
Health Care & Wellness Committee

HB 2613

Brief Description: Establishing safety and regulatory requirements for compounded medications.

Sponsors: Representatives Thai, Parshley, Duerr, Santos, Ormsby and Hill.

<p style="text-align: center;">Brief Summary of Bill</p> <ul style="list-style-type: none">• Prohibits entities from selling, transferring, or distributing compounded drugs that use bulk drug substances unless the compounder complies with certain quality assurance requirements.

Hearing Date: 1/30/26

Staff: Emily Poole (786-7106).

Background:

Food, Drug, and Cosmetic Act.

The federal Food and Drug Administration (FDA) is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs and biological products, among other products.

United States Pharmacopeia and National Formulary Monographs.

The United States Pharmacopeia (USP) and National Formulary (NF) monographs set out detailed quality expectations for a medicine, including for its identity, strength, purity, and performance. They also describe the tests to validate that a medicine and its ingredients meet these criteria.

Compounding.

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Compounding is generally a practice in which a licensed pharmacist, a licensed physician, or in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. Compounded drugs are not FDA approved, which means the FDA does not verify their safety, effectiveness, or quality before they are marketed.

The Food, Drug, and Cosmetic Act (FDCA) describes the conditions under which compounded human drug products are exempt from the FDCA sections on FDA approval prior to marketing, current good manufacturing practice requirements, and labeling with adequate directions for use.

Bulk Drug Substances.

Compounders sometimes prepare drugs using bulk drug substances, also known as active pharmaceutical ingredients. The FDCA limits the bulk drug substances that can be used in compounding. State-licensed physicians and pharmacists seeking to operate under the FDCA may only use bulk drug substances in compounding drug products that:

- comply with an applicable USP or NF monograph if one exists, and the USP chapter on pharmacy compounding;
- are components of FDA-approved drug products if an applicable USP or NF monograph does not exist; or
- appear on the FDA's list of bulk drug substances that can be used in compounding if such a monograph does not exist and the substance is not a component of an FDA-approved drug product.

In addition, bulk drug substances must be accompanied by a valid certificate of analysis and must have been manufactured by an establishment registered with the FDA.

State Requirements.

A medicinal product that is compounded for patient administration or distribution to a licensed practitioner for patient use or administration must meet the standards of the USP. At the direction of the Pharmacy Commission (Commission), the Department of Health is required to make inspections and investigations of pharmacies and other places in which drugs are stored, held, compounded, dispensed, sold, or administered.

Summary of Bill:

A person or entity may not engage in the sale, transfer, or distribution of a compounded drug, unless the compounder of the drug does the following:

- complies with the federal FDCA;
- confirms that any bulk drug substance used, which are components of drugs approved by the FDA, was reviewed as part of a new drug application approved by the FDA;
- ensures that the bulk drug substance is a pharmaceutical grade product;
- verifies that the bulk drug substance is accompanied by a valid certificate of analysis containing certain information;
- conducts and documents quality control testing of the bulk drug substance prior to its use

- in a compounded drug;
- obtains proof that the manufacture of the bulk drug substance took place in an establishment that is registered with the FDA and that has undergone an inspection within the last two years by the FDA as a human drug establishment; and
 - uses bulk drug substances that: (i) comply with the standards of an applicable USP or NF monograph and the USP chapter on pharmacy compounding; (ii) are drug substances that are components of drugs approved by the FDA; or (iii) appear on a list developed by the FDA.

Any person or entity engaging in the sale, transfer, or distribution of compounded drugs must maintain all records related to the acquisition, examination, and testing of bulk drug substances for at least two years after the expiration date of the last lot of the drug containing the bulk drug substance. The person or entity must provide such records upon a request by the Commission.

The Commission or its agent has the authority to conduct a compliance inspection regarding any person or entity that engages in compounding drugs, as well as any domestic supplier, wholesaler, repackager, or other provider of the bulk drug substance for compounding. If a person or entity refuses access for such an inspection, it constitutes a violation, punishable by a civil fine and revocation of the pharmacy license.

Appropriation: None.

Fiscal Note: Requested on January 22, 2026.

Effective Date: The bill contains an emergency clause and takes effect immediately.