions of §291.123 (centralized prescription drug or medication order processing) and/or §291.125 (centralized prescription drug order dispensing).

14. A Class C pharmacy with an ongoing clinical pharmacy program that proposes to allow a pharmacy technician to verify the accuracy of work performed by another pharmacy technician relating to the filling of floor stock and unit dose distribution systems for a patient admitted to the hospital if the patient’s orders have previously been reviewed and approved by a pharmacist shall make application to the Board as follows.
   a. The pharmacist-in-charge must submit an application on a form provided by the Board, containing the following information:
      (1) name, address, and pharmacy license number;
      (2) name and license number of the pharmacist-in-charge;
      (3) name and registration numbers of the pharmacy technicians;
      (4) anticipated date the pharmacy plans to begin allowing a pharmacy technician to verify the accuracy of work performed by another pharmacy technician;
(5) documentation that the pharmacy has an ongoing clinical pharmacy program; and

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(6) any other information specified on the application.

b. The pharmacy may not allow a pharmacy technician to check the work of another pharmacy technician until the Board has reviewed and approved the application and issued an amended license to the pharmacy.

c. Every two years, in connection with the application for renewal of the pharmacy license, the pharmacy shall provide updated documentation that the pharmacy continues to have an ongoing clinical pharmacy program as specified in subparagraph (A)(v) of this paragraph.

14. A rural hospital that wishes to allow a pharmacy technician to perform the duties specified in §291.73 E.2.d. of this title (relating to Personnel), shall make application to the Board as follows.

a. Prior to allowing a pharmacy technician to perform the duties specified in §291.73 E.2.d. of this title, the pharmacist-in-charge must submit an application on a form provided by the Board, containing the following information:

(1) name, address, and pharmacy license number;
(2) name and license number of the pharmacist-in-charge;
(3) name and registration number of the pharmacy technicians;
(4) proposed date the pharmacy wishes to start allowing pharmacy technicians to perform the duties specified in §291.73 E.2.d. of this title;
(5) documentation that the hospital is a rural hospital with 75 or fewer beds and that the rural hospital is either:
   (a) located in a county with a population of 50,000 or less as defined by the United States Census Bureau in the most recent U.S. census; or
   (b) designated by the Centers for Medicare and Medicaid Services as a critical access hospital, rural referral center, or sole community hospital; and
(6) any other information specified on the application.

b. A rural hospital may not allow a pharmacy technician to perform the duties specified in §291.73 E.2.d. of this title until the Board has reviewed and approved the application and issued an amended license to the pharmacy.

c. Every two years in conjunction with the application for renewal of the pharmacy license, the pharmacist-in-charge shall update the application for pharmacy technicians to perform the duties specified in §291.73 E.2.d. of this title.
§291.77 Pharmacies Compounding Sterile Preparations (Class C-S).

Note: This new rule requires all Class C pharmacies that are engaged in compounding sterile preparations to obtain a Class C-S license. This provides the Board information on which pharmacies are performing sterile compounding, but Class C-S pharmacies are still subject to all other Class C rules.

Licensing requirements. An institutional or ASC pharmacy engaged in the compounding of sterile preparations shall be designated as a Class C-S pharmacy.

1. A Class C-S pharmacy shall register annually or biennially with the Board on a pharmacy license application provided by the Board, following the procedures specified in §291.1 of this title (relating to Pharmacy License Application). A Class C-S license may not be issued unless the pharmacy has been inspected by the Board to ensure the pharmacy meets the requirements as specified in §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations).

2. A Class C-S pharmacy may not renew a pharmacy license unless the pharmacy has been inspected by the Board within the last renewal period.

3. If the Class C-S pharmacy is owned or operated by a hospital management or consulting firm, the following conditions apply (TSBP has generally interpreted this to mean the management or consulting company owns the drug inventory):
   a. The pharmacy license application shall list the hospital management or consulting firm as the owner or operator.
   b. The hospital management or consulting firm shall obtain DEA and (DPS until September 1, 2016) controlled substance registrations that are issued in their name, unless the following occurs:
      i. the hospital management or consulting firm and the facility cosign a contractual pharmacy service agreement which assigns overall responsibility for controlled substances to the facility; and
      ii. such hospital pharmacy management or consulting firm maintains dual responsibility for the controlled substances.

4. A Class C-S pharmacy which changes ownership shall notify the Board within 10 days of the change of ownership and apply for a new and separate license as specified in §291.3 of this title (relating to Required Notifications).

5. A Class C-S pharmacy which changes location and/or name shall notify the Board within 10 days of the change and file for an amended license as specified in §291.3 of this title.

6. A Class C-S pharmacy owned by a partnership or corporation which changes managing officers shall notify the Board in writing of the names of the new managing officers within 10 days of the change following the procedures in §291.3 of this title.

7. A Class C-S pharmacy shall notify the Board in writing within 10 days of closing, following the procedures in §291.5 of this title (relating to Closing a Pharmacy).

8. A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged for the issuance and renewal of a license and the issuance of an amended license.
§291.93 Operational Standards

A. Registration.
   1. General requirements.
      a. Pharmacy shall obtain a license from the Board following the procedures specified in §291.1 (Pharmacy License Application).
      b. A copy of the policy and procedure manual, which includes the formulary, shall be provided to the Board with the initial license application.
      c. Registration form shall be signed by the pharmacist-in-charge of the pharmacy.
      d. The owner or managing officer of the clinic shall sign the registration form and agree to comply with the rules adopted by the Board governing clinic pharmacies.
      e. The registration form shall be certified and state ownership.

   c.f. Fees.
      (1) A fee as specified in §291.6 will be charged for licensure.
      (2) A pharmacy operated by the state or a local government is not required to pay a license fee.

d.g. Change of ownership. A Class D pharmacy that changes ownership must notify the Board within 10 days of the change in ownership and apply for a new and separate license as specified in Board Rule 291.3. Application must be filed with the Board and the old license returned to the Board's office.

e.h. Change in name or location. A Class D pharmacy shall notify the Board of any change in name or location as specified in Board Rule 291.3. Note: Requires notification not later than 30 days prior to the date of the change. Notify the Board in writing of any change in name or location within 10 days.

f.i. A separate license is required for each principal place of business; only one pharmacy license may be issued to a specific location.

g.j. A Class D pharmacy shall notify the Board in writing within 10 days of a change of the pharmacist-in-charge or staff pharmacist or consultant pharmacist.

h.k. A Class D pharmacy shall notify the Board in writing within 10 days of permanent closing following the procedures specified in Board Rule 291.5.

Editorial Note: Renumber remaining sections 10-15.
g. Such drugs and/or devices shall be labeled by a pharmacist licensed by the Board. However, when drugs and/or devices are provided under the supervision of a physician according to standing delegation orders or standing medical orders, designated supportive personnel may at the time of provision affix an ancillary label or print on the label the following information:
   (1) Patient’s name; however, the patient’s partner or family member is not required to be on the label of a drug prescribed for a partner for a sexually transmitted disease or for a patient’s family members if the patient has an illness determined by the Centers for Disease Control and Prevention, the World Health Organization, or the Governor’s office to be pandemic;
   (2) Any information necessary to complete the directions for use;
   (3) Date of provision; and
   (4) Practitioner’s name.

h. Records of provision shall be maintained according to §291.94E (Records).

i. Controlled substances may not be provided or dispensed.

j. Non-sterile and sterile preparations may only be provided by the clinic pharmacy in accordance with Board Rule §291.131 and §291.133 of this title (relating to Pharmacies Compounding Non-sterile Compounding rule Preparations and Pharmacies Compounding Sterile Preparations).

7. Dispensing. Dangerous drugs may only be dispensed by a pharmacist pursuant to a prescription drug order in accordance with §291.31-291.35 (Class A Community Pharmacy Rules) and §291.131 (Non-sterile compounding rule) and §291.133 of this title.

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Board of Pharmacy Rule §291.104 Operational Standards

A. Licensing Requirements.
   1. A Class E pharmacy shall register with the Board on a pharmacy license application provided by the Board following the procedures specified in §291.1.
   2. On initial application, the pharmacy shall follow the procedures specified in Rule §291.1 (relating to Pharmacy License Application) and provide the following additional information specified in Section 560.052(c) and (f) of the Pharmacy Act (relating to Qualifications).
      a. Evidence that the applicant holds a pharmacy license, registration, or permit issued by the state in which the pharmacy is located;
      b. The name of the owner and pharmacist-in-charge of the pharmacy for service of process;
      c. Evidence of the applicant’s ability to provide to the Board a record of a prescription drug order dispensed by the applicant to a resident of this state not later than 72 hours after the time the Board requests the record;
d. An affidavit by the pharmacist-in-charge which states that the pharmacist has read and understands the laws and rules relating to a Class E pharmacy.

e. Proof of creditworthiness; and

f. An inspection report issued not more than two years before the date the license application is received and conducted by the pharmacy licensing Board in the state of the pharmacy’s physical location.

3. On renewal of a license prior to September 1, 2016, the pharmacy shall complete the renewal application provided by the Board and, as specified in Section 561.031 of the Pharmacy Act, provide an inspection report issued not more than two years before the date the renewal application is received and conducted by the pharmacy licensing Board in the state of the pharmacy’s physical location.

a. A Class E pharmacy may submit an inspection report issued by an entity other than the pharmacy licensing Board of the state in which the pharmacy is physically located if the state’s licensing Board does not conduct inspections as follows:

(1) An individual approved by the Board who is not employed by the pharmacy but acting as a consultant to inspect the pharmacy;

(2) An agent of the National Association of Boards of Pharmacy;

(3) An agent of another State Board of Pharmacy; or

(4) An agent of an accrediting body, such as the Joint Commission on Accreditation of Healthcare Organizations.

b. The inspection must be substantively equivalent to an inspection conducted by the Board.

3.4. On renewal of a license on or after September 1, 2016, the pharmacy shall complete the renewal application provided by the Board and, as specified in Section 561.031 of the Act, provide an inspection report issued not more than three years before the date the renewal application is received and conducted by the pharmacy licensing Board in the state of

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the pharmacy’s physical location. A Class E pharmacy may submit an inspection report issued by the Board or its designee if the state’s licensing Board does not conduct inspections.

4.5. A Class E pharmacy which changes ownership shall notify the Board within ten days of the change of ownership and apply for a new and separate license as specified in §291.3 of this title (relating to Required Notifications).

5.6. A Class E pharmacy which changes location shall notify the Board not later than 30 days before the date of the change and file for an amended license as specified in §291.3 of this title (relating to Required Notifications).

6.7. A Class E pharmacy owned by a partnership or corporation which changes managing officers shall notify the Board in writing of the names of the new managing officers within ten days of the change, following the procedures in §291.3 of this title (relating to Required Notifications).
7.8. A Class E pharmacy shall notify the Board in writing within ten days of closing.

8.9. A separate license is required for each principal place of business and only one pharmacy license may be issued to a specific location.

9.40. A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged for the issuance and renewal of a license and the issuance of an amended license.

10.41. The Board may grant an exemption from the licensing requirements of this Act on the application of a pharmacy located in a state of the United States other than this state that restricts its dispensing of prescription drugs or devices to residents of this state to isolated transactions.

11.42. A Class E pharmacy engaged in the centralized dispensing of prescription drug or medication orders shall comply with the provisions of §291.125 of this title (relating to Centralized Prescription Dispensing).

12.43. A Class E pharmacy engaged in central processing of prescription drug or medication orders shall comply with the provisions of §291.123 of this title (relating to Central Prescription or Medication Order Processing).

13.44. A Class E (Non-Resident) pharmacy engaged in the compounding of non-sterile preparations shall comply with the provisions of §291.131 of this title (relating to Pharmacies Compounding Non-sterile Preparations).

15. Prior to August 31, 2014, a Class E (Non-Resident) pharmacy engaged in the compounding of sterile preparations shall comply with the provisions of §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations).

14.16. Effective August 31, 2014, a Class E pharmacy shall not compound sterile preparations unless the pharmacy has applied for and obtained a Class E-S pharmacy.

15.47. A Class E pharmacy, which operates as a community type of pharmacy which would otherwise be required to be licensed under the Act §560.051(a)(1) (Community Pharmacy (Class A)), shall comply with the provisions of §291.31 of this title (relating to Definitions), §291.32 of this title (relating to Personnel), §291.33 of this title (relating to Operational Standards), §291.34 of this title (relating to Records), and §291.35 of this title (relating to Official Prescription Records), contained in Community Pharmacy (Class A); or which operates as a nuclear type of pharmacy which would otherwise be required to be licensed under the Act §560.051(a)(2) (Nuclear Pharmacy (Class B)), shall comply with the provisions of §291.51 of this title (relating to Purpose), §291.52 of this title (relating to Definitions), §291.53 of this title (relating to Personnel), §291.54 of this title (relating to Operational Standards), and §291.55 of this title (relating to Records), contained in Nuclear Pharmacy (Class B), to the extent such sections are applicable to the operation of the pharmacy.
F. **Prescriptions for Schedule II-V Controlled Substances.** Unless compliance would violate the pharmacy or drug laws or rules in the state in which the pharmacy is located, a pharmacist in a Class E pharmacy who dispenses a prescription for a Schedule II-V controlled substance for a resident of Texas shall electronically send the prescription information to the Texas State Board of Pharmacy as specified in Board Rule 315.6 (within 7 days of dispensing), issued by a prescriber registered with the Texas Department of Public Safety:

1. Mail a copy of the prescription to the Texas Department of Public Safety, Texas Prescription Program, P.O. Box 4087, Austin, Texas 78733 within seven days of dispensing; or

2. Electronically send the prescription information to the Texas Department of Public Safety per their requirements for electronic submissions within seven days of dispensing.

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d. In FEMCFs with a full-time pharmacist, if a practitioner orders a drug for administration to a bona fide patient of the facility when the pharmacy is closed, the following is applicable.

(1) Prescription drugs and devices only in sufficient quantities for immediate therapeutic needs of a patient may be removed from the FEMCF pharmacy.

(2) Only a designated licensed nurse or practitioner may remove such drugs and devices.

(3) A record shall be made at the time of withdrawal by the authorized person removing the drugs and devices. The record shall contain the following information:

   (a) name of the patient;
   (b) name of device or drug, strength, and dosage form;
   (c) dose prescribed;
   (d) quantity taken;
   (e) time and date; and
   (f) signature or electronic signature of person making withdrawal.

(4) The medication order in the patient’s chart may substitute for such record, provided the medication order meets all the requirements of clause (3) (iii) of this subparagraph.

(5) The pharmacist shall verify the withdrawal as soon as practical, but in no event more than 72 hours from the time of such withdrawal.

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d. A pharmacist shall verify the withdrawal according to the following schedule.
(1) In facilities with a full-time pharmacist, the withdrawal shall be verified as soon as practical, but in no event more than 72 hours from the time of such withdrawal.

(2) In facilities with a part-time or consultant pharmacist, the withdrawal shall be verified after a reasonable interval, such interval must occur at least once in every calendar week that the pharmacy is open.

(3) The medication order in the patient's chart may substitute for the record required in subparagraph (c) of this paragraph, provided the medication order meets all the requirements of subparagraph (c) of this paragraph.

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i. a copy of any notification required by the Texas Pharmacy Act or these rules, including, but not limited to, the following:
   (1) reports of theft or significant loss of controlled substances to DEA; DPS; and the Board;
   (2) notification of a change in pharmacist-in-charge of a pharmacy; and
   (3) reports of a fire or other disaster which may affect the strength, purity, or labeling of drugs, medications, devices, or other materials used in the diagnosis or treatment of injury, illness, and disease.

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C. Personnel.
      a. General. Each Class H pharmacy shall have one pharmacist-in-charge who is employed or under written agreement, at least on a part-time basis, but may be employed on a full-time basis, and who may be the pharmacist-in-charge for more than one limited prescription delivery pharmacy.
      b. Responsibilities. The pharmacist-in-charge shall have responsibility for the practice of pharmacy at the pharmacy for which he or she is the pharmacist-in-charge. The pharmacist-in-charge may advise the owner on administrative or operational concerns. The pharmacist-in-charge shall have responsibility for, at a minimum, the following:
         (1) educating education and training of pharmacy technicians and pharmacy technician trainees;
         (2) maintaining records of all transactions of the Class H pharmacy required by applicable state and federal laws and sections;
         (3) adhering adherence to policies and procedures regarding the maintenance of records; and
         (4) legally operating legal operation of the pharmacy, including meeting all inspection and other requirements of all state and federal laws or sections governing the practice of pharmacy.
2. Owner. The owner of a Class H pharmacy shall have responsibility for all administrative and operational functions of the pharmacy. The pharmacist-in-charge may advise the owner on administrative and operational concerns. The owner shall have responsibility for, at a minimum, the following, and if the owner is not a Texas licensed pharmacist, the owner shall consult with the pharmacist-in-charge or another Texas licensed pharmacist:
   a. providing the pharmacy with the necessary equipment and resources commensurate with its level and type of practice; and
   b. establishing policies and procedures regarding maintenance, storage, and retrieval of records in compliance with state and federal requirements.

3. Pharmacists.
   a. The pharmacist-in-charge shall be assisted by sufficient number of additional licensed pharmacists as may be required to operate the Class H pharmacy competently, safely, and adequately to meet the needs of the patients of the pharmacy.
   b. All pharmacists shall assist the pharmacist-in-charge in meeting his or her responsibilities.
   c. Pharmacists shall be responsible for any delegated act performed by the pharmacy technicians under his or her supervision.

4. Pharmacy Technicians and Pharmacy Technician Trainees.
   a. General. All pharmacy technicians and pharmacy technician trainees shall meet the training requirements specified in 297.6 of this title (relating to Pharmacy Technician and Pharmacy Technician Trainee Training).
   b. Duties. Duties include:
      (1) delivering previously verified prescription drug orders to a patient or patients agent provided a record of prescriptions delivered is maintained; and
      (2) maintaining pharmacy records.

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D. Operational Standards.
   1. General requirements. A Class A or Class E Pharmacy may outsource limited prescription delivery to a Class H pharmacy provided the pharmacies have entered into a written contract or agreement which outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws and regulations.
   2. Licensing requirements.
      a. A Class H pharmacy shall register with the Board on a pharmacy license application provided by the Board, following the procedures specified in Board Rule 291.1 of this title (relating to Pharmacy License Application).
      b. A Class H pharmacy must be owned by a hospital district and located in a county without another pharmacy. If a Class A or Class C pharmacy is established in a county in which a Class H pharmacy has been located under this section, the Class H pharmacy may continue to operate in that county.
c. A Class H pharmacy which changes ownership shall notify the Board within 10 days of the change of ownership and apply for a new and separate license as specified in Board Rule 291.3 of this title (relating to Required Notifications).

d. A Class H pharmacy which changes location and/or name shall notify the Board of the change within 10 days and file for an amended license as specified in Board Rule 291.3 of this title. Note: Requires notification not later than 30 days prior to the date of the change.

e. A Class H pharmacy shall notify the Board in writing within 10 days of closing, following the procedures in Board Rule 291.5 of this title (relating to Closing a Pharmacy).

f. A fee as specified in Board Rule 291.6 of this title (relating to Pharmacy License Fees) will be charged for issuance and renewal of a license and the issuance of an amended license. However, a pharmacy operated by the state or a political subdivision of the state that qualifies for a Class H license is not required to pay a fee to obtain a license.

g. A separate license is required for each principal place of business and only one pharmacy license may be issued to a specific location.