



S.B. 196

125th General Assembly

(As Introduced)

Sen. Wachtmann

BILL SUMMARY

- Authorizes a pharmacist to compound and dispense or sell a dangerous drug pursuant to a compounding order issued by a licensed prescriber.
- Requires the State Board of Pharmacy to adopt rules governing compounding orders, which are to be followed by pharmacists and prescribers.

CONTENT AND OPERATION

Background

Drug compounding in Ohio

Ohio law defines drug "compounding" as the preparation, mixing, assembling, packaging, and labeling of one or more drugs by a licensed pharmacist.¹ Current law includes compounding in the practice of pharmacy, but limits the circumstances under which a pharmacist may compound drugs to the following:

- (1) Pursuant to a prescription issued by an authorized prescriber;²

¹ *Compounding does not include any preparations, such as mixing, reconstituting, or other acts performed by a pharmacist in accordance with directions contained in approved labeling provided by a drug product's manufacturer and other manufacturer directions consistent with the product's labeling.*

² *"Prescriber" or "licensed health care professional authorized to prescribe drugs" means an individual authorized by law to prescribe drugs or dangerous drugs or drug therapy related devices in the course of the individual's professional practice, including the following professionals licensed under Ohio law: dentists; nurses who hold a certificate to prescribe; optometrists licensed to practice optometry under a therapeutic*

(2) Pursuant to the modification of a prescription made in accordance with a consult agreement;³

(3) As an incident to chemical analysis, research, or teaching;

(4) In anticipation of prescription drug orders based on routine, regularly observed dispensing patterns.⁴

Rules adopted by the Pharmacy Board specify that a prescription may be compounded and dispensed only pursuant to a valid prescription order issued by a licensed prescriber for an individual patient.⁵ Also, pharmacists may compound limited quantities of a drug in anticipation of prescription orders based on routine, regularly observed prescribing patterns.

Authority to compound drugs in Ohio

Pharmacists, and pharmacy interns who are under the supervision of a pharmacist, are authorized to compound drugs. An individual other than a pharmacist or pharmacy intern may assist in compounding prescriptions, provided that the individual meets the qualifications for employment under the pharmacist, does not perform any procedure requiring professional judgment, and does not engage in any procedure contrary to the statutes and rules regulating the compounding of drugs.⁶

Pharmacy Board rules permit pharmacists to compound drugs while employed with freestanding pharmacies, institutional pharmacies, and compounding facilities authorized to compound parental or sterile product prescriptions. Each facility must, however, meet certain standards regarding sufficient library resources, drug stocks, equipment, utilities, work areas, waste disposal, and storage facilities.⁷

pharmaceutical agents' certificate; physicians authorized to practice medicine, osteopathic medicine, or podiatric medicine; and veterinarians. (R.C. 4729.01(I).)

³ *A consult agreement is an agreement to manage an individual's drug therapy between a pharmacist and a physician who is authorized to practice medicine or osteopathic medicine. (R.C. 4729.01.)*

⁴ *R.C. 4729.01(C).*

⁵ *Ohio Administrative Code 4729-9-21.*

⁶ *OAC 4729-5-25.*

⁷ *OAC 4729-9-02; OAC 4729-17-08; OAC 4729-19-04.*



Procedures

Pharmacists are held accountable for the drugs they personally compound and those compounded under their supervision. For all compounded prescriptions, the pharmacist must inspect and approve the compounding process and perform the final check of the finished product; supervise the maintenance of all compounding records for each prescription compounded; and oversee the proper maintenance, cleanliness, and use of all equipment used in compounding. The pharmacist must also ensure that the finished product complies with the Pharmacy Board's labeling standards for compounded drugs.⁸

The bill

(R.C. 4729.01(C) and (D) and 4729.40)

The bill creates an additional circumstance under which a pharmacist may compound drugs: pursuant to a compounding order submitted by a licensed prescriber.⁹ The bill defines a "compounding order" as "a written, electronic, or oral request for a compounded drug submitted by a licensed health care professional authorized to prescribe drugs."

Under the bill, the State Pharmacy Board must adopt rules to govern compounding orders, to be followed by both pharmacists and prescribers, that establish the following:

- (1) Standards and procedures governing issuing, dispensing, and recording of compounding orders;
- (2) Standards and procedures for determining the expiration date of an order and for safe and timely disposal of expired orders;
- (3) Any categories of drugs or types of diseases for which a compounding order may not be issued;
- (4) Any other rules the Board considers necessary for the implementation and administration of compounding orders.

The bill authorizes a pharmacist to compound and dispense or sell a dangerous drug pursuant to a compounding order issued by a licensed prescriber in

⁸ OAC 4729-5-16.

⁹ See note on "prescriber" or "licensed health care professional authorized to prescribe drugs," above.



accordance with rules adopted by the Pharmacy Board, provided the Board has not excluded the drug by rule from compounding pursuant to a compounding order. All compounding orders must be preserved on file at the pharmacy for a period of three years, subject to inspection by the proper officers of the law. If a pharmacist receives a compounding order orally or electronically, the pharmacist must record the order in writing. The written record constitutes the original compounding order and must be preserved on file at the pharmacy.

Each drug dispensed or sold pursuant to a compounding order must be accompanied by the following information, in written form:

- (1) The name, address, and telephone number of the pharmacy dispensing the compounded drug;
- (2) The phrase, "For Prescriber's Use Only";
- (3) The name of the drug and the quantity of the drug dispensed;
- (4) An identification number and a lot number assigned by the pharmacy in accordance with standards established by the Board;
- (5) A list of the compounded drug's active and inactive ingredients, including the amount and potency of each active ingredient;
- (6) The drug's expiration date, as determined by the compounding pharmacist in accordance with standards established by the Board;
- (7) The dosage form and quantity per dose;
- (8) Directions for administration of the drug;
- (9) Directions for storage of the drug.

Drugs dispensed or sold pursuant to a compounding order must be administered by the prescriber who issued the order directly to the prescriber's patient. The bill prohibits a prescriber from providing any drug dispensed or sold pursuant to a compounding order to a patient for the purposes of self-administration. The bill also prohibits a prescriber from administering to a patient any drug dispensed or sold pursuant to a compounding order at a time that is beyond the expiration date indicated on the drug's label. The prescriber who issued the compounding order is responsible for ensuring that the drug is used or disposed of in a safe and timely manner, in accordance with the procedures established by the Board in rules.

COMMENT



There are some outstanding issues related to states' regulation of drug compounding by pharmacists. Federal law includes provisions that govern compounding by pharmacists. (21 United States Code Annotated 353a.) The Food and Drug Administration (FDA) Modernization Act of 1997 limits the circumstances under which pharmacists may compound drugs, but gives the authority to regulate compounding to state pharmacy boards. In November 1998, however, the solicitation and advertising provisions of the Act (in 21 U.S.C.A. 353a) were challenged by seven compounding pharmacies as an impermissible regulation of commercial speech. The United States District Court for the District of Nevada ruled in the pharmacies' favor. The FDA appealed to the U.S. Court of Appeals for the Ninth Circuit. On February 6, 2001, the Court declared 21 U.S.C.A. 353a invalid in its entirety. (*Western States Medical Center v. Shalala*, 238 F.3rd 1090 (9th Cir. 2001).)

In response to a petition by the government for a review of the circuit court opinion, on April 29, 2002, the Supreme Court issued a decision affirming the 9th Circuit Court's decision. (*Thompson v. Western States Medical Center*, No. 01-344, April 29, 2002.) The Supreme Court did not rule on, and therefore left in place, the 9th Circuit's holding that the unconstitutional restrictions on commercial speech could not be severed from the rest of 21 U.S.C.A. 353a and accordingly, all of that section is now invalid. As a result, federal law contains no guidelines regarding compounding by pharmacists.

To address this absence, the FDA released Section 460.200 of the FDA Compliance Policy Guides Manual. According to the Manual, the "FDA will continue to defer to state authorities regarding less significant violations of the [Food and Drug Administration Modernization] Act related to pharmacy compounding of human drugs. . . 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."



HISTORY

ACTION	DATE	JOURNAL ENTRY
Introduced	02-10-04	p. 1521

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