Drug Compounding Outsourcing Facilities

As Required by

2018-19 General Appropriations Act, Senate Bill 1, 85th Legislature, Regular Session, 2017 (Article II, Department of State Health Services, Rider 40)

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Contents

Executive Summary

Drug compounding is one type of mixing ingredients together to make drugs. It occurs in a facility which is not designated as a drug manufacturing facility. Drug compounding might occur in a setting like a pharmacy, a physician's office, or a special facility, called a compounding outsourcing facility. It occurs in a variety of settings and for a variety of reasons.

Usually, drug compounding in a pharmacy setting is the process of a pharmacist making a unique drug in response to a prescription written for a specific individual who needs a modified version of an FDA-approved drug. It may also include a pharmacist making an FDA-approved drug in response to a shortage of drugs produced by designated drug manufacturing facilities. In recent years, certain pharmacies have moved from patient-specific, prescription-based drug compounding to large-scale compounding of sterile drugs created for future use by unspecified patients. In this new large-scale (mass producing) process, distribution of the compounded drug to the patient is done by a health care practitioner, a clinic, or a health care facility setting or system.

With the increased distribution of mass-produced compounded drugs, there has been a rise in the number of adverse events from these drugs, including patient harm and death. As a result of actual public harm and the ongoing potential threat to public health, Congress created a new category for these large-scale operations, known as the compounding outsourcing facilities.

Texas laws have not yet been updated to include the regulation of compounding outsourcing facilities, and there are some specific issues in Texas laws which create misalignment and conflict with federal law and regulations. The 2018-19 General Appropriations Act, S.B. 1, 85th Legislature, Regular Session, 2017 (Article II, Department of State Health Services (DSHS), Rider 40) called on DSHS to examine how to: (1) achieve better alignment between state and federal regulations related to drug compounding; (2) achieve better compliance with the Drug Quality and Security Act; and (3) minimize regulatory overlap.

In compliance with this requirement, the DSHS reviewed current statutes, rules, regulations, and licensing procedures for compounding facilities. This review also examined direct dispensing to patients. In this review, inconsistencies and conflicts between federal and state law were considered. DSHS also consulted with the

Texas State Board of Pharmacy on current processes and the proposed recommendations included in this report.

In light of the past public harm and the potential for continued threats to public health, DSHS recommends that an outsourcing facility not be authorized to dispense compounded drugs directly to a patient.

In order to accommodate the federal minimum requirements regarding compounding outsourcing facilities, DSHS recommends the following:

- Require DSHS to regulate compounding outsourcing under a specific license category outlined in Texas Health and Safety Code, Chapter 431, with related changes also made in Chapter 483. Such a change should involve requiring compounding, community, and institutional pharmacies to either:
  - Identify solely as a pharmacy and be limited to pharmacy compounding practices consistent with Section 503A of the federal Food Drug and Cosmetic Act; or
  - Register as a compounding outsourcing facility and follow Section 503B of the federal Food Drug and Cosmetic Act.
- Define compounding outsourcing within the context of the practice of pharmacy, creating a clear line between the two actions in Texas Occupations Code, Chapters 551-566 and 568-569, and providing appropriate latitude for the Texas State Board of Pharmacy to adopt federal law by reference in the Texas Administrative Code to create this clear line.
- Resolve conflicts between federal and state law relating to the distribution of drugs by non-registered outsourcing facilities by amending Texas Occupations Code, Chapter 562, to specifically repeal or modify Section 562.151, 562.152, and 562.153.
- Allow DSHS authority to extend to pharmacies engaged in activities that appear to meet criteria of drug manufacturing facilities or drug compounding outsourcing facilities by repealing certain language in Texas Health and Safety Code, Chapter 431, specifically Section 431.002(23).

The clarification of state laws as consistent with Section 503A and Section 503B of the Federal Food, Drug, and Cosmetic Act allows for better patient protection, as well as possible protection of the Texas industry's reputation and place in the larger pharmaceutical market.

1. Introduction

The drug compounding marketplace has evolved in the last decade. It has gone from being centered in the physician's office or the traditional pharmacy, to mass-production and wide distribution of compounded drugs to unspecified patients by non-traditional facilities. The poor manufacturing and quality practices of certain non-traditional compounding facilities have produced some substandard, large-scale batches of medications, creating health problems or adverse events for patients to whom these drugs have been administered.

In September 2012, a large fungal meningitis outbreak was linked to a compounded drug. Congress passed the Drug Quality and Security Act (DQSA) of 2013 to address the risks to public health from this new large-scale compounding practice.[1] The DQSA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) (Title 21, U.S.C, Section 353b) by creating a new category for large-scale drug compounding operations called outsourcing facilities. The addition of Section 503B of the FD&C Act included regulations for drug compounding outsourcing facilities, which are distinct from requirements for pharmacies engaged in compounding (Section 503A of the FD&C Act).

Several key Texas laws have not yet been updated to incorporate federal requirements for compounding outsourcing facilities, and there are some existing conflicts between state and federal law. This lack of alignment can create challenges to provide clear direction to regulated entities, when enforcing relevant laws, and in protecting public health.

As a result of these issues, the 2018-19 General Appropriations Act, S.B. 1, 85th Legislature, Regular Session, 2017 (Article II, Department of State Health Services (DSHS), Rider 40) called on DSHS to conduct a review of rules, regulations, and licensing procedures for drug compounding outsourcing facilities registered under Section 503B of the FD&C Act.[2]

[1] Pub.L. No. 113-54, Section 102(a)
[2] 21 U.S.C. 353b

In its review, DSHS shall examine how to: (1) achieve better alignment between state and federal regulations; (2) achieve better compliance with the DQSA;[3] and (3) minimize regulatory overlap.

DSHS shall report findings and recommendations regarding rules, regulations, and licensing procedures for compounding outsourcing facilities to the legislature no later than January 1, 2019. Additionally, if the study contemplates the ability of a drug compounding outsourcing facility to dispense directly to a patient, the report, under Subsection (c) of this provision, shall include proposed recommended outsourcing facility licensing requirements that comply with rules adopted by the Texas State Board of Pharmacy.

DSHS has worked closely with the Texas Board of Pharmacy to make a determination about which state agency should regulate drug compounding outsourcing facilities and how these agencies should best consult and collaborate with one another.

[3] Pub. L. No. 113-54, Section 102(a)

2. Background

All drugs in the United States must go through a rigorous drug approval process by the Food and Drug Administration (FDA) as governed under the Federal Food, Drug, and Cosmetic Act (FD&C Act), Title 21, Chapter 9, Section 505 of the United States Code (U.S.C.), unless otherwise exempted. Section 505 addresses New Drug Approval processes.

Drug manufacturing facilities are registered with the FDA and are licensed in Texas by the Department of State Health Services (DSHS). Every step of a drug manufacturing process by an FDA-registered pharmaceutical company is stringently controlled and subject to regulatory inspections. The drugs produced are made using FDA-approved drug formulas and are required by law to be proven safe and effective through product testing and other means. Among other safeguards, the drug must be proven to be uniform in dose and to have been kept sterile. In addition to other minimum requirements, one of the tools for quality control that the FDA requires drug manufacturers to use are "Current Good Manufacturing Practices" (CGMPs) to ensure the drugs are of highest predictable quality.

Unlike FDA-registered drug manufacturing facilities that are also required to be licensed by the DSHS, some facilities in Texas that mass-produce compounded drugs are not adequately regulated by DSHS. Limited regulation and enforcement authority with certain compounding outsourcing facilities restricts the agency's role in protecting the health of Texans.

Drug Compounding

Drug compounding is one type of mixing ingredients together to make drugs. It occurs in a facility which is not designated as a drug manufacturing facility. Drug compounding might occur in a setting like a pharmacy, a physician's office, or a special facility, called a compounding outsourcing facility. Usually, drug compounding in a pharmacy setting is the process of a pharmacist[4] making a unique drug in response to a prescription written for a*n identified individual* who needs a modified version of an FDA-approved drug. Traditionally, drug compounding has been limited to the context of an identified patient-physician-

[4] Or by a pharmacy technician under the supervision of a pharmacist.

pharmacy relationship. Compounding of a drug has been initiated only when there is a specific or predicted prescription for an identified individual made by a specific physician to a specific pharmacy.

To meet the special needs of individual patients,[5] one need for drug compounding outside of a manufacturing facility is to mix drugs and other ingredients together in formulas that are not in final FDA-approved form. For many reasons, some individuals with unique health needs are not able to take certain FDA-approved drugs. For example, a patient may have an allergy to an inactive ingredient, such as a preservative or dye, in a commercially-available drug and need a version which does not contain that inactive ingredient. Also, certain patients may require a dose of a drug which is different than the one approved by the FDA because of an injury or illness in an organ such as the heart or liver. Historically, this compounding has occurred in physicians' offices or pharmacies to address individual patient needs.

Another need for drug compounding is in response to a widespread shortage of FDA-approved, sterile, finished prescription drugs being produced by drug manufacturers. This second need involves a non-drug-manufacturing facility that uses bulk active ingredients to create FDA-approved drug formulas in response to a limited supply. Supply may be limited by available drug manufacturing facilities' production schedules or by the cost of drugs purchased from a manufacturing facility.

A third aspect of drug compounding has to do with the packaging, labeling, and distribution or redistribution of the specially-made drug outside of the facility where it was made. Under certain circumstances, a compounded drug may be relabeled, repackaged, and/or redistributed by an entity other than the one which created it.

Compounding sterile drugs is extremely complex. Laws, rules, and standards for pharmacy drug compounding affirm the important role of pharmacies in individual patient treatment and consider practical constraints. Unlike traditional drug manufacturing standards, each step of the compounding process in a pharmacy does not require proof to ensure the integrity and sterility of the final product. In most cases, proof might be prohibitively restrictive.

At the state level, quality control is generally demonstrated through supervision by a pharmacist and completion of a checklist indicating that each step was performed. Absent environments and processes found in a drug manufacturing facility, it is

[5] As defined in the Texas Pharmacy Act (Texas Occupations Code 551.003(9)).

more difficult to ensure quality control of the drugs compounded in traditional pharmacies.

Drug Compounding Outsourcing Facilities

Drug compounding outsourcing facilities are a hybrid between drug manufacturers and traditional pharmacies. In recent years, certain pharmacies have moved from patient-specific, prescription-based drug compounding to large-scale compounding of sterile drugs created for future use by unspecified patients. In this new large-scale (mass producing) process, distribution of the compounded drug to a patient is done by a health care practitioner, a clinic, or a health care facility setting or system. These drugs are distributed nationwide to clinics and healthcare facilities. There are currently ten FDA-registered outsourcing facilities in Texas.

Outsourcing facilities have regulatory requirements which are more stringent than for pharmacy compounding but less stringent than for traditional drug manufacturers. Like drug manufacturers but unlike pharmacies, compounding outsourcing facilities are required to meet certain Current Good Manufacturing Practices" (CGMPs). The FDA indicates that these practices "contain requirements for facility design, training and qualified staff, control of incoming components, aseptic processing, air quality, environmental monitoring, and related requirements designed to ensure the quality of the finished drug product,"[6] and provide for better protection of the health and safety of the public.

On September 7, 2018, the FDA issued a statement expressing concerns regarding drug compounding and outsourcing facilities, a practice that the FDA anticipates will continue to grow. The FDA expressed the need for its collaboration with state governments to address the issue that the FDA continues to identify insanitary conditions during many inspections of compounding facilities.[7]

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[6] *Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act: Guidance for Industry*. Center for Drug Evaluation and Research, Food and Drug Administration, May 2018. Retrieved from: www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM496288.pdf

[7] *Statement from FDA Commissioner Scott Gottlieb, M.D., on new steps to help ensure the quality of and preserve access to compounded drugs by pursuing closer collaboration with states.* U.S. Food and Drug Administration, September 7, 2018. Retrieved from: www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm619796.htm

3. Regulatory and Statutory Overview for Compounding Outsourcing Facilities

Federal Level

Under 21 U.S.C. 355 (505), a person may not introduce or deliver any new drug into commerce unless the new drug's application has been approved. Once a drug has been approved, the drug must be produced in accordance with 21 USC, Chapter 9, Subchapter V, Part A (Drugs and Devices) and respective federal regulations. Congress created two exceptions for compounded drugs with the adoption of Sections 503A and 503B of the Federal Food, Drug and Cosmetic (FD&C) Act.

The pharmacy compounding process is regulated at the federal level in Section 503A of the FD&C Act (Title 21, U.S.C, Section 353a). Section 503A describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist in a state-licensed pharmacy. The law requires that the compounded drug must be for an identified individual patient pursuant to a prescription from a health care practitioner. A drug can only be compounded in anticipation of receiving a patient specific prescription, and only in limited quantities.[8] The prescription requirement under Section 503A was established to ensure drug products compounded by a licensed pharmacy are provided to a patient based on individual patient need. Following the process in Section 503A allows for exemption from certain requirements that other drugs must meet for approval by the Food and Drug Administration (FDA).

The Drug Quality and Security Act (DQSA), signed into law on November 27, 2013, created Section 503B, in the FD&C Act. Under Section 503B, a compounder can become an outsourcing facility. The law defines an outsourcing facility as a facility at one geographic location or address that is engaged in the compounding of sterile drugs, has elected to register as an outsourcing facility, and complies with all of the requirements of Section 503B.

Drug compounding outsourcing facilities can compound and distribute drugs without receiving prescriptions for individually identified patients. These facilities can also ship their products through interstate commerce without limitation on the quantity

[8] 21 USC Section 353a(a)(1).

of drugs they ship, but 503B prohibits wholesaling of compounded drugs so that only the outsourcing facility is able to sell or transfer its own compounded product.[9]

Drugs compounded by outsourcing facilities are not FDA-approved, meaning the FDA does not verify the safety or effectiveness of the compounded drugs. Drugs compounded by an outsourcing facility can qualify for exemptions from FDA approval requirements and the requirement to label products with adequate directions for use, and must comply with "Current Good Manufacturing Practices" (CGMPs) requirements. Entities must also meet certain other conditions, such as reporting adverse events and providing the FDA with certain information about the products they compound. Not meeting these requirements may place an entity out of compliance with the law.

Outsourcing facilities are not required to be licensed pharmacies. However, these facilities can get pharmacy licenses, if they choose, in addition to being outsourcing facilities. If a firm is both an outsourcing facility and a pharmacy, the production of compounded products defaults to the more stringent compounding practices.

State Level

Pharmacy practice, which is regulated at the state level by the Texas State Board of Pharmacy, has rigorous compounding requirements. As defined in the Texas Pharmacy Act, pharmacy compounding is the process of mixing drugs and other ingredients to create a unique drug for a patient. A compounded drug can only be made by a pharmacy after obtaining a prescription from a doctor. The compounded product must be made only for one person at the time the patient's prescription is received. A pharmacy is allowed to compound drug products in anticipation of receiving an individual's prescription as long as there is a history of prescribing for the patient.[10]

Under state law (Texas Occupations Code, Section 562.151), retail and institutional pharmacies are given the authority to compound non-patient-specific drugs[11] for distribution by health care providers for "office use." Texas Occupations Code, Section 562.151(1) of the Texas Pharmacy Act, defines office use as "…the provision and administration of a compounded drug to a patient by a practitioner in the practitioner's office or by the practitioner in a health care facility or treatment

[9] Section 503B(a)(8)
[10] Texas Occupations Code Chapter 551
[11] Meaning they are not for an identified individual.

setting, including a hospital, ambulatory surgical center, or pharmacy in accordance with Chapter 563." Under Texas State Board of Pharmacy rules, a large batch may be a "reasonable quantity" for a hospital or surgical center.

In addition, a Texas Supreme Court case Randol Mill Pharmacy v. Miller held that a pharmacist who compounds a drug for office use, as authorized by the Texas Pharmacy Act, is "dispensing a drug, whether or not the order identifies a patient." The court's decision did not take into consideration the Health and Safety Code definition of manufacturing, which only exempts patient specific compounding; thereby, supporting the larger scale compounding by pharmacies." [12]

As stated previously, drug manufacturing facilities are licensed in Texas by the Department of State Health Services (DSHS). This authority is governed by the Texas Food, Drug and Cosmetic Act.[13] DSHS is responsible for ensuring that these facilities meet all health, safety and quality standards in addition to other minimum requirements to ensure the drugs are of highest predictable quality. Further, Health and Safety Code, Section 431.002(23), requires DSHS to exempt all pharmacies from the definition of and regulation as a drug manufacturer if they comply with the office use provision in Section 562.151 of the Texas Pharmacy Act.

Texas Issues Regarding Drug Compounding

Currently, federal and state law relating to compounding and outsourcing facilities are misaligned. This misalignment drives inconsistency in regulations, standards, and enforcement, including compliance with the Drug Quality and Security Act (DQSA). State law does not contemplate the standards outlined in the DQSA,

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[12] Health and Safety Code, Section 431.002(23)(B): "Manufacture" means: (B) the process of preparing, propagating, compounding, processing, packaging, repackaging, labeling, testing, or quality control of a drug or drug product, but does not include compounding that is done within the practice of pharmacy and pursuant to a prescription drug order or initiative from a practitioner for a patient or prepackaging that is done in accordance with Section 562.154, Texas Occupations Code[.]
Texas Occupations Code, Section 551.003(23): "Manufacturing" means the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from a substance of natural origin or independently by a chemical or biological synthesis. The term includes packaging or repackaging a substance or labeling or relabeling a container and promoting and marketing the drug or device and preparing and promoting a commercially available product from a bulk compound for resale by a person, including a pharmacy or practitioner. The term does not include compounding.

[13] Texas Health and Safety Code Chapter 431.

meaning that no state entity (the Department of State Health Services (DSHS) or the Texas State Board of Pharmacy) has clear statutory authority regarding these types of facilities. This exclusion leaves the Food and Drug Administration (FDA) as the only entity able to protect public health as related to compounding and outsourcing facilities. Additionally, there are current state laws that are in direct conflict with the DQSA, and if not addressed, leave in place an environment that endangers public health.

Misalignment of Federal and State Laws

Texas does not have a regulatory category for outsourcing facilities. Therefore, regulation of these facilities in Texas was uncertain after the DQSA was passed. Unlike most other food and drug safety issues, the federal government would be solely responsible for protecting public health in this situation, without any action on behalf of the state.

Despite the passage of the DQSA, Texas continued to experience a series of violations resulting in injuries and product recalls in the state. Rather than risk the possibility of further delayed correction of poor compounding practices under federal oversight alone, DSHS decided to license FDA-registered outsourcing facilities as a subcategory of prescription drug manufacturers. This licensing decision was made: (1) with the authority granted by the Legislature in a budget rider for DSHS to regulate Section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) regarding outsourcing facilities[14]; (2) using its enforcement discretion over drug manufacturing activities under Health and Safety Code 431.002(23)(B); and (3) in consultation with the Texas State Board of Pharmacy Board.

DSHS licenses and regulates drug manufacturers and distributors, and as a result, has investigators who have experience working with "Current Good Manufacturing Practices" (CGMPs) in drug production. Compliance with many CGMPs is required for compounding outsourcing facilities. DSHS adopted FDA drug manufacturing regulations[15] and uses federal guidance pertaining to compounding.

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[14] In the 2016-2017 General Appropriations Act, H. B. 1, 84th Legislature, Regular Session, 2015 (Article II, Department of State Health Services, Rider 78) and the 2018-2019 General Appropriations Act, S. B. 1, 85th Legislature, Regular Session, 2017 (Article II, Department of State Health Services, Rider 15).

[15] Title 21 Code of Federal Regulations, Sections 210 and 211

While a mechanism to minimally regulate these entities was identified, DSHS cannot fully apply the requirements and restrictions under the DQSA. Because of the patchwork of authority and unclear jurisdiction, DSHS is limited in its ability to take enforcement actions to gain compliance or to address those facilities that may otherwise fit the definition of an outsourcing facility.

Health and Safety Code, Section 431.002(23) requires DSHS to exempt all pharmacies from the definition of and regulation as a drug manufacturer if they comply with Section 562.151 of the Texas Pharmacy Act. Therefore, DSHS does not have clear authority to intervene or demand corrective actions even if the pharmacy is engaging in large-scale drug compounding and distribution, which is more akin to drug manufacturing and distribution than pharmacy compounding. However, the Texas State Board of Pharmacy and DSHS agree that regulation of FDA-registered outsourcing facilities is most appropriate by DSHS, which has inspectors who are knowledgeable and experienced with some of the more restrictive federal requirements for outsourcing facilities and drug manufacturers.

State Law Conflicting with DQSA and Other Federal Compounding Laws

Texas Occupations Code, Section 562.151, allows for retail and institutional pharmacies to dispense and deliver a reasonable quantity of a compounded drug to a practitioner for office use. It also allows for the practitioner to repackage and relabel the product, which means that the compounded drug was not prepared for an identified individual. This section conflicts with Section 503A of the FD&C Act, which prohibits distribution of non-patient-specific compounded drugs by pharmacies to health care practitioners or facilities. This allows for the situation that the DQSA intended to address by re-redirecting sole authorization for large-scale drug compounding to outsourcing facilities, which operate under more stringent production requirements than pharmacies.

Example of Misalignment

To illustrate these issues, last year a Texas pharmacy compounded an injectable eye medication for surgeons to use after cataract surgery to prevent infection. After its use, a significant number of patients suffered varying degrees of vision loss, including blindness. It was determined that the poor quality of the compounded drug was the cause of the problem. Also, the medications were not compounded for an identified patient. Under federal law, the activities would be seen as that of a drug compounding outsourcing facility as opposed to a pharmacy. However, the

practice is allowed under the current Texas Pharmacy Act. DSHS, under current state law, is not clearly authorized to assess the pharmacy's sterile processing methods or to take any action.

Eventually, the FDA determined that the pharmacy met the definition of an outsourcing facility and not of a traditional pharmacy and were thus subject to the stricter requirements for compounding under the DQSA. State law allows for pharmacies to compound in this manner without additional scrutiny or requirements and also prevents DSHS investigation and action that can help address future outbreaks or incidents like this one.

4. DSHS Recommendations

In light of the past public harm and the potential for continued threats to public health, the Department of State Health Services (DSHS) recommends that an outsourcing facility not be authorized to dispense compounded drugs directly to a patient.

DSHS also recommends modification of state law related to drug compounding in order to achieve better alignment between state and federal regulations as well as to achieve better compliance, specifically with the Drug Quality and Security Act (DQSA). One set of standards across the nation also assists the industry in having a predictable regulatory framework in which to work. Adoption of minimum requirements by reference to federal law regarding drug compounding would minimize regulatory overlap.

To accommodate the federal minimum requirements regarding compounding outsourcing facilities, DSHS also recommends the following:

- Texas Health and Safety Code, Chapter 431, the Texas Food, Drug, and Cosmetic Act, should adopt federal law by reference and should be amended to include a separate category for compounding outsourcing facilities, including amendments to definitions, prohibited acts, licensing, and scope of allowable functions.
- Texas Health and Safety Code, Chapter 483, the Dangerous Drug Act, should adopt federal law by reference and should be amended to include staff of compounding outsourcing facilities under categories of persons authorized to possess dangerous drugs. Section 483.001, pertaining to the practice of pharmacy should also be updated to accommodate both new federal regulations and current state law.
- Texas Occupations Code, Chapters 551-566 and 568-569, known as the Texas Pharmacy Act, should be updated to define compounding outsourcing facilities within the context of the practice of Pharmacy, and a clear line between the two should be established. The Texas State Board of Pharmacy should determine whether it is appropriate to adopt federal law by reference and/or modification in its Act.

In addition to these changes, specific conflicts in federal and state law should be addressed. A repeal or modification of Texas Occupations Code, Sections 562.151[16], 562.152, and 562.153 would address part of the issue. This includes prohibiting certain types of distribution by community and institutional pharmacies that are not registered as outsourcing facilities, as well as certain types of distribution by pharmacies that are not registered as outsourcing facilities to practitioners for "office use."

DSHS recommends that for the purposes of compounding, community and institutional pharmacies should be required to either:

- Identify solely as a pharmacy and be limited to pharmacy compounding practices consistent with Section 503A of the Federal Food, Drug and Cosmetics Act; or
- Register as a compounding outsourcing facility and follow Section 503B.

Finally, references in Health and Safety Code Chapter 431 that refer to the Texas Pharmacy Act and Texas Occupations Code, Section 562.151 should be repealed to allow DSHS authority to extend to pharmacies engaged in activities that appear to meet criteria of drug manufacturing facilities or drug compounding outsourcing facilities.

[16] 562.151(2) definition of Prepackaging should be retained.

5. Conclusion

Consumers and health professionals rely on the Food and Drug Administration's (FDA) drug approval process to ensure that drugs are safe and effective and are made in accordance with federal quality standards. Compounded drugs do not have an FDA-approved formula. In federal law, traditional pharmacies can only compound drugs for identified individuals based on a specific prescription.

Compounding outsourcing facilities do not compound drugs for specific individuals, but rather do so for sale to health care practitioners, clinics, or systems to have on hand for as-of-yet unidentified patients. The FDA does not require a compounding outsourcing facility to meet all of the minimum standards for a drug manufacturer but does require more regulation than those for compounding in a pharmacy context. In light of a rise in adverse events, including patient harm and death from poor large-scale drug compounding, the FDA does require compliance with certain "Current Good Manufacturing Practices" which are tailored to address patient protection in large-scale drug compounding.

In this review, the inconsistencies and conflicts between federal and state law are considered. The Department of State Health Services recommends the Texas Legislature update state laws to be consistent with minimum requirements of the FDA by reference and by revision. This includes specific recommendations for the:

- Health and Safety Code, Chapter 431, the Texas Food, Drug, and Cosmetics Act;
- Health and Safety Code, Chapter 483, the Dangerous Drug Act; and
- Texas Occupations Code, Chapters 551-566 and 568-569, the Texas Pharmacy Act.

The clarification of state laws as consistent with Section 503A and Section 503B of the Federal Food, Drug, and Cosmetic Act, allows for better patient protection as well as possible protection of the Texas industry's reputation and place in the larger pharmaceutical market.

List of Acronyms

Acronym	Full Name
21 U.S.C. Section 353a Pharmacy Compounding	Food, Drug, and Cosmetic Act, Section 503A, 21 United States Code Chapter V. Drugs and Devices, Part A. Drugs and Devices, Section 353a. Pharmacy Compounding.
21 U.S.C. Section 353b Outsourcing Facilities	Food, Drug, and Cosmetic Act (FD&C), Section 503B, 21 United States Code Chapter V. Drugs and Devices, Part A. Drugs and Devices, Section 353b. Outsourcing Facilities.
CGMP	Current Good Manufacturing Practices
DQSA	Drug Quality and Security Act
DSHS	Department of State Health Services
FDA	Food and Drug Administration
FD&C Act	Federal Food, Drug, and Cosmetic Act
Section 503A	Federal Food, Drug, and Cosmetic Act, Section 503A, 21 United States Code Section 353a, regarding drug compounding by a licensed pharmacist in a state-licensed pharmacy or federal facility or by a licensed physician
Section 503B	Federal Food, Drug, and Cosmetic Act, Section 503A, 21 United States Code Section 353a, regarding drug compounding outsourcing facilities
U.S.C.	United States Code