January 2015 Supplement to
The Guide to Texas and Federal Pharmacy and Drug Law
9th Edition

The following changes, clarifications and corrections should be made to
The Guide to Texas and Federal Pharmacy and Drug Law 9th Edition:

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

Please note that 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 take a few minutes and highlight or mark each page number that is referenced in this supplement to serve as a reminder 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.

Page 17     Glossary

| CE       | Continuing Education |
| CFR      | Code of Federal Regulations |
| CGMP or cGMP | Current Good Manufacturing Practices |

Pages A.2-A.4

   Note: Many provisions of the PDMA were modified by the Drug Quality and Security Act of 2013. See Section 15. below.
   a. The PDMA became law in 1988 and amended the Federal Food, Drug, and Cosmetic Act to reduce the potential public health risks that may result from diversion of prescription drugs from legitimate commercial channels. Congress found that the reintroduction of these drugs into commercial channels could lead to the distribution of mislabeled, adulterated, and subpotent or counterfeit drugs to the American public. The PDMA requires that states license wholesale distributors of prescription human drugs in conformance with federal guidelines that will provide minimum standards for prescription drug storage, handling, and record keeping. It also requires that wholesale distributors who are not authorized manufacturers’ distributors provide a written statement to the purchaser identifying each prior sale. The PDMA bans the reimportation of prescription human drugs produced in the United States except when reimported by the manufacturer or, after FDA approval, for emergency use. It also bans the sale, trade, or purchase of drug samples and the trafficking in and counterfeiting of drug coupons (forms that may be redeemed for a prescription drug at no cost or reduced cost). The PDMA requires that all requests for drug samples be made in writing by licensed practitioners. It also requires that drug samples be properly stored and handled and
that certain record keeping be followed. The PDMA also bans, with certain specific exceptions, the resale of prescription drugs purchased by hospitals or health care facilities or donated or supplied to charitable institutions is prohibited. The PDMA originally addressed prescription drug wholesaling and the provision of a drug “pedigree” or statement of prior sales of a drug, but these requirements have been superseded by the Drug Supply Chain Security Act of 2013. See section 15.b. below.

The FDA finally issued the regulations implementing the PDMA on December 3, 1999. The rules set forth the details for reimportation of prescription drugs by a manufacturer, wholesale distribution of prescription drugs, and prescription drug samples.

b. Summary of PDMA:
   (1) Requires state licensing of prescription drug wholesale distributors under federal guidelines.
   (2) Requires wholesale distributors who are not the manufacturer or an authorized distributor of record of a prescription drug to provide to the person who receives the drug a statement identifying each prior sale, purchase, or trade of the drug, commonly called a drug pedigree.
   (3) Bans reimportation of prescription drugs produced in U.S.
   (4) Bans sale, trade, or purchase of samples.
   (5) Mandates storage, handling, and record-keeping requirements for drug samples.
   (6) Prohibits, with certain exceptions, the resale of prescription drugs purchased by hospitals or health care facilities.
   (7) Establishes criminal and civil penalties for violations of the Act.

c. PDMA and Texas Laws/Rules on Prescription Drug Samples
   (1) Authority of Advanced Practice Registered Nurses (APRN) Nurse Practitioners (ANP) and Physician Assistants (PA) concerning prescription drug samples.

   The PDMA allows manufacturers to provide prescription samples upon the written (i.e., signed) request of a practitioner. In Texas, an APRN ANP or PA may also sign the request for samples, receive samples from the manufacturer, and distribute samples to patients.

   (2) Texas State Board of Pharmacy Rule §291.16 is in compliance with the PDMA. This rule prohibits a pharmacy from selling, purchasing, trading or possessing prescription drug samples, unless the pharmacy meets all of the following conditions:

   (a) the pharmacy is owned by a charitable organization described in the Internal Revenue Code of 1986, or by a city, state or county government;
   (b) the pharmacy is a part of a health care entity which provides health care primarily to indigent or low income patients at no or reduced cost;
   (c) the samples are for dispensing or provision at no charge to patients of such health care entity; and
   (d) the samples are possessed in compliance with the federal Prescription Drug Marketing Act of 1987.

   (3) Although the PDMA requires states to license wholesalers, Texas law exempts hospitals or other health care entities that sell drugs to other hospitals or health care entities that are under common control and also the sale of drugs for emergency medical reasons which includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage.
If a pharmacy does not meet all of the exemptions and is in possession of prescription drug samples, the drugs must be properly disposed of immediately. Since sale or offer to sell, purchase, or trade of prescription drug samples is prohibited, the drugs must be properly destroyed in compliance with Board rules. Pharmacies may possess and dispense prescription drugs which have been provided by the manufacturer as starter prescriptions or as replacement for outdated drugs. In addition, a pharmacy may possess and dispense prescription drugs which have been provided by a manufacturer in replacement for such manufacturer’s drugs that were dispensed pursuant to written starter prescriptions from practitioners. The PDMA does not apply to OTC drugs; therefore a pharmacy may be in possession of sample OTC drugs.

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13. 2009 – Biologics Price Competition and Innovation Act
   a. Creates an abbreviated approval pathway for biological products that are shown to be “biosimilar” and thus “interchangeable” with an FDA-licensed biological product. This is similar to the ANDA process for generic drugs.
   b. Biosimilarity means that the biological product is highly similar to the U.S.-licensed reference biological product notwithstanding minor differences in clinically inactive components; and that there are no clinically meaningful differences between the biologic product and the reference product in terms of the safety, purity, and potency of the product.
   c. Interchangeability means that the biologic product is biosimilar to the U.S.-licensed reference biological product and can be expected to produce the same clinical result as the reference product in any given patient. For a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product will not be greater than the risk of using the reference product without such alternation or switch. Interchangeable biological products may be substituted at the pharmacy level without the intervention of a healthcare provider.
   d. The FDA began publishing lists of biosimilar biological agents in the Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations or “The Purple Book” in September 2014.

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(f) Starting six years after enactment (2019), wholesale distributors may only accept products that contain a product identifier and must verify product before redistributing returned product.
(g) Starting seven years after enactment (2020), pharmacies may only accept products that contain a product identifier.
(h) Ten years after enactment (2023), supply chain members will be required to electronically track and trace product at the individual package level using the product identifier.
(4) Wholesale Licensing Standards
   (a) Updates the standards for licensing of wholesale drug distributors originally found in the PDMA including facility requirements, recordkeeping, furnishing of a bond or other security, background checks of facility managers or designated representatives, personnel qualifications, and facility inspections.
   (b) The FDA will issue regulations further detailing these standards.
   (c) States will no longer license manufacturers and repackagers as drug wholesalers.

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2. OTC (proprietary or patent) or Over-the-Counter
   a. Proprietary or Patent—OTCs that are labeled and advertised for consumer self-use, usually marketed under a trade name or trademark, and are sold in an unbroken, original manufacturer’s labeled container.
   
   In the past, the distinction between Ethical OTCs and Proprietary OTCs was made. There was a belief among various manufacturers that promoting drugs, regardless of legal status, should be restricted to the health professions and thus a category of drugs, Ethical OTCs, was created. The last of these was the A. H. Robins’ line of cough syrups, Robitussin.
   
   a. b. Defined as drugs recognized among experts to be safe and effective for self-use (self-administration).
   
   b. c. Must be labeled with directions for the layperson that indicate their safe and effective use.
   
   c. d. An OTC drug may be approved for marketing by:
   
   (1) filing a New Drug Application (NDA) or Abbreviated New Drug Application (ANDA); or
   
   (2) by marketing the product in compliance with the requirements of an OTC monograph which sets for the active ingredients, labeling, and other general requirements.

Pages A.22-24

XV. Compounding vs. Manufacturing
   —Note: The following summary of the status of pharmacy compounding was written by Kerstin Arnold, General Counsel for the Texas State Board of Pharmacy. The authors thank her for granting permission to reprint this article.

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Status of Pharmacy Compounding in Texas
February 2010
By: Kerstin Arnold, General Counsel
Texas State Board of Pharmacy
A. History
The FDA has historically considered drug compounding to be subject to FDA oversight based on its authority to regulate the safety and quality of new drugs. But the agency has relied on states, including state pharmacy boards, to regulate limited compounding of drugs as part of the traditional practice of pharmacy, which would include when a pharmacist compounds a drug pursuant to a prescription for a patient and provides the drug to the patient. A small part of that practice has also historically been compounding for physician office use without a prescription. As a matter of policy, the FDA did not bring enforcement actions against pharmacies engaged in traditional compounding.

In the 1990s, the FDA became increasingly concerned about the amount of compounding and particularly of office use compounding done without a prescription, based on the fact that several pharmacies developed business practices that resembled drug manufacturing without the appropriate controls, such as those established under Good Manufacturing Practices (GMPs). The FDA established enforcement guidelines to provide criteria for distinguishing compounding pharmacy from manufacturing and essentially exempted compounding for patients pursuant to prescriptions and also allowed for a limited amount of other compounding, such as that done in anticipation of receiving prescriptions.

B. Passage of FDAMA
In 1997, the Food and Drug Administration Modernization Act (FDAMA) was passed with a provision relating to pharmacy compounding and was codified in section 503A of the federal Food, Drug, and Cosmetic Act (FDCA). Specifically, section 503A exempted pharmacy compounding from key provisions of the FDCA, including the requirements for the approval of new drugs and restrictions regarding misbranding and adulteration. These exemptions were based on a prohibition on advertising for the compounding services.

C. Western States Decision
In the Western States v. Shalala case, the 9th Circuit Court of Appeals held the exemptions for pharmacy compounding in FDAMA unconstitutional based on the advertising provisions. The court ruled that those restrictions on commercial speech could not be separated from the rest of section 503A and, therefore, declared the entire section 503A invalid based on the restrictions. The US Supreme Court in 2002 agreed that the advertising provisions were an unconstitutional restriction on commercial speech, but didn’t address whether the rest of section 503A was invalid. For several years, the general consensus was that the entire compounding section of the FDAMA was invalid.

In the meantime, the FDA realized that applying the FDCA’s new drug approval requirements to drugs compounded on a small scale was unrealistic and that it would not be economically feasible to require compounding pharmacies to undergo the testing requirement for the new drug approval process for drugs compounded to meet the needs of an individual person. A primary concern for the agency apparently was whether drug compounding was being conducted on a scale equivalent to manufacturing in an effort to circumvent the FDCA’s new drug approval requirements. The FDA then issued Compliance Policy Guidelines that it would consider taking action regarding drug compounding in situations more analogous to drug manufacturing, but would defer to the states for “less significant” violations. The enforcement policy listed factors that would be taken into consideration before the FDA would consider disciplinary action against compounders.

D. Texas Law
(Note: For Texas laws and regulations on compounding see Chapter H of this book.)
Around the same time that FDA was issuing the new Compliance Policy Guidelines, the Texas legislature passed a law as part of the Texas Pharmacy Act to address compounding for office use, which was one of the concerns of the FDA. The law allows a pharmacy to dispense and deliver a reasonable quantity of a compounded drug to a practitioner for office use. The Board then defined reasonable quantity in such a manner that essentially allowed for any amount of compounding under additional conditions, such as a practitioner-pharmacy agreement, verification of raw materials, and compliance with USP guidelines.

E. Medical Center Pharmacy Case
After the FDA issued the CPGs for compounded drugs, a group of pharmacies sued the FDA to challenge the authority of the FDA to regulate compounded drugs under the FDCA in Medical Center Pharmacy v. Mukasey. The case was ultimately decided by the 5th Circuit Court of Appeals (which covers Texas, Louisiana, and Mississippi). The court ruled that the unconstitutional advertising restrictions were severable from the rest of section 503A, and the rest of the section was still in effect without the restrictions. The court also held that compounded drugs are “new drugs,” but
that section 503A exempts compounded drugs from the adulteration, misbranding, and new drug approval provisions of the FDCA, if the compounding pharmacy meets certain criteria. The safe harbors provide for regulation by the state pharmacy boards, and not the FDA, as long as they continue to be met.

**F. Post-Medical Center Pharmacy Interpretation of FDAMA for Texas**

FDAMA carves out an exception to the new drug approval process for compounding pharmacies who comply with a number of specific, mandatory requirements, which are:

1. The drugs must be compounded by a pharmacist or physician in response to a valid prescription for an identified patient, or, if prepared before the prescription is received, the drugs must be compounded in limited quantities and in response to a history of receiving prescriptions for that drug within an established relationship between the pharmacist and the patient or prescriber.

2. The drugs must be compounded from approved ingredients that meet certain manufacturing and safety standards, and the compounded drug may not appear on an FDA list of drug products that have been withdrawn or removed from the market because they were unsafe or ineffective.

3. The pharmacist or physician compounding the drug may not regularly compound or compound inordinate amounts of any drug products that are essentially copies of a commercially available drug product.

4. The drug product must not be identified by the FDA as one that presents demonstrable difficulties for compounding in terms of safety or effectiveness.

5. In states that have not entered into a Memorandum of Understanding with the FDA addressing the distribution of “inordinate amounts” of compounded drugs in interstate commerce, the pharmacy, pharmacist, or physician may not distribute drugs out of the state in quantities exceeding 5% of that entity’s total prescription orders.

Pharmacies compounding drugs while complying with these provisions would be exempted from the new drug approval process and the provisions of the FDCA involving adulteration and misbranding. The regulation of this pharmacy compounding would be left to the states rather than under the scrutiny of the FDA.

**G. Issues**

However, the provisions of FDAMA do not allow for compounding without a prescription and then selling that compounded drug product directly to a physician for office use. Therefore, it appears that federal law may now be in conflict with the state law.

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**A. History**

1. The distinction between compounding and manufacturing is sometimes difficult to make, but it is important because the manufacturing of drugs is primarily regulated by the FDA while compounding is generally considered part of the practice of pharmacy and is regulated by the states.

2. In the 1990s, the FDA became concerned about some pharmacies whose compounding practices began to resemble drug manufacturing operations. To address these concerns, the FDA issued a Compliance Policy Guideline (CPG) in 1992 that set for the factors that FDA would use to determine if a pharmacy’s practices constituted manufacturing. The CPG included a statement that the FDA considered all compounded drugs to be “new drugs” requiring a New Drug Application, but that the agency would exercise “enforcement discretion” and only take action against pharmacies that appeared to acting as manufacturers.
3. The Food and Drug Administration Modernization Act of 1997 (FDAMA) included provisions that attempted to clarify the distinction between manufacturing and compounding. FDAMA created Section 503A of the FDCA which forth several conditions that would allow a pharmacy’s compounding activities to be exempt from FDA regulation. Among these conditions was a restriction that a pharmacy could not advertise the compounded products.

4. A group of pharmacists sued the FDA challenging the constitutionality of the advertising restrictions as a violation of free speech. In 2001, the 9th Circuit Court of Appeals held that the advertising restrictions were a violation of commercial free speech and also held that the advertising restrictions could not be separated from the other non-advertising portions of Section 503A thus invalidating all of Section 503A. The Supreme Court affirmed the 9th Circuit Court’s ruling in 2002, but did not comment on whether the advertising provision could be separated from the rest of Section 503A.

5. With Section 503A invalidated, FDA responded in 2002 by issuing a new Compliance Policy Guideline (CPG) on pharmacy compounding listing factors the agency will consider in determining when a pharmacy’s activities may be considered manufacturing. The new guideline included most of the non-advertising factors that were in Section 503A.

6. Later, the distinction between compounding and manufacturing became even more complex when the 5th Circuit Court of Appeals disagreed with the 9th Circuit’s ruling and held that the non-advertising provisions of Section 503A could be separated and are still valid.

2012 Fungal Meningitis Outbreak and passage of the 2013 Compounding Quality Act

7. Fungal Meningitis Outbreak and Passage of the 2013 Compounding Quality Act

   a. On September 21, 2012, the Tennessee Department of Health notified the Centers for Disease Control (CDC) that a patient developed meningitis 19 days after being injected with an epidural steroid at a Tennessee ambulatory care facility. Four days later the New England Compounding Center (NECC), a pharmacy in Massachusetts, recalled three lots of preservative-free methylprednisolone acetate. Within a week there were 25 meningitis cases reported in Tennessee with three deaths and other cases reported in five other states. NECC later expanded its recall to all products and then shut down operations as over 700 meningitis cases were eventually reported in 20 states with over 60 deaths.

   b. This incident brought the issue of the distinction between pharmacy compounding (which is regulated by the states) and pharmaceutical manufacturing (which is regulated by FDA) to the forefront. Investigations following the tragedy placed blame on both state and federal regulators. In testimony before Congress, FDA argued it needed new authority to regulate entities that compound sterile drug products in advance of or without a prescription and ship them interstate.

   c. In response to this tragedy, Congress passed the Compounding Quality Act as part of the Drug Product Quality and Security Act in late 2013. The Act attempts to distinguish between pharmacies that are performing traditional compounding for specific patients based on individual prescriptions from pharmacies that are compounding large
quantities of drugs that are not based on individual prescriptions. The Act creates a new type of FDA registrant called an “Outsourcing Facility”. While registration with FDA as an Outsourcing Facility is voluntary, pharmacies that register and meet the Act’s requirements are permitted to compound sterile products without obtaining patient-specific prescriptions. Outsourcing Facilities are exempt from the new drug provisions [Section 505], adequate directions for use [Section 505(f)(1)] and the new track and trace provisions [Section 582] of the FDCA, however they are not exempt from cGMP requirements and also must meet other specific requirements in the Act. An outsourcing facility does not have to be a licensed pharmacy unless they are also compounding individual prescriptions, but all outsourcing facilities must be under direct supervision of a licensed pharmacist.

d. The Compounding Quality Act also resolved the conflict between the 9th Circuit opinion in the Western States case and the 5th Circuit opinion in the Medical Center Pharmacy case as to whether or not the remaining portions of the compounding provisions in FDAMA (Section 503A) were still in effect. The 2013 Act removed the provisions in Section 503A related to advertising and promotion that were found to be unconstitutional, in Western States, but retained the other provisions in Section 503A. This means that pharmacies are exempt from the new drug requirements, adequate directions for use, and cGMP requirements when compounding products for an identified individual patient based on receipt of a valid prescription or in limited quantities based on a history of receiving prescriptions for the product. Larger scale compounders of sterile products will likely have to register with FDA as an outsourcing facility or risk being considered a full scale manufacturer by FDA subject to the new drug requirements.

e. There are still some areas of uncertainty as only compounders of sterile products are allowed to register with FDA as Outsourcing Facilities. Pharmacies compounding non-sterile products are now subject to Section 503A and there are no provisions in Section 503A that allow “office use compounding” which many states, including Texas, specifically allow. Note: The 2013 Compounding Quality Act appears to preempt state laws so there is a valid legal argument that the Office Use Compounding laws and regulations (See Chapter H in this book) are not invalid. At the time of publication of this book, neither the Texas State Board of Pharmacy nor Texas Attorney General have specifically ruled on this issue.

Note: Just prior to publication of this book, the FDA issued draft guidance under the 2013 Compounding Quality Act in which they withdrew the 2002 Compliance Policy Guideline below. Due to publication deadlines we were unable to remove the guidance from the book. Please refer to FDA’s website for their current guidance on compounding vs. manufacturing and implementation of the Compounding Quality Act.
FDA’s 2002 Policy on Pharmacy Compounding

B. FDA’s 2013 Compliance Policy on Compounding

Under section 503A of the FDC Act, a compounded drug product is exempt from sections 501(a)(2)(B), 502(f)(1) and 505 of the FDC Act if it meets the conditions of section 503A of the FDC Act. Specifically, the compounded drug product qualifies for the exemptions if:

1. The drug product is compounded for an identified individual patient based on the receipt of a valid prescription order, or a notation approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient (section 503A(a) of the FDC Act).

2. The compounding of the drug product is performed:
   a. By a licensed pharmacist in a state licensed pharmacy or a Federal facility, or by a licensed physician on the prescription order for an individual patient made by a licensed physician or other licensed practitioner authorized by state law to prescribe drugs; or
   b. By a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient and:
      (1) is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the human drug product; and
      (2) those orders have been generated solely within an established relationship between the licensed pharmacist or licensed physician and either such patient for whom the prescription order will be provided or the physician or other licensed practitioner who will write such prescription order (sections 503A(a)(1) and (2) of the FDC Act).

3. The drug product is compounded in compliance with the United States Pharmacopoeia (USP) chapters on pharmacy compounding using bulk drug substances, as defined in 21 CFR 207.3(a)(4), that comply with the standards of an applicable USP or National Formulary (NF) monograph, if one exists. If such a monograph does not exist, the drug substance(s) must be a component of an FDA-approved human drug product. If a monograph does not exist and the drug substance is not a component of an FDA-approved human drug product, it must appear on a list of bulk drug substances for use in compounding developed by FDA through regulation (section 503A(b)(1)(A)(i) of the FDC Act).

4. The drug product is compounded using bulk drug substances that are manufactured by an establishment that is registered under section 510 of the FDC Act (including a foreign establishment that is registered under section 510(i) of the FDC Act) (section 503A(b)(1)(A)(ii) of the FDC Act).
5. The drug product is compounded using bulk drug substances that are accompanied by valid certificates of analysis for each bulk drug substance (section 503A(b)(1)(A)(iii) of the FDC Act).

6. The drug product is compounded using ingredients (other than bulk drug substances) that comply with the standards of an applicable USP or NF monograph, if one exists, and the USP chapters on pharmacy compounding (section 503A(b)(1)(B) of the FDC Act).

7. The drug product does not appear on the list, published at 21 CFR 216.24, that includes drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective (section 503A(b)(1)(C) of the FDC Act).

8. The licensed pharmacist or licensed physician does not compound regularly or in inordinate amounts any drug products that are essentially copies of commercially available drug products (section 503A(b)(1)(D) of the FDC Act).

9. The drug product is not a drug product identified by FDA by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product (section 503A(b)(3)(A) of the FDC Act).

10. The drug product is compounded in a state that has entered into a memorandum of understanding (MOU) with FDA that addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a state agency of complaints relating to compounded drug products distributed outside such state; or, in states that have not entered into such an MOU with FDA, the licensed pharmacist, licensed pharmacy, or licensed physician does not distribute, or cause to be distributed, compounded drug products out of the state in which they are compounded, more than 5% of the total prescription orders dispensed or distributed by such pharmacy

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Generally, FDA will continue to defer to state authorities regarding less significant violations of the Act related to pharmacy compounding of human drugs. FDA anticipates that, in such cases, cooperative efforts between the states and the Agency will result in coordinated investigations, referrals, and follow-up actions by the states.

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However, when the scope and nature of a pharmacy’s activities raise the kinds of concerns normally associated with a drug manufacturer and result in significant violations of the new drug, adulteration, or misbranding provisions of the Act, FDA has determined that it should seriously consider enforcement action. In determining whether to initiate such an action, the Agency will consider whether the pharmacy engages in any of the following acts:

1. Compounding of drugs in anticipation of receiving prescriptions, except in very limited quantities in relation to the amounts of drugs compounded after receiving valid prescriptions.
2. Compounding drugs that were withdrawn or removed from the market for safety reasons. FDA maintains a list of such drugs that will be updated in the future, as appropriate. This list can be obtained from the FDA website: http://www.fda.gov.

3. Compounding finished drugs from bulk active ingredients that are not components of FDA approved drugs without an FDA sanctioned investigational new drug application (IND) in accordance with 21 U.S.C. § 355(i) and 21 CFR 312.

4. Receiving, storing, or using drug substances without first obtaining written assurance from the supplier that each lot of the drug substance has been made in an FDA-registered facility.

5. Receiving, storing, or using drug components not guaranteed or otherwise determined to meet official compendia requirements.

6. Using commercial scale manufacturing or testing equipment for compounding drug products.

7. Compounding drugs for third parties who resell to individual patients or offering compounded drug products at wholesale to other state licensed persons or commercial entities for resale.

8. Compounding drug products that are commercially available in the marketplace or that are essentially copies of commercially available FDA-approved drug products. In certain circumstances, it may be appropriate for a pharmacist to compound a small quantity of a drug that is only slightly different than an FDA-approved drug that is commercially available. In these circumstances, FDA will consider whether there is documentation of the medical need for the particular variation of the compound for the particular patient.

9. Failing to operate in conformance with applicable state law regulating the practice of pharmacy. Note: Texas has specific laws and rules on compounding including compounding for office use.

XVI. Information on Medication Use During Pregnancy and Breastfeeding FDA Pregnancy Categories

A. In December 2014, FDA published a final rule that replaces the product letter categories (A, B, C, D and X) previously used to classify the risk of using prescription drugs during pregnancy.

B. The new labeling is required starting June 30, 2015 and requires three subsections in the drug’s labeling:

1. Pregnancy – will provide information relevant to the use of the drug in pregnant women such as dosing and potential risks to the developing fetus, and will require information about whether there is a registry that collects and maintains data on how pregnant women are affected when they take the drug.

2. Lactation – will provide information about using the drug while breastfeeding, such as the amount of drug in breast milk and potential effects on the breastfeeding child.

3. Females and Males of Reproductive Potential – will include information about pregnancy testing, contraception, and about fertility as it relates to the drug

A. Category A – Controlled studies show no risk. Adequate, well-controlled clinical studies in pregnant women have failed to show a risk to the fetus during the first trimester of pregnancy and there is no evidence of risk during the last two trimesters.
B. Category B—No evidence of risk in humans. Adequate, well-controlled studies have not been conducted in pregnant women, animal reproduction studies have failed to demonstrate a risk to the fetus, or animal studies have shown an adverse effect, but human studies have not shown a risk to the fetus in the first trimester and there is no evidence of risk in the last two trimesters.

C. Category C—Risk can not be ruled out. The safety of the drug during human pregnancy has not been determined. Animal studies are either positive for fetal risk or have not been conducted. The drug should not be used in human females unless the potential benefit outweighs the potential risk to the fetus.

D. Category D—Positive Evidence of risk. There has been positive evidence of risk to the human fetus mainly based upon adverse reaction data from either investigational or marketing experiences. The drug should only be administered if the potential benefits from use of the drug in pregnant women may be accepted despite its potential risks.

E. Category X—Contraindicated in pregnancy. Studies in animals or reports in pregnant women indicate that the risk of damage caused by the drug clearly outweighs any possible benefit.

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Note: On November 4, 2009, FDA published a proposed rule on pregnancy and lactation drug labeling that would eliminate the current pregnancy category system and require pregnancy and lactation subsections in prescription drug labeling. Both the pregnancy and lactation subsections would have three principal components: a risk summary, clinical considerations, and a data section.

[As of the publication date of this book, this proposed rule had not yet been finalized.]

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C. History

The Drug Enforcement Administration (DEA), an agency of the Department of Justice, is the lead federal law enforcement agency charged with the responsibility for combating controlled substance abuse. The DEA was established on July 1, 1973. It resulted from the merger of the Bureau of Narcotics and Dangerous Drugs (BNDD), the Office for Drug Abuse Law Enforcement, the Office of National Narcotic Intelligence, those elements of the Bureau of Customs which had drug investigative responsibilities, and those functions of the Office of Science and Technology which were drug enforcement related. The DEA was established to control more effectively narcotic and dangerous drug abuse through enforcement and prevention. In carrying out its mission, the Administration cooperates with other federal agencies (foreign as well as state and local governments), private industry, and other organizations.

Since 1914, the Congress has enacted more than 50 pieces of legislation relating to control and diversion of drugs. The FCSA became effective May 1, 1971. It collected and conformed most of these diverse laws into one piece of legislation. The law is designed to improve the administration and regulation of manufacturing, distribution, and dispensing of controlled substances by providing a “closed” system of legitimate handlers of these drugs. Such a closed system is intended to help reduce the widespread diversion of these drugs out of legitimate channels into the illicit market.
B. Schedule II (C-II)
   1. Drugs having a currently accepted medical use and a high abuse potential
   2. Abuse of the drug or other substance may lead to severe physical or psychological dependence.
   3. Includes opium and other narcotics as single active ingredients such as morphine, codeine, dihydrocodeine, hydrocodone, oxycodone, methadone, meperidine, hydromorphone, fentanyl, and cocaine; some narcotic combination products such as hydrocodone with acetaminophen (Vicodin®), oxycodone with acetaminophen (Percocet®), and oxycodone with oxycodone (Percodan®); stimulants such as amphetamine, methamphetamine, phenmetrazine, and methylphenidate; depressants such as pentobarbital (oral), secobarbital (oral), amobarbital (oral), glutethimide, and phencyclidine.

C. Schedule III (C-III)
   1. Drugs having a currently accepted medical use and an abuse potential less than those in Schedule I and II.
   2. Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.
   3. Includes many some narcotic Schedule II drugs, but in combination with another ingredient, such as aspirin with codeine; acetaminophen with codeine; acetaminophen with hydrocodone (Vicodin®); suppository forms of amobarbital, secobarbital, or pentobarbital; stimulants such as chlorphentermine, phendimetrazine, and benzphetamine; anabolic steroids; ketamine; and paregoric.
   4. Use of anabolic steroids in Texas
      a. These drugs may be dispensed, prescribed, delivered, or administered by a practitioner for a valid medical purpose and in the course of professional practice.
      b. These drugs may be dispensed or delivered by a pharmacist pursuant to a prescription of a practitioner for a valid medical purpose and in the course of professional practice.
      c. Bodybuilding, muscle enhancement, or increasing muscle bulk or strength through the use of anabolic steroids by a person who is in good health is not a valid medical purpose.
      d. The provisions of the Texas Controlled Substances Act relating to the possession and distribution of anabolic steroids do not apply to the use of anabolic steroids that are administered to livestock or poultry.

D. Schedule IV (C-IV)
   1. Drugs having a currently accepted medical use and an abuse potential less than those in Schedule III.
   2. Abuse may lead to limited physical or psychological dependence relative to Schedule III.
   3. Includes narcotics such as propoxyphene, dextropropoxyphene, butorphanol, pentazocine, and products with not more than 1mg of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit; depressants such as alprazolam, diazepam, lorazepam, chloral hydrate, and phenobarbital; stimulants such as diethylpropion and phentermine.
4. Carisoprodol (Soma®) has been a Schedule IV controlled substance under Texas law since 2009. DEA also made carisoprodol a Schedule IV controlled substance under federal law effective January 11, 2012. Tramadol (Ultram®) was added to Schedule IV effective August 18, 2014.

E. Schedule V (C-V)
1. Drugs having a currently accepted medical use and an abuse potential less than those in Schedule IV.
2. Abuse of the drug or other substance may lead to limited physical or psychological dependence relative to Schedule IV.
3. Includes antitussive products containing codeine (Robitussin AC®), antidiarrheal products containing opium, diphenoxylate and atropine (Lomotil®), and pregabalin (Lyrica®) for neuropathic pain.
4. Some C-V products were formerly classified as “X” narcotics or “exempt” narcotics. (Example: Robitussin AC®)

NOTE: The term “narcotic” refers to drugs that are derivatives of opium, poppy straw, cocaine, or ecgonine. While all narcotics are controlled substances, not all controlled substances are narcotics.

F. Exempted Products
1. Manufacturers may apply to DEA to exempt a product or chemical from certain provisions of the Controlled Substances Act (labeling and inventory) the controlled substance schedules if certain conditions are met and the product or chemical is not likely to be abused. These products are still prescription drugs but are not labeled as nor treated as controlled substances. Note: These products may still be considered controlled substances for certain criminal violations. 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 preparations include non-narcotic products containing small amounts of phenobarbital, butalbital, chlordiazepoxide, or meprobamate. Note: The drug Fioricet (acetaminophen, butalbital and caffeine) is an exempt product (i.e. non-controlled) while the drug Fiorinal (aspirin, butalbital and caffeine) is not exempt, it is a Schedule III controlled substance.
3. Exemption lists can be found at:
http://www.deadiversion.usdoj.gov/schedules/exempt/exempt_rx_list.pdf
http://www.deadiversion.usdoj.gov/schedules/exempt/exempt_list.htm

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C. Dispenser Registrations Definition of dispenser includes
1. The definition of dispense under the CSA includes not only dispensing of controlled substances but also prescribing and administering controlled substances. Thus, dispenser registrations include:
   4. a. Pharmacies — Pharmacist Licensed by the state to dispense controlled substances to patients pursuant to a lawful prescription of an individual practitioner. Note: Pharmacies are considered practitioners under the CSA, but are not institutional or individual practitioners.
   2. b. Institutional practitioners — A hospital Hospitals or other facilities authorized to dispense a-controlled substances, but does not include pharmacies a pharmacy.
3. c. Individual practitioners – A physician, dentists, veterinarians, podiatrists, or other practitioners who are authorized to prescribe, dispense or administer controlled substances, but does not include pharmacists, pharmacies, or institutional practitioners.

2. For individual practitioners (physicians, dentists, etc.), hospital/clinics, pharmacies, and teaching institutions, the first letter of the DEA number is an “A”, “B”, or “F” (or “G” for Department of Defense personal service contractors). The second letter of the prefix will be the first letter of the practitioner’s last name (“B” for Dr. Brown) for individual practitioners or the first letter of a pharmacy’s or hospital’s name (“C” for Crestview Pharmacy).

3. Midlevel Practitioners
   a. DEA issues DEA Registrations that begin with the letter “M” to Mid-Level Practitioners.
   b. Midlevel Practitioners are individual practitioners, other than physicians, dentists, veterinarians, or podiatrists who are authorized (by state law) to dispense (includes prescribe and administer) controlled substances.
   c. Examples of Midlevel Practitioners include physician assistants (PAs), advanced registered nurse practitioners (including nurse anesthetists), ambulance services, animal shelters, or veterinary euthanasia technicians.
   d. The second letter of a Midlevel Practitioner registration corresponds to the first letter of the midlevel practitioners’ last name or the facility name.

Midlevel practitioners which may include physician assistants, advanced nurse practitioners, ambulance services, animal shelters, or veterinary euthanasia technicians have DEA numbers beginning with the letter “M”. The second letter corresponds to the first letter of the midlevel practitioner’s last name or the facility name.

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G. Application for Registration and Renewal of Registration
1. DEA registrations are issued contingent upon meeting state requirements and obtaining appropriate state licenses.
2. For a pharmacy, one must first obtain a pharmacy license from the state board of pharmacy and in Texas, a controlled substances registration from the Department of Public Safety (DPS).
3. Application forms for registration differ depending on the type of activity.
   a. DEA-224 Form – for dispensers, including retail pharmacies, hospitals/clinics, practitioners, mid-level practitioners, and teaching institutions. Renewal Form is DEA-224a.
   b. DEA-225 Form – for manufacturers, distributors, researchers, analytical laboratories, importers, and exporters. Renewal form is DEA-225a.
   c. DEA-363 Form – for narcotic treatment facilities. Renewal From is DEA-363a.
4. To expedite registration, an affidavit attesting that a new pharmacy license has been issued by the Board of Pharmacy may be submitted with the DEA-224. (See 21 CFR §1301.17)
5. If the registration is defective, DEA will return it for completion.
6. Although not required for dispenser registrations, recently some DEA offices have been conducting pre-registration inspections before issuing pharmacies new DEA registrations.

7. Initial registrations for dispensers are valid for a period of at least 28 months but not more than 39 months.

8. The DEA registration period for dispensers (pharmacies and practitioners, etc.), is for a three year period. The DEA registration period for other activities (manufacturing, distributing, etc.) is for a one year period. The DPS registration period for all registrants is for one year.

9. A renewal registration form is mailed to the pharmacy within 60 days of expiration. If the renewal application is not received 45 days prior to expiration, contact DEA in writing.

10. Both initial registrations and renewals may be filed out online at: 

   http://www.deadiversion.usdoj.gov/

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VII. Confirmation of Registrant’s DEA Number

A. Add 1st, 3rd, and 5th digits.
B. Add 2nd, 4th, and 6th digits and multiply the sum by 2.
C. Add the sum of A and B above, and the last digit of the sum should correspond to last digit of DEA number.

Example:

DEA #: AB1234563
1+3+5 = 9
(2+4+6) x 2 = 24
TOTAL = 33

The last digit in the total is “3” which corresponds to the last digit in the DEA number: AB1234563.

D. The second letter of the DEA registration should also match the first letter of the practitioner’s last name.

The first letter of the prefix of a DEA number is an “A” if the registrant is a pharmacy or practitioner (MD, DDS, etc.) if registered before 6/1/85; the first prefix letter will be a “B” if registered after 6/1/85.

D. For practitioners (physicians, dentists, etc.), the first letter of the DEA number is an “A”, “B”, or “F”. The second letter of the prefix will be the first letter of the practitioner’s last name (“B” for Dr. Brown) or the first letter of a pharmacy’s name (“C” for Crestview Pharmacy).

E. Midlevel practitioners which may include physician assistants, advanced nurse practitioners, ambulance services, animal shelters, or veterinary euthanasia technicians have DEA numbers beginning with the letter “M”. The second letter corresponds to the first letter of the midlevel practitioner’s last name or the facility name.

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XIII. Disposal and Destruction of Controlled Substances (21 CFR §1301.17) Return of Dispensed Controlled Substances to a Pharmacy for Destruction

A. The return of unused controlled substances to a pharmacy for destruction has been an issue particularly for long term care facilities where these products tend to accumulate.

B. Despite several state laws that allowed return of controlled substances from long term care facilities (LTCFs) to pharmacies, DEA’s position is that there is no provision in the FCSA that allows pharmacy registrant to accept controlled substances from a non-registrant (such as a LTCF or a patient).

C. DEA realized this was causing an accumulation of unwanted controlled substances at patient homes and LTCFs and began sponsoring drug take back days in conjunction with local law enforcement agencies beginning in 2010.

D. The Secure and Responsible Drug Disposal Act of 2010 amended the FCSA to allow patients who have lawfully obtained a controlled substance to deliver it to another person for destruction if the person receiving the controlled substance is authorized to dispose of the drug. The law requires DEA to develop rules to implement its provisions.

E. On December 29, 2012, DEA proposed rules under the new law that would:
   1. Continue to allow law enforcement agencies to voluntarily conduct take-back events, administer mail-back programs, and maintain collection boxes;
   2. Allow authorized manufacturers, distributors, reverse distributors, and retail pharmacies to voluntarily administer mail-back programs and maintain collection boxes;
   3. Allow authorized retail pharmacies to voluntarily maintain collection boxes at long term care facilities.

   — Note: At the time of publication of this book, these proposed rules were yet to be finalized.

A. Disposal of Stock Controlled Substances By Pharmacies

Pharmacies may dispose of a controlled substances in one of the following manners:

1. On-Site Destruction
   (a) On-site destruction of controlled substances must be done utilizing DEA Form 41 which now requires recoding the method by which the drugs were destroyed and two signatures of employees who witnessed the destruction.
   (b) Destructions must be done in compliance with all federal, state and local laws and must render the controlled substances non-retrievable which is defined as “to permanently alter any controlled substance’s physical and/or chemical condition or state through irreversible means in order to render the controlled substance unavailable and unusable for all practical purposes.”

   — Note: This is difficult to do. In addition to the difficulty of complying with other laws such as EPA laws, DEA has stated that methods such as mixing controlled substances with items such as kitty litter or coffee grounds and depositing in the garbage do not meet the non-retrievable standard. For this reason, most pharmacies do not participate in on-site destruction.
(c) Any request for on-site destruction should be made to the DEA Special Agent in Charge following the procedures in paragraph below.

2. Delivery to a Reverse Distributor
   (a) This is the preferred method of disposal and is simply a transfer from one DEA registrant (the pharmacy) to another DEA registrant (the reverse distributor).
   (b) Because this is a transfer between registrants, a DEA Form 41 is not required. Instead the transfer must be documented by an invoice for Schedule II-V drugs and a DEA 222 Form for Schedule II drugs.

3. Returns or Recalls – may be delivered to:
   (a) The registered person from whom it was obtained (e.g. wholesaler).
   (b) The registered manufacturer of the drug, or
   (c) Another registrant authorized by the manufacturer to accept returns or recalls on the manufacturer’s behalf.

   Note: These are also transfers between registrants and require an invoice or DEA 222 form.

4. Request assistance from the Special Agent in Charge of the Administration in the area in which the practitioner is located.
   (a) The request shall be made by submitting one copy of the DEA Form 41 to the Special Agent in Charge in the practitioner’s area. The DEA Form 41 shall list the controlled substance or substances which the registrant desires to dispose.
   (b) The Special Agent in Charge shall instruct the registrant to dispose of the controlled substance in one of the following manners:
      a. By transfer to a registrant authorized to transport or destroy the substance;
      b. By delivery to an agent of the Administration or to the nearest office of the Administration; or
      c. By destruction in the presence of an agent of the Administration or other authorized person.

5. In the event that a pharmacy is required regularly to dispose of controlled substances, the Special Agent in Charge may authorize the practitioner to dispose of such substances using on-site destruction with DEA Form 41, without prior application in each instance, on the condition that the practitioner keep records of such disposals and file periodic reports with the Special Agent in Charge summarizing the disposals. The Special Agent in Charge may place such conditions as he/she deems proper on practitioner procedures regarding the disposal of controlled substances.

B. Disposal of Controlled Substances Collected from Ultimate Users and Other Non-Registrants
This is a new DEA Rule became that became effective in October 2014 that allows a number of ways for ultimate users (patients), those who are legally entitled to dispose of controlled substances in the event of death of the ultimate user, and long term care facilities to dispose of unwanted controlled substances. These proposed collection methods are voluntary. A pharmacy or hospital is not required to serve as a collector. The methods include:

1. Collection Receptacles
   
   (a) Pharmacies and Hospitals with an on-site pharmacy may amend their DEA registrations to be designated as an “Authorized Collector” and may also operate collection receptacles at long term care facilities.
   
   (b) Collectors may allow ultimate users to deposit controlled substances into collection receptacles at the registered location (or at an authorized LTCF).
   
   (c) The controlled substances may be co-mingled with non-controlled substances.
   
   (d) The deposited substances may not be counted, sorted, inventoried or individually handled. This means that pharmacist should not be handling these controlled substances on the patient’s behalf. Patients must be the ones who place the controlled substances into the collection receptacles.
   
   (e) LTCF staff may dispose of a patient’s controlled substances into an authorized collection receptacle. Disposal into a collection receptacle must occur within 3 business days after the discontinuation of use by the patient.
   
   (f) Collection receptacles must be in the immediate proximity (where it can be seen) from where controlled substances are stored (i.e. the pharmacy).
   
   (g) Collection receptacles must be securely fastened to a permanent structure, locked, securely constructed with permanent outer container and removable inner container.
   
   (h) The inner liner must be waterproof, tamper-evident, removable and able to be sealed immediately upon removal with no emptying or touching the contents or ability to view the contents. They also must have a permanent unique identification number that allows tracking.
   
   (i) The inner liner must be removed by or under the supervision of at least two employees of the Authorized Collector
   
   (j) Sealed inner liners may not be opened, x-rayed, analyzed, or otherwise penetrated.
   
   (k) Collectors can either destroy the collected drugs on-site (Note: Most pharmacies do not have capability to do this), transfer the collected drugs for final disposal to a reverse distributor, or they can contact the DEA Special Agent in Charge for assistance.
2. Mail-back programs
   (a) Pharmacies and other authorized collectors may also conduct a mail-back program to allow patients to return unwanted controlled substances for destruction.
   (b) Packages used in mail-back programs must be:
       (1) non-descript and shall not have any markings or other information that might indicate that the package contains controlled substances
       (2) waterproof, tamper-evident, tear-resistant, and sealable,
       (3) preaddressed with and delivered to the collector’s registered address;
       (4) include prepaid shipping costs;
       (5) have a unique identification number to enable tracking; and
       (6) include instructions for the user
   (c) A collector that conducts a mail-back program may only accept packages that the collector made available. If the collector receives a package that the collector did not make available, the collector must notify DEA within 3 business days of receipt.

3. Collection Events
   (a) Only law enforcement agencies can run drug take back events.
   (b) Pharmacies and other entities may partner or co-sponsor such events with law enforcement agencies.

C. Waste of Controlled Substances
   1. The destruction rules above apply to a pharmacy’s inventory (Section A. above) and to controlled substances from patients (Section B. above) but not to pharmaceutical waste.
   2. In a “Dear Practitioner” letter posted on DEA’s website on October 17, 2014, DEA states: “…once a controlled substance has been dispensed by an institutional practitioner on the basis of an order for immediate administration to a patient at the registered location, the substance is no longer in the practitioner’s inventory. For example, after a pre-filled syringe or a single-dose vial or syringe is administered to the patient, any remaining substance in the syringe or vial is not required to be destroyed in accordance with the new Part 1317. However, the remaining substance should be destroyed in accordance with applicable Federal, State, tribal and local laws or regulations.
   3. Texas Class C pharmacy rules require records of waste of controlled substances to be witnessed, co-signed electronically or manually, by another individual. See Board Rule 291.75.

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i. In addition to all controlled substances, TSBP also requires the inventory include all dosage forms of nalbuphine (Nubain®) and tramadol (Ultram®), and that the inventory is signed by the pharmacist-in-charge and notarized within three days of
the day the inventory is completed, excluding Saturdays, Sundays, and federal holidays. _Note: On November 4, 2013 DEA issued a Notice of Proposed Rulemaking to make tramadol a Schedule IV controlled substance._

j. Although many pharmacies maintain a perpetual inventory of Schedule II controlled substances or all controlled substances, neither DEA nor Texas require this. A perpetual inventory is only required in Texas for:
(1) Schedule II drugs only in Class C (Institutional) pharmacies
(2) All controlled drugs (as well as nalbuphine and tramadol) stored at a remote location under the Remote Pharmacy Rules [see Chapter D in this book].

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6. Real-time Electronic Logging System
   a. Effective January 1, 2012, prior to completing the sale of a product containing ephedrine, pseudoephedrine, or norpseudoephedrine, business establishments (including pharmacies) in Texas, must submit a record of the sale, including the name and date of birth of the person making the purchase, the address of the purchaser, the date and time of the purchase, the type of identification displayed by the person, the identification number, and the item and number of grams purchased to a real-time electronic logging system.

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VI. Inventories
   A. FCSA – Required Biennially (every 2 years)
   B. TCSA – Required Biennially (every 2 years)
   C. TSBP – Required Annually (every year) and includes
      1. all dosage forms of nalbuphine (Nubain®) which is not a controlled substance but is included in inventories.
      2. all dosage forms of tramadol (Ultram®) which is not a controlled substance but is included in inventories. _Note: On November 4, 2013 DEA issued a Notice of Proposed Rulemaking to make tramadol a Schedule IV controlled substance._
   2.3 a requirement that the inventory be signed by the pharmacist-in-charge and notarized within three days of the day the inventory is taken, excluding Saturdays, Sundays and federal holidays.
   D. Perpetual Inventory Requirements
      1. Required for Schedule II controlled substances in Class C (institutional) pharmacies.
      2. Required for all controlled substances in remote pharmacies (see Rule 291.20).

Page C.2

7. Prescriptions may only be issued to a patient. Prescriptions may not be written “For Office Use.” If a practitioner wishes to obtain prescription drugs for office use, they may order the drugs from a wholesaler, manufacturer or a pharmacy and must use appropriate forms for controlled substances.
8. What happens to existing refills on a prescription if the prescriber dies? While there are no specific rules or regulations on this, this topic has been discussed by the Texas Medical Board and Texas State Board of Pharmacy and both have agreed by policy that pharmacists are authorized to provide a single prescription refill for a 30 day supply for all medications (except Schedule II controlled substances which have no refills) no later than 30 days after the date of the physician’s death if failure to refill the prescription might result in an interruption of a therapeutic regimen or create patient suffering. DEA has not given an opinion on this however, so pharmacists should use professional judgment if it is a prescription for a controlled substance. If there are no refills remaining on the prescription, it may be best to utilize the existing emergency refills rules.

Pages C.7-C.8

E. Controlled Substances. A PA/APRN may prescribe controlled substances under the following conditions:
1. The prescription is for a controlled substance listed in Schedules III, IV, or V.
2. The PA/APRN must be registered with the Texas Department of Public Safety (DPS) and Drug Enforcement Administration (DEA).
3. Schedule II prescriptions are generally not allowed. The exception to this is a physician may delegate to a PA/APRN the authority to prescribe or order a Schedule II controlled substance in a hospital-based practice in accordance with policies approved by the hospital’s medical staff to a patient who has been admitted to the hospital for an intended length of stay of 24 hours or greater; or is receiving services in the emergency department of the hospital, or as part of a plan of care for the treatment of a person who has executed a written certification of a terminal illness, has elected to receive hospice care, and is receiving hospice treatment from a qualified hospice provider.
4. For Schedule III, IV, and V products, the prescription, including a refill of the prescription, may not exceed a 90 day supply. Note: Although it states “a refill” both the Board of Pharmacy and the Medical Board have agreed that a prescription for a Schedule III-V controlled substance from an APRN or PA can have more than one refill but the prescription and the refills are only valid for 90 days. Essentially, a controlled substance prescription from an APRN or PA expires after 90 days. After that, a new prescription would be required.
5. Refills of Schedule III, IV or V prescriptions may be authorized after consultation with the delegating physician and the consultation is noted in the patient’s chart.
6. For controlled substance prescriptions for a child less than two years of age, the PA/APRN must consult with the delegating physician and the consultation is noted in the patient’s chart.
7. A physician may also delegate to a PA who provides board-certified obstetrical services or a certified nurse midwife (CNM) the administering or providing of controlled substances (No C-IIs) to a patient during intra-partum and immediate post-partum care.
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 (no 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 the Texas Department of Public Safety and the Federal Drug Enforcement Administration.

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.

Pages D.51-D.52

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, and 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. Numbers; however if an individual is unable to obtain a social security number, an individual tax payer 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 of all owners; if a partnership or corporation, the name, title, home address, home phone number, date of birth, and social security number or tax payer identification number as above of all managing officers;

4. Name and license number of pharmacist-in-charge and other pharmacists;

5. Names and license numbers of other pharmacists employed by the pharmacy;

6. Anticipated date of opening and hours of operation;

7. Copy of lease agreement or if location is owned by the applicant, a notarized statement certifying such location ownership;

8. The signature of the pharmacist-in-charge;

9. The notarized signature of the owner; or if the pharmacy is owned by a partnership or corporation, the notarized signature of an owner or managing officer;

10. Federal tax ID number of the owner;

11. Description of business services that will be offered;

12. Name and address of malpractice insurance carrier or statement that the business will be self-insured;
13. An approved credit application from a primary wholesaler or other documents showing credit worthiness as approved by the Board;

14. An official copy of the business formation documents filed with the Secretary of State;

15. A Certificate of Good Standing for the business structure from the state where the business structure is located; and

12. The certificate of authority, if applicant is an out-of-state corporation;

13. The articles of incorporation, if the applicant is a corporation;

14. A current Texas Franchise Tax Certificate of Good Standing; and

15. Any other information requested on the application.

B. If a pharmacy is to be licensed as a new Class A (community) pharmacy, a Class C (institutional) pharmacy, or Class F (freestanding emergency medical care center) pharmacy owned by a management company, the following additional documents must be submitted unless the entity already owns a pharmacy licensed in Texas:

1. The birth certificate or passport of each individual owner, or each managing officer if the pharmacy is owned by a partnership or a closely held corporation. This requirement does not apply if the owner or managing officer possesses an active Texas pharmacist license.

2. An approved credit application from a primary wholesaler or other documents showing credit worthiness as approved by the Board; and

3. A current driver’s license or state issued photo ID card of each individual owner or each managing officer if the pharmacy is owned by a partnership or closely held corporation. This requirement does not apply if the owner or managing officer possesses an active Texas pharmacist license.

C. Prior to the issuance of a license for a pharmacy located in Texas, the Board shall conduct an on-site inspection of the pharmacy in the presence of the pharmacist-in-charge and owner or representative of the owner, to ensure that the pharmacist-in-charge and owner can meet the requirements of the Texas Pharmacy Act and Board Rules. This requirement may be waived by the Board if the applicant has an active pharmacy license in Texas on the date of application for a new pharmacy license or for other good cause.

D. For the purpose of this section, managing officers are the top four executive officers, including the corporate officer in charge of pharmacy operations, who are designated by the partnership or corporation to be jointly responsible for the legal operation of the pharmacy.

E. The applicant may be required to 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. The criminal history information may be required for each individual owner, or if the pharmacy is owned by a partnership or closely held corporation for each managing officer.

F. A fee as specified under §291.6 for issuing initial, renewal, and duplicate or amended pharmacy licenses will be charged.

D. For the purpose of this section, managing officers are the top four executive officers, including the corporate officer in charge of pharmacy operations, who are designated by the partnership or corporation to be jointly responsible for the legal operation of the pharmacy.

E. Prior to the issuance of a license for a pharmacy located in Texas, the board shall conduct an on-site inspection of the pharmacy in the presence of the pharmacist-in-
charge and owner or representative of the owner, to ensure that the pharmacist-in-charge and owner can meet the requirements of the Texas Pharmacy Act and Board Rules.

F. If the applicant holds an active pharmacy license in Texas on the date of application for a new pharmacy license or for other good cause shown as specified by the board, the board may waive the pre-inspection as set forth in subsection E. of this section.

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Board of Pharmacy Rule §295.1 Change of Address and/or Name

A. Change of address. Notify the Board in writing within 10 days of a change of address, giving old and new addresses and license number.

B. Change of name. Notify the Board in writing within 10 days of a change of name by:

1. Sending a copy of the official document reflecting the name change (e.g., marriage certificate, divorce decree, etc.); and


3. Pharmacists who change their name may retain the original license to practice pharmacy (wall certificate). However, if the pharmacist wants an amended certificate issued which reflects the pharmacist’s name change, the pharmacist must:

   a. Return the original certificate; and

   b. Pay a fee of $35.

4. An amended license and/or certificate reflecting the new name will be issued by the Board.

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5. Contents of the emergency medication kit shall be determined by the consultant pharmacist, pharmacist-in-charge of the provider pharmacy, medical director and director of nursing and shall be limited to those drugs necessary to meet the resident’s emergency medication needs. This means a situation in which a drug cannot be supplied by a pharmacy within a reasonable time.

6. Stocking of drugs in an emergency medication kit shall be provided at the provider pharmacy or the remote site automated pharmacy system must be done by a pharmacist pharmacy technician, or pharmacy technician trainee. However, if the emergency medication kit is an automated pharmacy system using bar-coding, microchip or other technologies to ensure that the containers or unit-dose drugs are accurately loaded, prepackaging of the containers or unit-dose drugs may take place at the provider pharmacy and the containers or unit dose drugs may be sent to the remote site in secure tamper evident containers to be loaded into the machine by personnel designated by the pharmacist-in-charge, unless the system uses removable cartridges or containers and other specific requirements of §291.121 (b)(4)(F)(ii) are met.
7. A record must be maintained of all drugs sent to and returned from the remote location and should be kept separate from the records of the provider pharmacy and from other remote site records.

8. A perpetual inventory of all controlled substances (and nalbuphine and tramadol) must be maintained for each remote location and each remote location’s controlled substances must be inventoried on the same day as the provider pharmacy’s inventory.

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7. Drugs used in the automated pharmacy system must be in the original manufacturer’s container or be prepackaged in the provider pharmacy.

8. Stocking of drugs in an automated pharmacy system at the remote site must be done by a pharmacist, pharmacy technician, or pharmacy technician trainee. However, if the system uses removable cartridges or containers, prepackaging of the cartridges or containers may take place at the provider pharmacy and the cartridges or containers can then be sent to the remote site in secure, tamper-evident containers to be loaded into the machine by personnel at the facility designated by the pharmacist-in-charge. The automated system must use bar-coding, microchip or other technologies to ensure that the containers are accurately loaded into the automated pharmacy system and other specific requirements of §291.20(a)(4)(F)(ii) are met.

9. A record must be maintained of all drugs sent to and returned from the remote location and should be kept separate from the records of the provider pharmacy and from other remote site records.

10. A perpetual inventory of all controlled substances (and nalbuphine and tramadol) must be maintained for each remote location and each remote location’s controlled substances must be inventoried on the same day as the provider pharmacy’s inventory.

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9. A record must be maintained of all drugs sent to and returned from the remote location and should be kept separate from the records of the provider pharmacy and from other remote site records.

10. A perpetual inventory of all controlled substances (and nalbuphine and tramadol) must be maintained for each remote location and each remote location’s controlled substances must be inventoried on the same day as the provider pharmacy’s inventory.

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§297.9 Notifications

A. Display of Registration Certificate.

1. A pharmacy technician or pharmacy technician trainee shall publicly display his/her current registration certificate in their primary place of employment except as noted in paragraph 2 of this subsection.
2. A pharmacy technician or pharmacy technician trainee who only works in the inpatient portion of a Class C pharmacy is not required to publicly display his/her current registration certificate in the pharmacy, provided the pharmacist in charge makes and retains a copy of their current registration certificate for inspection by a Board representative.

### A. B.

#### Change of Address and/or Name

1. Change of address. A pharmacy technician or pharmacy technician trainee shall notify the Board electronically or in writing within 10 days of a change of address, giving the old and new address and registration number.

2. Change of name.
   a. A pharmacy technician or pharmacy technician trainee shall notify the Board in writing within 10 days of a change of name by:
      1. Sending a copy of the official document reflecting the name change (e.g., marriage certificate, divorce decree, etc.);
      2. Returning the current renewal certificate which reflects the previous name; and
   b. An amended registration and/or certificate reflecting the new name of the pharmacy technician or pharmacy technician trainee will be issued by the Board.

### B. C.

#### Change of Employment. A pharmacy technician or pharmacy technician trainee shall report electronically or in writing to the Board within 10 days of a change of employment giving the name and license number of the old and new pharmacy and registration number.

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B. Change of Managing Officers.

1. The owner of a pharmacy shall notify the board in writing within 10 days of a change of any managing officer of a partnership or corporation which owns a pharmacy. The written notification shall include the effective date of such change and the following information for all managing officers:
   a. name and title;
   b. home address and telephone number;
   c. date of birth; and
   d. copies of social security number card, 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 documenting why the individual is unable to obtain a social security number; and
   e. a copy of current driver license, state-issued photo identification card, or passport.

2. For purposes of this subsection, managing officers are defined as the top four executive officers, including the corporate officer in charge of pharmacy operations, who are designated by the partnership or corporation to be jointly responsible for the legal operation of the pharmacy.
C. Change of Ownership.

1. When a pharmacy changes ownership, a new pharmacy application must be filed with the Board following the procedures specified in rule 291.1 (relating to Pharmacy License Application). In addition a copy of the purchase contract or mutual agreement between the buyer and seller must be submitted. A new/completed pharmacy application must be filed with the board and the license issued to the previous owner shall be returned to the board.

2. The license issued to the previous owner must be returned to the Board. The new application shall include the following information:
   a. the name and address of pharmacy;
   b. the type of ownership;
   c. the names, home addresses, dates of birth, phone numbers, and social security numbers of all owners; if a partnership or corporation, the name, title, home address, home phone number, date of birth, and social security number of all managing officers;
   d. the name and license number of the pharmacist-in-charge and of other pharmacists employed by the pharmacy;
   e. a copy of lease or if the location of the pharmacy is owned by the applicant, a notarized statement certifying such location ownership;
   f. a copy of the purchase contract or mutual agreement between the buyer and seller, or a notarized statement of intent to convey ownership signed by both the buyer and seller, stating the proposed date of ownership change;
   g. the signature of the pharmacist-in-charge;
   h. the notarized signature of the owner, or if the pharmacy is owned by a partnership or corporation, the notarized signature of an owner or managing officer;
   i. federal tax ID number;
   j. description of business services that will be offered;
   k. name and address of malpractice insurance carrier or statement that the business will be self-insured;
   l. the certificate of authority, if applicant is an out-of-state corporation;
   m. the articles of incorporation, if the applicant is a corporation;
   n. a current Texas Franchise Tax Certificate of Good Standing; and
   o. any other information requested on the application.

3. Paragraph 4. of this subsection applies to all change of ownership applications for Class A (Community) pharmacies, Class C (Institutional) pharmacies, or Class F (Freestanding Emergency Medical Care Center) pharmacies, owned by a management company with the following exceptions.
   a. Paragraph 4. of this subsection does not apply to a change of ownership application submitted by an entity which already owns a pharmacy licensed in Texas.
   b. Paragraph 4.a and c of this subsection do not apply to each individual owner or managing officer listed on a new pharmacy application if the individual possesses an active pharmacist license in Texas.

4. If the pharmacy is to be licensed as a Class A (Community) Pharmacy, a Class C (Institutional) pharmacy, or a Class F (Freestanding Emergency Medical Care Center) pharmacy owned by a management company, the applicant must submit copies of the...
following documents in addition to the information required in paragraph 2. of this subsection:
a. the birth certificate, passport, or other document proving the date of birth of the owner, or, if the pharmacy is owned by a partnership or a closely held corporation:
   (1) one of these documents for each managing officer; and
   (2) a list of all owners of the corporation;
b. an approved credit application from a primary wholesaler or other documents showing credit worthiness as approved by the Board; and
c. a current driver license or state issued photo ID card of each individual owner, or, if the pharmacy is owned by a partnership or a closely held corporation, a current driver license or state issued photo ID card for each managing officer.
5. A fee as specified in §291.6 of this title will be charged for issuance of a new license.

D. Change of Pharmacist Employment.
1. Change of pharmacist employed in a pharmacy. When a change in pharmacist employment occurs, the pharmacist shall report such change in writing to the board within 10 days.
   a. On the date of change of the pharmacist-in-charge of a Class A, Class A-S, (community), Class C, Class C-S (institutional), or Class F (Freestanding Emergency Medical Care Center) pharmacy, an inventory specified in §291.17 (See Change of PIC Inventory in this Chapter) must be taken.
   b. This inventory shall constitute, for the purpose of this section, the closing inventory of the departing pharmacist-in-charge and the beginning inventory of the incoming pharmacist-in-charge.

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§291.17 Inventory Requirements

A. General Requirements.
   1. Pharmacist-in-charge is responsible for taking all required inventories; may delegate performance of inventory to another person(s).
   2. Maintain in written, typewritten, or printed form; inventory taken by oral recording device must be promptly transcribed.
   3. Keep in pharmacy and have available for inspection for two years.
   4. File separately from all other records.
   5. Include all stocks of the following drugs on hand on the date of the inventory (including any which are out-of-date):
      a. All controlled substances; and
      b. All dosage forms containing nalbuphine (e.g., Nubain®); and
      c. All dosage forms containing tramadol (e.g., Ultram®).
         Note: On November 4, 2013 DEA issued a Notice of Proposed Rulemaking to make tramadol a Schedule IV controlled substance.
   6. Take either as of the opening of business or close of business on the inventory date.
   7. Inventory record shall indicate whether the inventory is taken as of the opening of business or as the close of business on the inventory date. If the pharmacy is open 24 hours a day, the opening of business shall be 12:01 a.m. and the close of business shall
be 12 midnight. The inventory shall indicate that it is a record of drugs on-hand as of
the opening or closing of the business day.
8. Make an exact count or measure of all substances listed in Schedule II.
9. Make an estimated count or measure of substances listed in Schedule III, IV or V; if
container holds more than 1,000 tablets or capsules, an exact count of contents must be
made (not necessary unless container has been opened).
10. Schedule II controlled substances shall be listed separately from inventory of Schedule
III, IV and V controlled substances which shall be separate from the inventory of
dangerous drugs.
11. If pharmacy maintains perpetual inventory of controlled substances, perpetual
inventory shall be reconciled on date of inventory.

B. Initial Inventory.
1. New Class A (Community) pharmacy, Class C (Institutional), or Class F (Freestanding
Emergency Medical Care Center) pharmacy shall take an inventory on the opening day
of business. The inventory shall include all stocks (including any out-of-date drugs) of
the drugs specified in subsection A.5. of this section (controlled substances, and
nalbuphine and tramadol).
2. If a Class A, C, or F pharmacy commences business with none of the drugs specified
in paragraph 1 above, the pharmacy shall record this fact as the initial inventory.
3. The initial inventory shall serve as the pharmacy’s inventory until the next May 1, or
until the pharmacy’s regular general physical inventory date, at which time the Class
A, C, or F pharmacy shall take an annual inventory as specified in Subsection C (annual
inventory). Such inventory may be taken within 4 days of the specified inventory date
and shall include all stocks (including out-of-date drugs).

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D. Change of Ownership of Class A, C, or F pharmacy.
1. A Class A, C, or F pharmacy that changes ownership shall take an inventory on the
date of the change of ownership. Such inventory shall include all stocks (including any
out-of-date drugs) of the drugs specified in subsection A.5. of this section (controlled
substances, and nalbuphine and tramadol).
2. The inventory constitutes the closing inventory for the seller and the initial inventory
for the buyer.
3. All schedule II controlled substances must be transferred from the seller to the buyer
by use of a DEA order form (222).
4. The person(s) taking the change of ownership inventory and the pharmacist-in-charge
shall indicate the time the inventory was taken (as specified in subsection A.7 of this
section) and shall sign and date the inventory with the date the inventory was taken.
The signature of the pharmacist-in-charge and the date of the inventory shall be
notarized within three days of the day the inventory is completed, excluding Saturdays,
Sundays, and federal holidays.

E. Closed Pharmacies.
1. The pharmacist-in-charge of a closed Class A, C, or F pharmacy shall notify the Board
within 10 days of closing, shall forward to the Board a statement that an inventory of
drugs specified in Subsection A.5. of this section (controlled substances, and
nalbuphine and tramadol) on hand has been taken, the date of closing, and the manner by which the dangerous drugs and controlled substances of the pharmacy were transferred or disposed.

2. The person(s) taking the closing inventory and the pharmacist-in-charge shall indicate the time the inventory was taken (as specified in subsection A.7. of this section) and shall sign and date the inventory with the date the inventory was taken. The signature of the pharmacist-in-charge and the date of the inventory shall be notarized within three days of the day the inventory is completed, excluding Saturdays, Sundays, and federal holidays.

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G. Inventory Required Upon the Change of Pharmacist-in-Charge of a Class A, C, or F Pharmacy.

1. For an inventory taken after June 1, 2013, on the date of the change of the pharmacist-in-charge of a Class A (Community), Class C (Institutional), or Class F (Free Standing Emergency Medical Care Center) pharmacy, an inventory shall be taken. Such inventory shall include all stocks (including any out-of-date drugs) of the drugs specified in subsection A.5. of this section (controlled substances, and nalbuphine and tramadol).

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institutions (nursing homes). A consultant pharmacist may not destroy controlled substances unless as allowed to do so by federal laws or rules of the Drug Enforcement Administration. Dangerous drugs may be destroyed provided the following condition are met:

a. A written agreement exists between the facility or institution and the consultant pharmacist;

b. The drugs are inventoried and the inventory is verified by the consultant pharmacist. The inventory shall include:
   (1) Name and address of the facility or institution;
   (2) Name and pharmacist license number of the consultant pharmacist;
   (3) Date of drug destruction;
   (4) Date the prescription was dispensed;
   (5) Unique identification number assigned to the prescription by the pharmacy;
   (6) Name of dispensing pharmacy;
   (7) Name, strength, and quantity of drug;
   (8) Signature of consultant pharmacist destroying drugs;
   (9) Signature of the witness(es); and
   (10) Method of destruction.

c. The signature of the consultant pharmacists and witness(es) to the destruction and the method of destruction specified in Subparagraph b. of this paragraph may be on a cover sheet attached to the inventory and not on each individual inventory sheet, provided the cover sheet contains a statement indicating the number of inventory pages that are attached and each of the attached pages are initialed by the consultant pharmacist and witness(es).
d. The drugs are destroyed in a manner to render the drugs unfit for human consumption and disposed of in compliance with all applicable state and federal requirements.

e. The actual destruction of the drugs is witnessed by one of the following:
   (1) A commissioned peace officer;
   (2) An agent of the Texas State Board of Pharmacy;
   (3) An agent of the Texas Health and Human Services Commission, authorized by the Texas State Board of Pharmacy to destroy drugs;
   (4) An agent of the Texas Department of State Health Services as authorized by Texas State Board of Pharmacy;
   (5) Any two individuals working in the following capacities at the facility:
      (a) facility administrator;
      (b) director of nursing;
      (c) acting director of nursing; or
      (d) licensed nurse.
   (6) If actual destruction of the drugs is conducted at a location other than the facility or institution, the consultant pharmacist witness(es) shall retrieve the drugs from the facility, transport, and destroy the drugs at such other location.

2. Destruction by a waste disposal service

   Note: This is not the same as a transfer of drugs to a reverse distributor for destruction.

   A consultant pharmacist may utilize a waste disposal service to destroy dangerous drugs dispensed to patients in health care facilities or institutions. A consultant pharmacist may not use a waste disposal service to destroy controlled substances unless as allowed to do so by federal laws or rules of the Drug

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§303.2 Destruction of Stock Prescription Drugs

These procedures apply to stock prescription drugs belonging to a pharmacy (drugs that are packaged in an original manufacturer’s container or have been repackaged by the pharmacy for internal distribution).

Stock Dangerous Drugs

1. Pharmacists licensed by the Texas State Board of Pharmacy may destroy stock dangerous drugs if the drugs are destroyed in a manner to render the drugs unfit for human consumption (i.e. destroyed beyond reclamation) and disposed of in compliance with all applicable state and federal requirements. Records of destruction are not required except for nalbuphine.

2. Any brand of nalbuphine (e.g. Nubain®) must be inventoried prior to destruction and the destruction must be witnessed by another licensed pharmacist or commissioned peace officer. Records for destruction of these drugs must be maintained for two years from the date of destruction.

Stock Controlled Substances

See DEA rules for disposal of controlled substances in Chapter B, Section XIII in this book.
Class A and C pharmacies

1. Transfer to a DEA Registered Reverse Distributor
   a. This is the preferred method of destruction.
   b. Because this is a distribution between registrants, it must be documented with appropriate invoices for Schedule III-V drugs and DEA 222 forms for Schedule II drugs.

2. Destruction at the Pharmacy with Prior DEA Approval
   
   Note: The Texas rules for destruction of stock controlled substances found in §303.2(c) are listed below, however DEA no longer generally grants permission for pharmacies to destroy controlled substances at the pharmacy. All requests to dispose of controlled substances must be made to closest DEA Special Agent in Charge per 21 CFR §1307.21 and the DEA Special Agent in Charge will authorize and instruct the pharmacy on the manner to dispose of the controlled substances. While the Texas rules state that no response from the DEA constitutes approval, it is prudent to obtain specific authorization in writing from DEA.
   
   a. Class A (community) pharmacies
      (1) This method of destruction may only be used one time per calendar year.
      (2) Pharmacy must inventory controlled substances to be destroyed and itemize the inventory on DEA Form 41, making three copies.
      (3) Must send registered or certified letter to DEA at least 14 days prior to the anticipated destruction date indicating the day, time and place of the anticipated destruction and a copy of the DEA Form 41. No response from DEA constitutes approval.
      (4) Controlled substances must be destroyed beyond reclamation and in compliance with all applicable state and federal requirements on the approved date/time/place in the presence of one of the following witnesses:
         (a) A commissioned peace officer
         (b) A DEA agent
         (c) A DPS agent
         (d) An agent of the Texas State Board of Pharmacy
      (5) After destruction, DEA Form 41 must be completed to indicate method of destruction and must be signed and dated by the registrant and witness.
      (6) Original copy of DEA Form 41 must remain in the pharmacy for two years, and third copy is mailed to DEA divisional office.

   b. Class C (institutional) pharmacies
      (1) This method may be used by a hospital anytime provided the written authorization is maintained on file in the pharmacy.
      (2) Written approval from DEA must be obtained from DEA divisional office.
      (3) Pharmacy must inventory the controlled substances to be destroyed and itemize the inventory on DEA Form 41, making two copies.
      (4) The controlled substances must be destroyed beyond reclamation and disposed of in compliance with all applicable state and federal requirements.
      (5) Destruction must be made in front of one of the following witnesses:
         (a) A commissioned peace officer
         (b) A supervisory member of the hospital’s security department
(c) A DEA agent
(d) A DPS agent
(e) An agent of the Texas State Board of Pharmacy

(6) After destruction, DEA Form 41 must be completed to indicate the method of destruction and be signed and dated by the registrant and witness.

(7) Original copy of DEA Form 41 must be maintained in the pharmacy for two years and second copy is mailed to the DEA divisional office.

§303.3 Records

All inventory records and forms of disposed drugs shall be kept for two years from the date of transfer, disposal, or destruction and be available for inspection.

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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.

SUBCHAPTER B. DISCIPLINARY ACTIONS AND PROCEDURES

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(2) Offenses involving possession of drugs, fraudulent prescriptions, or theft of drugs:

(a) Pharmacists:
   (i) 0-5 years since date of disposition – 5 years probation;
   (ii) 6-10 years since date of disposition – 3 years probation;

(b) Pharmacy Technicians and Pharmacy Technician Trainees:
   (i) 0-5 years since date of disposition and offense determined to be in violation of §568.003(a)(5) or (9) of the Act – 5 years probation;
   (ii) 0-5 years since date of disposition and determined not to have a drug or alcohol dependency in violation of §568.003(a)(5) or (9) of the Act – 1 year probation;
   (iii) 6-10 years since date of disposition and offense determined to be in violation of §568.003(a)(5) or (9) of the Act – 3 years probation;

(c) If 0-5 years since date of disposition, and the offense did not involve only personal use of the drugs and/or chemical impairment, an additional 30-to 90-day suspension will be imposed preceding the probation for the offenses in this clause.

b. Intoxication and alcoholic beverage offenses as defined in the Texas Penal Code, if two such offenses involving intoxication due to ingestion of alcohol occurred in the previous five ten years or if one such offense involving intoxication due to
ingestion of controlled substances or dangerous drugs occurred in the previous five
(1) Pharmacists:
 (a) 0-5 years since date of disposition and offense determined to be in violation of §565.001(a)(4) or (7) of the Act – 5 years probation;
 (b) 6-10 years since date of disposition and offense determined to be in violation of §568.001(a)(4) or (7) of the Act – 3 years probation;
(2) Pharmacy Technicians and Pharmacy Technician Trainees: 0-5 years since date of disposition and offense determined to be in violation of §568.003(a)(5) or (9) of the Act – 5 years probation;

c. Other misdemeanor offenses involving moral turpitude:
 (1) 0-5 years since date of disposition – reprimand;
 (2) 6-10 years since date of disposition – reprimand;
D. When an individual has multiple criminal offenses or other violations, the Board shall consider imposing additional more severe types of disciplinary sanctions, as deemed necessary.
E. An individual who suffers from an impairment as described by Section 565.001(a)(4) or (7) or Section 568.003(a)(5) or (9), may provide mitigating information including treatment, counseling, and monitoring in order to mitigate the sanctions imposed.

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3. Advanced practice registered nurse – A registered nurse licensed approved by the Texas State Board of Nurse Examiners to practice as an advanced practice nurse on the basis of completion of an advanced education program. The term includes a nurse practitioner, a nurse midwife, a nurse anesthetist, and a clinical nurse specialist and is synonymous with advanced nurse practitioner.
4. Automated checking device - A device that confirms that the correct drug and strength has been labeled with the correct label for the correct patient prior to delivery of the drug to the patient.
5. Automated compounding or counting device – An automated device that compounds, measures, counts, and/or packages a specified quantity of dosage units of a designated drug product.
6. Automated pharmacy dispensing systems – A mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, counting, labeling, dispensing, and distribution of medications, and which collects, controls, and maintains all transaction information. “Automated pharmacy dispensing systems” does not mean “Automated compounding or counting devices” or “Automated medication supply devices.”
7. Beyond use date - The date beyond which a product should not be used.
8. Board – The Texas State Board of Pharmacy

Note: At the time of publication of this book this term was still defined in the Class A rules however, these terms are no longer used in the statute to describe the prescriptive authority of APRNs and PAs and have been replaced by the terms “prescribe” or “order”.
9. **Confidential record** – Any health-related record that contains information that identifies an individual and that is maintained by a pharmacy or pharmacist such as a patient medication record, prescription drug order, or medication order.

10. **Controlled substance** – A drug, immediate precursor, or other substance listed in Schedules I-V or Penalty Groups 1-4 of the Texas Controlled Substances Act, as amended, or a drug, immediate precursor, or other substance included in Schedule I, II, III, IV, or V of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended (Public Law 91-513).

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14. **Designated Agent** –
   a. An individual including a licensed nurse, physician assistant, or pharmacist designated by a practitioner and authorized to communicate a prescription drug order to a pharmacist, and for whom the practitioner assumes legal responsibility;
   b. A licensed nurse, physician assistant, or pharmacist employed in a health care facility to whom the practitioner communicates a prescription drug order;
   c. An advanced practice registered nurse or physician assistant authorized by a practitioner to prescribe or order drugs or devices administer a prescription drug order for dangerous drugs under Subtitle B, Chapter 157 of the Medical Practice Act;
   d. A person who is a licensed vocational nurse or has an education equivalent to or greater than that required for a vocational nurse designated by the practitioner to communicate prescriptions for an advanced practice registered nurse or physician assistant authorized by the practitioner to sign prescription drug orders.

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26. **New prescription drug order** – A prescription drug order that:
   a. Has not been dispensed to the patient in the same strength and dosage form by this pharmacy within the last year;
   b. Is transferred from another pharmacy; and/or
   c. Is a discharge (hospital) prescription drug order (Note: Furlough prescription drug orders are not considered new prescription orders.)

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C. Pharmacists – General (Includes pharmacist-in-charge and staff pharmacists).
   1. General
      a. 4. Pharmacist-in-charge shall be assisted by sufficient number of additional licensed pharmacists as may be required to operate the pharmacy competently, safely, and adequately to meet the needs of the patients of the pharmacy.
      b. 2. Assist the pharmacist-in-charge in meeting responsibilities in ordering, dispensing, and accounting for prescription drugs.
      c. 3. Pharmacists are solely responsible for the direct supervision of pharmacy technicians and pharmacy technician trainees and for designating and delegating duties, other than those listed in subsection D below, to pharmacy technicians and pharmacy
technician trainees. Each pharmacist shall be responsible for any delegated act performed by pharmacy technicians and pharmacy technician trainees under his or her supervision.

d. 4. Pharmacists shall directly supervise pharmacy technicians and pharmacy technician trainees who are entering prescription data into a pharmacy’s data processing system by one of the following methods:

i. a. Physically present supervision. A pharmacist shall be physically present to directly supervise a pharmacy technician or pharmacy technician trainee who is entering prescription data into the data processing system. Each prescription entered into the data processing system shall be verified at the time of data entry. If the pharmacist is not physically present due to a temporary absence as allowed by board rule 291.33(b)(3), on return from such temporary absence the pharmacist must:

(I.) Conduct a drug regimen review for prescription data entered during the temporary absence as specified in board rule 291.33(c)(2).
(II.) Verify that prescription data entered during the temporary absence was entered accurately prior to delivery of the prescription to the patient or the patient’s agent.

ii. b. Electronic supervision. A pharmacist may electronically supervise a pharmacy technician or pharmacy technician trainee who is entering prescription data into the data processing system provided the pharmacist:

(I.) Is on-site, in the pharmacy where the technician/trainee is located;
(II.) Has immediate access to any original document containing prescription information or other information related to the dispensing of the prescription. Such access may be through imaging technology provided the pharmacist has the ability to review the original hardcopy documents if needed for clarification and;
(III.) Verifies the accuracy of data entered prior to the release of the information to the system for storage and/or generation of the prescription label

iii. c. Electronic verification of data entry by pharmacy technicians or pharmacy technician trainees. A pharmacist may electronically verify the data entry of prescription information into a data processing system provided:

(I.) a pharmacist is onsite in the pharmacy where the pharmacy technicians/trainees are located;
(II.) the pharmacist electronically conducting the verification is either a:
(-a-) Texas licensed pharmacist; or
(-b-) pharmacist employed by a Class E pharmacy that
(-1-) has the same owner as the Class A pharmacy where the pharmacy technician/trainee are located; or
(-2-) has entered into a written contract or agreement with the Class A pharmacy, which outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws and regulations;
(III.) the pharmacy establishes controls to protect the privacy and security of confidential records; and
(IV.)(4) the pharmacy keeps permanent records of prescriptions electronically verified for a period of two years.

e. 5. All pharmacists, while on duty, shall be responsible for the legal operation of the pharmacy and for complying with all state and federal laws or rules governing the practice of pharmacy.

f. 6. A dispensing pharmacist shall be responsible for and ensure that drugs are dispensed and delivered safely and accurately as prescribed, unless the pharmacy’s data processing system can record the identity of each pharmacist involved in a specific portion of the dispensing processing, in which case each pharmacist involved in the dispensing process shall be responsible for and ensure that the portion of the process the pharmacist is performing results in the safe and accurate dispensing and delivery of the drug as prescribed. The dispensing process shall include, but not be limited to, drug regimen review and verification of accurate prescription data entry, including data entry of prescriptions placed on hold, packaging, preparation, compounding, transferring and labeling and performance of the final check of the dispensed prescription. An intern has the same duties under this subsection but must perform his or her duties under the supervision of a pharmacist. Note: Although the rule states “under the supervision of a pharmacist” it should probably say “under the supervision of a preceptor” because an intern that is not under the supervision of a preceptor functions as a pharmacy technician. Also note that an intern may not transfer a prescription to another intern.

D. 2. Pharmacist Duties – Duties which may only be performed by a pharmacist (and intern under supervision):

a. 1. Receiving oral prescription drug orders and reducing these orders to writing, either manually or electronically;

b. 2. Interpreting prescription drug orders;

c. 3. Selecting drug products (means generic drug product selection);

d. 4. Performing the final check of the dispensed prescription before delivery to the patient to ensure that the prescription has been dispensed accurately as prescribed;

e. 5. Communicating to the patient or patient’s agent information about the prescription drug or device which in the exercise of the pharmacist’s professional judgment, the pharmacist deems significant, as specified in §291.33(C)(1) (patient counseling).

f. 6. Communicating to the patient or the patient’s agent on his/her request, information concerning any prescription drugs dispensed to the patient by the pharmacy.

g. 7. Assuring that a reasonable effort is made to obtain, record, and maintain patient medication records;

h. 8. Interpreting patient medication records and performing drug regimen reviews;

i. 9. Performing a specific act of drug therapy management for a patient delegated to a pharmacist by a written protocol from a physician licensed in this state in compliance with the Texas Medical Practice Act; and

j. 10. Verifying that controlled substances listed on invoices are received by clearly recording his/her initials and date of receipt of the controlled substances.

3. Special Requirements for Compounding. All pharmacists engaged in compounding non-sterile preparations shall meet the training requirements specified in §291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations).
E. Pharmacy Technicians

1. General.
   a. All pharmacy technicians and pharmacy technician trainees shall meet the training requirements specified in §297.6 of this title (relating to Pharmacy Technician Training).
   
   b. Special requirements for compounding.
      (1) Non-sterile preparations. All pharmacy technicians and pharmacy technician trainees engaged in compounding non-sterile preparations shall meet the training requirements specified in board rule 291.131.
      (2) Sterile preparations. All pharmacy technicians and pharmacy technician trainees engaged in compounding sterile preparations shall meet the training requirements specified in board rule 291.133.

   Editing Note: The changes above do not mean that pharmacy technicians no longer have to meet training requirements to compound sterile preparations. It is only removing the language from this section because Class A pharmacies can no longer compound sterile preparations. Class A pharmacies that compound sterile preparations are now licensed as Class A-S pharmacies. The training requirements for all personnel participating in the compounding of sterile preparations are found in Rule 291.133.

2. Duties.
   a. Pharmacy technicians and pharmacy technician trainees may not perform any of the duties listed in Section C.2.D above. Note: There is no difference between the duties that a pharmacy technician and a pharmacy technician trainee can perform.
   
   b. A pharmacist may delegate to pharmacy technicians and pharmacy technician trainees any nonjudgmental technical duty associated with the preparation and distribution or prescription drugs provided:
      (1) A pharmacist verifies the accuracy of all acts, tasks, and functions performed by pharmacy technicians and pharmacy technician trainees;
      (2) Pharmacy technicians and pharmacy technician trainees are under the direct supervision of and responsible to a pharmacist; and
      (3) Only pharmacy technicians and pharmacy technician trainees who have been properly trained on the use of an automated pharmacy dispensing system and can demonstrate comprehensive knowledge of the written policies and procedures for the operation of the system may be allowed access to the system.

   c. Pharmacy technicians and pharmacy technician trainees may perform only nonjudgmental technical duties associated with the preparation and distribution of prescription drugs, as follows:
      (1) Initiating and receiving refill authorization requests;
      (2) Initiating electronic transfer requests between pharmacies electronically sharing a common prescription database. Note: This is allowed per Board Rule 291.34(g)(8)(iii.) although not specifically listed in this part of the rules so it was added here for completeness.
(3) Entering prescription data into a data processing system;
(4) Selecting a stock container from the shelf for a prescription;
(5) Preparing and packaging prescription drug orders (e.g. counting tablets/capsules, measuring liquids and/or placing them into the prescription container);
(6) Affixing prescription labels and auxiliary labels to the prescription container;
(7) Reconstituting medications;
(8) Prepackaging and labeling prepackaged drugs;
(9) Loading bulk unlabeled drugs into an automated dispensing system provided a pharmacist verifies that the system is properly loaded prior to use;
(10) Compounding non-sterile and sterile prescription drug orders; and
(11) Compounding bulk non-sterile preparations.

Editing Note: The changes in (10) and (11) above do not mean that pharmacy technicians can no longer compound sterile preparations. It is only removing the language from this section because Class A pharmacies can no longer compound sterile preparations. Class A pharmacies that compound sterile preparations are now licensed as Class A-S pharmacies. The requirements for all personnel participating in the compounding of sterile preparations are found in Rule 291.133.

F. Ratio of Onsite Pharmacists to Pharmacy Technicians.
   1. The ratio of onsite pharmacists to pharmacy technicians and pharmacy technicians in a Class A pharmacy may be 1:3–1:4 provided that at least one of the four three technicians is a pharmacy technician and not a pharmacy technician trainee. The ratio of pharmacists to pharmacy technician trainees may not exceed 1:3–1:2.
   Note: At the time of publication of this book, the Board of Pharmacy had proposed increasing the ratio of pharmacists to pharmacy technicians to 1:4. The new rules were expected to be adopted at the Board’s February 2014 meeting.
   2. There is a special statutory exception in Section 568.006 of the Pharmacy Act that allows a ratio of 1:5 for pharmacies that dispense no more than 20 different prescription drugs.

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b. Such communication:
   (1) Shall be provided to new and existing patients of a pharmacy with each new prescription drug order. A new prescription drug order is one that has not been dispensed to the patient by the pharmacy in the same strength and dosage form within the last year. Note: If a transferred prescription has not been dispensed to the patient in the same strength and dosage form within the last year by the pharmacy who received the transfer, counseling would be required for the transferred prescription.
   Note: New prescription drug orders include prescriptions that have not been dispensed to the patient in the same strength and dosage form by the pharmacy.
within the past year, prescriptions that have been transferred from another
pharmacy, and discharge prescriptions from hospitals;

(2) Shall be provided for any prescription drug order dispensed by the pharmacy
on the request of the patient or patient’s agent;

(3) Shall be communicated orally in person unless the patient or patient’s agent is
not at the pharmacy or a specific communication barrier prohibits such oral
communication; and

(4) Shall be documented by recording the name of the patient, date of counseling,
prescription number, and initials or identification code of the pharmacist
providing the counseling in the prescription dispensing record as follows:

(a) on the original hard-copy prescription provided the counseling pharmacist
clearly records his or her initials on the prescription for the purpose of
identifying who provided the counseling;

(b) in the pharmacy’s data processing system (computer);

(c) in an electronic logbook; or

(d) in a hard-copy log; and

(5) Shall be reinforced with written information relevant to the prescription and
provided to the patient or patient’s agent. The following is applicable
concerning this written information.

(a) Written information must be in plain language designed for the patient,
and printed in an easily readable font size comparable but not smaller than
ten-point Times Roman. This information may be provided in an
electronic format such as e-mail, if the patient or patient’s agent requests
an electronic format and the pharmacy documents the request.

(b) When a compounded preparation is dispensed, information shall be
provided for the major active ingredient(s), if available.

(c) For new drug entities, if no written information is initially available, the
pharmacist is not required to provide information until such information
is available, provided:

(i) The pharmacist informs the patient or the patient’s agent that the
product is a new drug entity and written information is not available;

(ii) The pharmacist documents the fact that no written information was
provided; and

(iii) If the prescription is refilled after written information is available,
such information is provided to the patient or patient’s agent.

(d) The written information accompanying the prescription or the
prescription label shall contain the statement “Do not flush unused
medications or pour down a sink or drain.” A drug product on a list
developed by the Federal Food and Drug Administration of medicines
recommended for disposal by flushing is not required to bear this
statement.

c. Only a pharmacist may verbally provide drug information to a patient or patient’s
agent and answer questions concerning prescription drugs. Non-pharmacist
personnel may not ask questions of a patient or patient’s agent which are intended
to screen and/or limit interaction with the pharmacist.
d. Nothing herein shall be construed as requiring a pharmacist to provide consultation when a patient or patient’s agent refuses such consultation. The pharmacist shall document such refusal for consultation.

e. **Note:** This section describes procedures for delivering a completed prescription to a patient when the pharmacy department is closed. In addition to the requirements of subparagraphs a - d of this paragraph, if a prescription drug order is delivered to the patient at the pharmacy, the following is applicable:

(1) So that a patient will have access to information concerning his/her prescription, a prescription may not be delivered to a patient unless a pharmacist is in the pharmacy, except as provided above (Section 3. Temporary Absence of Pharmacist).

(2) Any prescription delivered to a patient when a pharmacist is not in the pharmacy must meet the requirements described in subparagraph h. of this paragraph.

(3) A Class A pharmacy shall make available for use by the public, a current or updated patient prescription drug information text or leaflets designed for the patient.

f. Except as specified in 3. above (Temporary Absence of Pharmacist), in the best interest of public health and to optimize drug therapy, upon delivery of a refill prescription, a pharmacist shall ensure that the patient or patient’s agent is offered information about the refilled prescription. Either a pharmacist or other pharmacy personnel shall inform the patient or patient’s agent that a pharmacist is available to discuss the patient’s prescription and provide information.

g. A pharmacy shall post a sign no smaller than 8.5 inches by 11 inches in clear public view at all locations in the pharmacy where a patient may pick up prescriptions. The sign shall contain the following statement in a font that is easily readable: “Do you have questions about your prescription? Ask the pharmacist.” Such notification shall be in both English and Spanish.

f. h. **Note:** This section describes procedures for providing drug information if a prescription is delivered when the pharmacy department is closed as described in section e. or when a prescription is delivered to a patient at his/her home or any other location. In addition to the requirements of subparagraphs a - c of this paragraph, if a prescription drug order is delivered to the patient or his/her agent at the patient’s residence or other designated location, the following is applicable:

(1) The information specified in subparagraph a. above of this paragraph shall be delivered with the dispensed prescription in writing.

(2) If prescriptions are routinely delivered outside the area covered by the pharmacy’s local telephone service, the pharmacy shall provide a toll-free telephone line which is answered during normal hours to enable communication between the patient and a pharmacist.

(3) The pharmacist shall place on the prescription container or on a separate sheet delivered with the prescription container in both English and Spanish the local and, if applicable, toll free telephone number of the pharmacy and the statement:

“Written information about this prescription has been provided for you. Please read this information before you take the medication. If you have questions
concerning this prescription, a pharmacist is available during normal business hours to answer these questions. at (insert phone number).”

(4) The pharmacy shall maintain and use adequate storage or shipment containers and use shipping processes to ensure drug stability and potency. Such shipping processes shall include the use of appropriate packaging material and/or devices to ensure that the drug is maintained at an appropriate temperature range to maintain the integrity of the medication throughout the delivery process.

(5) The pharmacy shall use a delivery system which is designed to assure that the drugs are delivered to the appropriate patient.

The provisions of this paragraph do not apply to patients in facilities where drugs are administered to patients by a person required to do so by the laws of the State (i.e., nursing homes; hospital inpatients).

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2. Out-of-date drugs or devices.
   Shall not be dispensed beyond the expiration date. Shall be removed from dispensing stock and shall be quarantined until disposed of properly; check stock regularly to ensure you don’t have expired drugs or devices on the shelf.

3. Non-Prescription C-Vs. Note: Although these rules are in place, there are no commercially available products available that can be sold as a non-prescription product in Texas. See Chapter B.

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G. Transfer of Prescription Drug Order Information
   For the purposes of initial or refill dispensing, the transfer of original prescription drug order information is permissible between pharmacies, subject to the following requirements:
   1. The transfer of original prescription drug order information for controlled substances listed in Schedule III, IV, or V is permissible between pharmacies on a one-time basis only. However, pharmacies electronically sharing a real-time, on-line database may transfer up to the maximum refills permitted by law and the prescribers authorization.
   2. The transfer of original prescription drug order information for dangerous drugs is permissible between pharmacies without limitation up to the number of originally authorized refills.
   3. The transfer is communicated orally or by telephone or via facsimile directly by a pharmacist to another pharmacist; by a pharmacist to a student intern, extended intern, or resident intern or by a student intern, extended intern, or resident intern to another pharmacist. Note: transfer between interns is not allowed.
   4. Both the original and the transferred prescription drug orders are maintained for a period of two years from the date of last refill.
   5. The individual transferring the prescription drug order information shall ensure the following occurs:
a. the word “void” is written on the face of the invalidated prescription or the prescription is voided in the computer system
b. record the name, address, if for a controlled substance, the DEA registration number of the pharmacy to which it is transferred and the name of the individual on the reverse of the invalidated prescription or stored with the invalidated prescription drug record in the data processing system.
c. record the date of the transfer and the name of the individual transferring the information; and
d. if the prescription is transferred electronically, provide the following:

   (1) the date of original dispensing and prescription number;
   (2) number of refills remaining and the date(s) and location(s) of previous refills;
   (3) name, address, and if for a controlled substance, the DEA registration number of the transferring pharmacy;
   (4) name of the individual transferring the prescription; and
   (5) if a controlled substance, the name address and DEA registration number, and prescription number from the pharmacy that originally dispensed the prescription, if different.

the following information is recorded on the reverse of the invalidated prescription drug order or is stored with the invalidated prescription drug order in the computer system:

   (1) the name, address, and if a controlled substance, the DEA registration number of the pharmacy to which such prescription is transferred;
   (2) the name of the individual receiving the prescription drug order information;
   (3) the name of the individual transferring the prescription drug order information;

6. The individual receiving the prescription drug order information shall ensure the following occurs:

   a. write the word “transfer” is written on the prescription or the prescription record in the computer system indicates the prescription was a transfer; and
   b. reduce to writing all of the information required to be on a prescription as specified in subsection B.7 of this section (related to prescriptions); and including the following information:

      (1) date of issuance and prescription number;
      (2) original number of refills authorized on the original prescription drug order;
      (3) date of original dispensing;
      (4) number of valid refills remaining and date(s) and location(s) of previous refills;
      (5) name, address, and if for a controlled substance, the DEA registration number of the transferring pharmacy;
      (6) name of the individual transferring the prescription; and if a controlled substance, the name address and DEA registration number, and prescription number from the pharmacy that originally dispensed the prescription, if different;

   or

   c. if the prescription transferred electronically, create an electronic record for the prescription that includes the receiving pharmacist’s name and all of the information required to be on a prescription as specified in subsection B.7 of this section (related to prescriptions); and including the following information:
(1) the date of original dispensing;
(2) number of refills remaining and the date(s) and location(s) of previous refills;
(3) name, address, and if for a controlled substance, the DEA registration number;
(4) name of the individual transferring the prescription; and
(5) if a controlled substance, the name address and DEA registration number of the pharmacy that originally dispensed the prescription.

b. the following information is recorded on the prescription drug order or is stored with the prescription drug order in the computer system:
   date of issuance;
(2) original prescription number and the number of refills authorized on the original prescription drug order;
(3) number of valid refills remaining and the date of the last refill, if applicable;
(4) name, address, and if a controlled substance, the DEA registration number of the pharmacy from which such prescription drug order information is transferred; and
(5) name of the individual transferring the prescription drug order information.

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 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.

8. Pharmacies using a data processing (computer) system transferring a prescription electronically shall comply with the following:
   a. Prescription drug orders may not be transferred by non-electronic means during periods of downtime except on consultation with and authorization by a prescribing practitioner; provided however, during downtime, a hard copy of a prescription drug order may be made available for informational purposes only, to the patient, a pharmacist or pharmacist intern, and the prescription may be read to a pharmacist or pharmacist intern by telephone.
   b. The original prescription drug order shall be invalidated in the data processing system for purposes of filling or refilling, but shall be maintained in the data processing system for refill history purposes.
   c. If the data processing system does not have the capacity to store all the information as specified required in subparagraphs 5. and 6. of this paragraph, the pharmacist is required to record this information on the original or transferred prescription drug order.
   d. The data processing system shall have a mechanism to prohibit the transfer or refilling of controlled substance prescription drug orders which have been previously transferred.
   e. Pharmacies electronically accessing the same prescription drug order records may electronically transfer prescription information if the following requirements are met.
(1) The original prescription is voided and the pharmacies’ data processing systems shall store all the information as specified required in paragraphs 5. and 6 of this paragraph.

(2) Pharmacies not owned by the same person may electronically access the same prescription drug order records, provided the owner or chief executive officer of each pharmacy signs an agreement allowing such access to such prescription drug order records.

(3) An electronic transfer between pharmacies may be initiated by a pharmacist intern, pharmacy technician or pharmacy technician trainee acting under the direct supervision of a pharmacist.

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 done in a timely manner. 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. The electronic transfer of multiple or bulk prescription records between two pharmacies is permitted provided:

   a. a record of the transfer as specified in paragraph (5) of this section is maintained by the transferring pharmacy;

   b. the information specified in paragraph 6. of this subsection is maintained by the receiving pharmacy; and

   c. in the event that the patient or patient's agent is unaware of the transfer of the prescription drug order record, the transferring pharmacy must notify the patient or patient's agent of the transfer and must provide the patient or patient's agent with the telephone number of the pharmacy receiving the multiple or bulk prescription drug order records.

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Section 562.153 Requirements for Office Compounding
To dispense and deliver a compounded drug under Section 562.152, a pharmacy must:
A. Verify the source of the raw materials to be used in a compounded drug;
B. Comply with applicable United States Pharmacopoeia guidelines, including the testing requirements, and the Health Insurance Portability and Accountability Act of 1996.
C. Comply with all applicable competency and accrediting standards as determined by the Board; and
D. Comply with Board rules, including rules regarding the reporting of adverse events by practitioners and recall procedures for compounded products.
Note: These provisions for office use compounding should be read in conjunction with the new federal law on compounding, the Drug Compounding Quality Act. See Chapter A, Section XV. A.7.
Non-Sterile Compounding

Note: These non-sterile compounding provisions, particularly those sections dealing with office use compounding, should be read in conjunction with the new federal law on compounding, the Drug Compounding Quality Act. See Chapter A. Section XV. A.7.

§291.131. Pharmacies Compounding Non-Sterile Preparations.
(a) Purpose. Pharmacies compounding non-sterile preparations, prepackaging pharmaceutical products and distributing those products shall comply with all requirements for their specific license classification and this section. The purpose of this section is to provide standards for the:

1. compounding of non-sterile preparations pursuant to a prescription or medication order for a patient from a practitioner in Class A (Community), Class C (Institutional), and Class E (Non-resident) pharmacies;
2. compounding, dispensing, and delivery of a reasonable quantity of a compounded non-sterile preparation in a Class A (Community), Class C (Institutional), and Class E (Non-resident) pharmacies to a practitioner’s office for office use by the practitioner;
3. compounding and distribution of compounded non-sterile preparations by a Class A (Community) pharmacy for a Class C (Institutional) pharmacy; and
4. compounding of non-sterile preparations by a Class C (Institutional) pharmacy and the distribution of the compounded preparations to other Class C (Institutional) pharmacies under common ownership.

Sterile Compounding

See also provisions of the 2013 Compounding Quality Act in Section A of this book. Note: these sterile compounding provisions, particularly those sections dealing with office use compounding, should be read in conjunction with the new federal law on compounding, the Drug Compounding Quality Act. See Chapter A. Section XV. A.7. Pharmacies compounding sterile products that are not for identified individual patients pursuant to a valid prescription or order may also need to register with FDA as an Outsourcing Facility or risk being considered a manufacturer by FDA.

§291.133 Pharmacies Compounding Sterile Preparations.
(a) Purpose. Pharmacies compounding sterile preparations, prepackaging pharmaceutical products, and distributing those products shall comply with all requirements for their specific license classification and this section. The purpose of this section is to provide standards for the:

1. compounding of sterile preparations pursuant to a prescription or medication order for a patient from a practitioner in Class A-S, Class B-S, Class C-S, and Class E-S pharmacies;
(2) compounding, dispensing, and delivery of a reasonable quantity of a compounded sterile preparation in Class A-S, Class B-S, Class C-S, and Class E-S pharmacies to a practitioner’s office for office use by the practitioner;

(3) compounding and distribution of compounded sterile preparations by a Class A-S pharmacy for a Class C-S pharmacy; and

(4) compounding of sterile preparations by a Class C-S pharmacy and the distribution of the compounded preparations to other Class C or Class C-S pharmacies under common ownership.

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(ii) All pharmacy technicians and pharmacy technician trainees who compound sterile preparations for administration to patients shall comply with the following:

(I) have initial training obtained either through the completion of:

(I) (-a-) complete through completion of a single course, a minimum of 40 hours of instruction and experience in the areas listed in paragraph (4)(D) of this subsection. Such training shall be obtained through completion of a course sponsored by an ACPE accredited provider which provides 40 hours of instruction and experience in the areas listed in paragraph (4)(D) of this subsection; or

(-b-) A training program which is accredited by the American Society of Health-System Pharmacists.

(II) And

(II) (-a-) complete a structured on-the-job didactic and experiential training program at this pharmacy which provides 40 hours of instruction and experience in the facility’s compounding policies and procedures. Areas listed in paragraph (4)(D) of this subsection. Such training may not be transferred to another pharmacy unless the pharmacies are under common ownership and control and use a common training program; and

(III) (-b-) possess knowledge about:

(a) (-1-) aseptic processing;

(b) (-2-) quality control and quality assurance as related to environmental, component, and finished preparation release checks and tests;

(c) (-3-) chemical, pharmaceutical, and clinical properties of drugs;

(d) (-4-) container, equipment, and closure system selection; and

(e) (-5-) sterilization techniques.

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O. Medication order – A written order from a practitioner or a verbal order from a practitioner or his/her authorized agent for administration of a drug or device, usually to an inpatient.
M. **Number of Beds** - The total number of beds is determined by the number of beds for which the hospital is licensed by the Texas Department of State Health Services or average daily census as calculated by dividing the total number of inpatients admitted during the previous calendar year by 365 (or 366 if the previous calendar year is a leap year).

N. **Part-time pharmacist** – A pharmacist either employed or under contract, who routinely works less than full-time.

*Editing Note: Re-letter remainder of definitions.*

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**CLASS C PHARMACIES LOCATED IN A FREE STANDING AMBULATORY SURGICAL CENTER RULES**

§291.76 Class C Pharmacies Located in a Free Standing Ambulatory Surgical Center (ASC)

Rules governing ASC pharmacies are substantively similar as for Institutional (Class C) pharmacy rules, with the following exceptions:

A. **Personnel and Licensing**

1. **Pharmacist-in-charge.** Each ASC pharmacy shall have one pharmacist-in-charge who is employed or under contract, at least on a consulting or part-time basis, but may be employed on a full-time basis.

2. **Consultant.** A written contract shall exist between the ASC and any consultant pharmacist and a copy of the written contract shall be made available to the Board upon request. The consultant pharmacist may be the pharmacist-in-charge.

3. **An ASC pharmacy shall not compound sterile preparations unless it has applied for and obtained a Class C-S pharmacy license.**

B. **Environment.**

1. **General requirements (ASC has only two general requirements for environment).**
   a. Each ambulatory surgical center shall have a designated work area separate from patient areas (different from Class C Rules), and which shall have space adequate for the size and scope of pharmaceutical services and shall have adequate space and security for the storage of drugs.
   b. The ASC pharmacy shall be arranged in an orderly fashion and shall be kept clean. All required equipment shall be clean and in good operating condition.

2. **Special requirements – Basically the same as Class C.**

3. **Security.**
   a. Only authorized personnel may have access to storage areas for prescription drugs and/or devices.
   b. All storage areas for prescription drugs and/or devices shall be locked by key or combination so as to prevent access by unauthorized personnel.
   c. The pharmacist-in-charge shall consult with ASC personnel with respect to security of the drug storage areas, including provisions for adequate safeguards against theft or diversion of prescription drugs and/or devices.

3. **Library.** A reference library shall be maintained which includes:
   a. Current copy of laws and regulations
b. At least one current or updated reference from each of the following categories:

1. Drug interactions
2. General drug information reference book
3. Reference on injectable drug products
4. Basic antidote information and the telephone number of the nearest poison control center; and
5. Metric-Apothecary weights and measures conversion charts

B. Library.

A reference library shall be maintained which includes:

1. Laws: same as for Class A and C Pharmacies.
2. The following current or updated references:
   a. “American Hospital Formulary Service” with current supplements or “Facts and Comparisons” with current supplements; and
   b. A reference on injectable drug products, such as “Handbook on Injectable Drugs” (if sterile parenteral or enteral products are compounded in the facility).
3. Basic antidote information and the telephone number of the nearest regional poison control center.

C. Policies and Procedures.

Written policies and procedures shall be established by the pharmacist-in-charge with the advice of the appropriate committee for a drug distribution system.

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F. Drugs Supplied for Postoperative Use.

1. May only be supplied to patients who have been admitted to the ASC.
2. May only be supplied in accordance with the system of control and accountability for drugs supplied from the ASC.
3. Only drugs on the approved postoperative drug list may be supplied; such list shall consist of drugs to meet the immediate postoperative needs of the ASC patient.
4. Drugs may only be supplied in prepackaged quantities not to exceed a 72-hour supply in suitable containers and appropriately prelabeled (including name, address, phone number (of the facility), and necessary auxiliary labels) by the pharmacy provided, however, that topicals and ophthalmics in original manufacturer’s containers may be supplied in a quantity exceeding a 72-hour supply.

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4. Ratio of authorized nuclear pharmacists to pharmacy technicians and pharmacy technician trainees.
   a. The ratio of authorized nuclear pharmacists to pharmacy technicians and pharmacy technician trainees may be 1:4 1:3, provided at least one of the four technicians is a pharmacy technician and is trained in the handling of radioactive materials.
   b. The ratio of authorized nuclear pharmacies to pharmacy technician trainees may not exceed 1:3 1:2.

Note: At the time of publication of this book the Board of Pharmacy had proposed increasing the ratio of pharmacists to pharmacy technicians to 1:4. The new rules were expected to be adopted at the Board’s February 2014 meeting.
c. Special requirements for compounding non-sterile preparations.
   (1) Non-Sterile Preparations. All pharmacists engaged in compounding non-sterile preparations shall meet the training requirements specified in 291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations).
   (2) Sterile Preparations. All pharmacists engaged in compounding sterile preparations shall meet the training requirements specified in 291.133 of this title (relating to Pharmacies Compounding Sterile Preparations).

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b. Duties. Duties may include, but need not be limited to, the following functions, under the direct supervision of a pharmacist:
   (1) prepacking and labeling unit and multiple dose packages, provided a pharmacist supervises and conducts a final check and affixes his or her name, initials, electronic signature to the appropriate quality control records prior to distribution;
   (2) preparing, packaging, compounding, or labeling prescription drugs pursuant to medication orders, provided a pharmacist supervises and checks the preparation;
   (3) compounding non-sterile preparations pursuant to medication orders provided the pharmacy technicians or pharmacy technician trainees have completed the training specified in 291.131 of this title;
   (4) compounding sterile preparations pursuant to medication orders provided the pharmacy technicians or pharmacy technician trainees:
      (a) have completed the training specified in 291.133 of this title; and
      (b) are supervised by a pharmacist who has completed the sterile preparations training specified in 291.133 of this title, conducts in-process and final checks, and affixes his or her name, initials, or electronic signature to the label or if batch prepared to the appropriate quality control records. (The name, initials, or electronic signature are not required on the label if it is maintained in a permanent record of the pharmacy.)
   (4) bulk compounding, provided a pharmacist supervises and conducts in-process and final checks and affixes his or her name, initials, or electronic signature to the appropriate quality control records prior to distribution;
   (5) distributing routine orders for stock supplies to patient care areas;
   (6) entering medication order and drug distribution information into a data processing system, provided judgmental decisions are not required and a pharmacist checks the accuracy of the information entered into the system prior to releasing the order or in compliance with the absence of pharmacist requirements contained in subsection (d)(6)(E) and (F) of this section;
   (7) maintaining inventories of drug supplies;
   (8) maintaining pharmacy records; and
   (9) loading bulk unlabeled drugs into an automated drug dispensing system provided a pharmacist supervises, verifies that the system was properly
loaded prior to use, and affixes his or her name, initials or electronic signature to the appropriate quality control records.

c. Procedures.
(1) Pharmacy technicians and pharmacy technician trainees shall handle medication orders in accordance with standard written procedures and guidelines.

(2) Pharmacy technicians and pharmacy technician trainees shall handle prescription drug orders in the same manner as pharmacy technicians or pharmacy technician trainees working in a Class A pharmacy.

d. Special requirements for non-sterile compounding.
(1) Non-Sterile Preparations. All pharmacy technicians and pharmacy technician trainees engaged in compounding non-sterile preparations shall meet the training requirements specified in 291.131 of this title.

(2) Sterile Preparations. All pharmacy technicians and pharmacy technician trainees engaged in compounding sterile preparations shall meet the training requirements specified in 291.133 of this title.

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i. A FEMCC pharmacy engaged in the compounding of non-sterile preparations shall comply with the provisions of 291.131 of this title.

j. A FEMCC pharmacy engaged in the compounding of sterile preparations shall comply with the provisions of 291.133 of this title.

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4. Library. A reference library shall be maintained that includes the following in hard-copy or electronic format and that pharmacy personnel shall be capable of accessing at all times:

a. current copies of the following:
(1) Texas Pharmacy Act and rules;
(2) Texas Dangerous Drug Act and rules;
(3) Texas Controlled Substances Act and rules; and
(4) Federal Controlled Substances Act and rules or official publication describing the requirements of the Federal Controlled Substances Act and rules;

b. at least one current or updated reference from each of the following categories:
(1) Drug interactions. A reference text on drug interactions, such as Drug Interaction Facts. A separate reference is not required if other references maintained by the pharmacy contain drug interaction information including information needed to determine severity or significance of the interaction and appropriate recommendations or actions to be taken;

(2) General information. A general information reference text, such as:
(a) Facts and Comparisons with current supplements;
(b) United States Pharmacopeia Dispensing Information Volume I (Drug Information for the Healthcare Provider);
(c) AHFS Drug Information with current supplements;
(d) Remington’s Pharmaceutical Sciences; or
(e) Clinical Pharmacology;
c. a current or updated reference on injectable drug products, such as Handbook of Injectable Drugs;
d. basic antidote information and the telephone number of the nearest regional poison control center; and
e. if the pharmacy compounds sterile preparations, specialty references appropriate for the scope of services provided by the pharmacy, e.g., if the pharmacy prepares cytotoxic drugs, a reference text on the preparation of cytotoxic drugs, such as Procedures for Handling Cytotoxic Drugs.

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h. drugs brought into the facility by the patient;
i. self-administration;
j. emergency drug tray;
k. formulary, if applicable;
l. drug storage areas;
m. drug samples;
n. drug product defect reports;
o. drug recalls;
p. outdated drugs;
q. preparation and distribution of IV admixtures;
r. procedures for supplying drugs for postoperative use, if applicable;
s. use of automated drug dispensing systems; and
t. use of data processing systems.

9. Drugs supplied for outpatient use. Drugs supplied to patients for outpatient use shall be supplied according to the following procedures.
a. Drugs may only be supplied to patients who have been admitted to the freestanding emergency medical center.
b. Drugs may only be supplied in accordance with the system of control and accountability established for drugs supplied from the freestanding emergency medical center; such system shall be developed and supervised by the pharmacist-in-charge or staff pharmacist designated by the pharmacist-in-charge.
c. Only drugs listed on the approved outpatient drug list may be supplied; such list shall be developed by the pharmacist-in-charge and the medical staff and shall consist of drugs of the nature and type to meet the immediate postoperative needs of the freestanding emergency medical center patient.
d. Drugs may only be supplied in prepackaged quantities not to exceed a 72-hour supply in suitable containers and appropriately prelabeled (including name, address, phone number of the facility, and necessary auxiliary labels) by the pharmacy, provided, however that topicals and ophthalmics in original
manufacturers’ containers may be supplied in a quantity exceeding a 72-hour supply.

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d. Records of controlled substances listed in Schedule II shall be maintained as follows.
(1) Records of controlled substances listed in Schedule II shall be maintained separately from records of controlled substances in Schedules III, IV, and V, and all other records.
(2) A FEMCC pharmacy shall maintain a perpetual inventory of any controlled substance listed in Schedule II.
(3) Distribution records for Schedule II - V controlled substances floor stock shall include the following information:
   (a) patients name;
   (b) practitioner who ordered drug;
   (c) name of drug, dosage form, and strength;
   (d) time and date of administration to patient and quantity administered;
   (e) signature or electronic signature of individual administering controlled substance;
   (f) returns to the pharmacy; and
   (g) waste (waste is required to be witnessed and cosigned, manually or electronically, by another individual).
(4) The pharmacist shall verify each distribution after a reasonable interval but in no event may such interval exceed 7 days.

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(2) The record required by clause (i) of this subparagraph shall be maintained separately from patient records.
(3) The pharmacist shall verify each distribution after a reasonable interval but in no event may such interval exceed 7 days.
(4) A pharmacist shall review distribution records with medication orders on a periodic basis to verify proper usage of drugs, not to exceed 30 days between such reviews. Note: This is a requirement to conduct a general drug use review every 30 days as opposed to the requirement in (3) which is to review each distribution within 7 days to ensure that the proper drug was provided.
f. General requirements for records maintained in a data processing system are as follows.
c. Ratio of on-site pharmacist’s to pharmacy technicians and pharmacy technician trainees. A Class G pharmacy may have a ratio of pharmacists to pharmacy technicians and pharmacy technician trainees of 1:8.6 provided:
(1) at least seven five are pharmacy technicians and not pharmacy technician trainees; and
(2) the pharmacy has written policies and procedures regarding the supervision of pharmacy technicians and pharmacy technician trainees.

Note: The ratio for Class G only allows one technician to be a technician trainee. At the time of publication of this book the Board of Pharmacy had proposed increasing the ratio of pharmacists to pharmacy technicians in a Class G to 1:8. The new rules were expected to be adopted at the Board’s February 2014 meeting.

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