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Bill Analysis
Legislative Service Commission

S.B. 188

126th General Assembly
(As Introduced)

Sens. Grendell, Schuring

BILL SUMMARY

- Creates a license to be issued by the State Board of Pharmacy authorizing a terminal distributor of dangerous drugs to compound, on a routine basis, drugs and sell those drugs to an authorized prescriber of drugs.
- Limits the drugs that may be compounded under a new license to those that are commercially unavailable.
- Provides that a terminal distributor compounding license is valid for one year and requires the Board to review and renew licenses.
- Requires a terminal distributor that holds a compounding license to submit an annual report to the Board that demonstrates the distributor's progress in obtaining approval from the United States Department of Health and Human Services to manufacture drugs.

CONTENT AND OPERATION

Background: manufacturers, wholesalers, and terminal distributors of dangerous drugs

(R.C. 4729.01)

Both state and federal laws regulate the manufacture, distribution, and sale of dangerous drugs. In Ohio, manufacturers, wholesale distributors, and terminal distributors are licensed by the State Board of Pharmacy. Terminal distributors include pharmacies, hospitals, nursing homes, laboratories, and others who

procure dangerous drugs for sale or other distribution by or under the supervision of a pharmacist or licensed health professional authorized to prescribe drugs.¹

Terminal distributors are not permitted to manufacture drugs, but a pharmacist may compound a drug under the following circumstances:

(1) Pursuant to a prescription issued by a licensed health professional authorized to prescribe drugs;

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

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

(4) In anticipation of orders for drugs pursuant to prescriptions, based on routine, regularly observed dispensing patterns;

(5) Pursuant to a request made by a licensed health professional authorized to prescribe drugs for a drug that is to be used by the professional for the purpose of direct administration to patients in the course of the professional's practice, if certain conditions are met.

"Compounding" is defined in existing law as the preparation, mixing, assembling, packaging, and labeling of one or more drugs in any of the circumstances listed above.

¹ "Licensed health professional authorized to prescribe drugs" (or "prescriber") 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 who hold a therapeutic pharmaceutical agents certificate; physicians authorized to practice medicine, osteopathic medicine, or podiatric medicine; and veterinarians.

² A consult agreement is an agreement between a physician and a pharmacist to manage an individual's drug therapy.

The bill

Authority to compound drugs

(R.C. 4729.01)

In addition to the circumstances in existing law, the bill authorizes compounding pursuant to a license issued by the State Board of Pharmacy to a terminal distributor of dangerous drugs who meets the bill's requirements.

Creation of terminal distributor compounding license

(R.C. 4729.552)

The bill requires the State Board of Pharmacy to establish and administer a drug compounding license program for terminal distributors that meet licensure requirements but have not obtained federal approval to manufacture drugs. The bill does not alter current requirements for a license to do business as a manufacturer, wholesaler, or terminal distributor of dangerous drugs.

Requirements of compounding license

(R.C. 4729.522)

To be eligible for the compounding license, the distributor must be licensed as a terminal distributor of dangerous drugs. The distributor must also be registered, or in the process of registering, with United States Secretary of Health and Human Services to manufacture, prepare, propagate, compound, or process drugs in accordance with the "Federal Food, Drug and Cosmetic Act" (21 United States Code 360) or have filed, or be in the process of filing, one of the following with the Secretary:

(1) An application to manufacture, process, and pack a new drug as required by the Act (21 U.S.C. 355).

(2) An application for approval of a fast track product as required by the Act (21 U.S.C. 356).

The terminal distributor seeking a compounding license must provide satisfactory evidence to the Board that the distributor's pharmacy staff is in compliance with training guidelines established by the Board and United States Pharmacopoeia.

Issuance of license

(R.C. 4729.552)

The Board is required by the bill to issue a compounding license to a terminal distributor that meets the requirements of the bill and any rules adopted by the Board, satisfactorily completes the application process, and pays any fees required by the Board. The bill authorizes the Board to inspect the premises of any applicant or license holder and impose inspection fees. It also gives the Board authority to contract with an independent third party for assistance in processing applications, conducting inspections, and regulating license holders.

Compounding authority under the new license

(R.C. 4729.552)

A distributor with a compounding license is authorized by the bill to provide to a prescriber at any one time the lesser of 100 vials or a 30-day supply of a dangerous drug for which the distributor has applied for approval to manufacture. The drug may be provided only under the following circumstances:

(1) On receipt of a signed order from the prescriber, the distributor may have pharmacists and staff authorized to assist pharmacists compound on a routine basis dangerous drugs that are not otherwise commercially available and sell those drugs to the prescriber.

(2) On a signed request of a prescriber, the distributor may supply a compounded drug to the prescriber based on routine, regularly observed dispensing patterns.

Licenses issued are valid for one year unless earlier terminated or relinquished and may be renewed on review by the Board.

Obligations of distributors

Commercial availability of drug

(R.C. 4729.553)

A terminal distributor that holds a compounding license must establish a system for determining whether a dangerous drug is commercially available. The terminal distributor can use the authority given by the bill only if the drug is not commercially available and must discontinue compounding any drug that becomes commercially available.

Annual report

(R.C. 4729.554)

A terminal distributor holding a compounding license must annually submit to the Board a written report that does the following:

(1) Demonstrates the terminal distributor's progress in obtaining approval from the United States Secretary of Health and Human Services to manufacture dangerous drugs;

(2) Includes any data the terminal distributor generates or prepares for the purpose of obtaining approval from the Secretary to manufacture dangerous drugs including chemistry, manufacturing and control information, bioequivalency data, and proposed product labeling;

(3) Submits any communications between the terminal distributor and the Secretary regarding the distributor's actions to seek approval to manufacture drugs.

Compounding process

(R.C. 4729.555)

A distributor licensed to compound drugs must meet all of the following requirements when compounding:

(1) Have a pharmacist monitor all aspects of the compounding process and permit only a pharmacist to release compounded drugs for delivery to a licensed health professional authorized to prescribe drugs;

(2) Have compounded drugs tested for sterility, potency, and endotoxins by an independent laboratory following standards for sterile drugs established in the United States Pharmacopoeia;

(3) Label containers in which compounded drugs are delivered to prescribers with the name and phone number of the terminal distributor, and enclose literature that clearly explains to the prescriber how the drug is to be used and any known adverse reactions to the drug;

(4) Assign each drug a lot number and each batch of a compounded drug a batch record and date beyond which the drug should not be used;

(5) Reserve samples of each batch of compounded drug until the expiration date and maintain adequate distribution records sufficient to trace receipt of an order to delivery in event that a recall is determined necessary;

(6) Use only ingredients for which the distributor has a certificate of analysis on file, and store and maintain the ingredients properly;

(7) Report any adverse reactions to the Board;

(8) Comply with any other requirements of the Board or any other government entity that regulates compounding, sale, or distribution of dangerous drugs.

Rules

(R.C. 4729.556)

The bill requires the Board to adopt rules in accordance with R.C. Chapter 119. (the Administrative Procedure Act) to govern the drug compounding program for terminal distributors of dangerous drugs. The rules are to specify all of the following: the application process, fee, and requirements for issuance of the license; the schedule, fee, and requirements for renewal of the license; standards and procedures for denying, suspending, and revoking a license, including reasons for imposing sanctions;³ the types of drugs that may be compounded under the license, and any categories that may not be compounded; standards and procedures, including safety standards and procedures, to be followed by a distributor in compounding, dispensing, and recording a drug; and any other standards or procedures the Board considers relevant in the administration of the licensure program.

COMMENT

The federal government, through the Food and Drug Administration Modernization Act of 1997 regulates who can and cannot manufacture dangerous drugs. The FDA has stated that anyone conducting compounding in violation of the Act (regarding the alteration and manufacture of drugs) will be subject to regulatory action, including a warning letter, seizure, injunction, or prosecution.⁴ This statement occurred after unrelated parts of the Act were ruled unconstitutional in *Tommy G. Thompson, Secretary of Health and Human*

³ *The reasons for imposing sanctions must be substantially similar to those for imposing sanctions on terminal distributors under existing law, but may include additional reasons related to violation of the bill.*

⁴ *Food and Drug Administration, Office of Regulatory Affairs "Guidance for FDA Staff and Industry," May 2002 (available online at: http://www.fda.gov/OHRMS/DOCKETS/98fr/02D-0242_gdl0001.pdf).*

Services, et al. v. Western States Medical Center et. al. However, compounding is permitted under certain circumstances.

HISTORY

ACTION	DATE	JOURNAL ENTRY
Introduced	09-27-05	p. 1452

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