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Bill Analysis
Legislative Service Commission

Sub. S.B. 196
125th General Assembly
(As Passed by the Senate)

Sens. Wachtmann, Blessing, Fedor, Dann

BILL SUMMARY

- Permits a pharmacist to compound a limited quantity of a drug that is not commercially available and to provide the drug to a health professional for the purpose of direct administration to patients.
- Specifies that the pharmacist's provision of the compounded drug must occur as an occasional exception to the normal practice of dispensing drugs pursuant to patient-specific prescriptions.

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 as one of the activities that constitutes the practice of pharmacy, but limits the circumstances under which a pharmacist may compound drugs to the following:

¹ According to the United States Food and Drug Administration Center for Drug Evaluation and Research, compounding does not include mixing, reconstituting, or other acts performed by a pharmacist in accordance with directions contained in approved labeling provided by a drug's manufacturer (Center for Drug Evaluation and Research, U.S. Food and Drug Admin., *REPORT: LIMITED FDA SURVEY OF COMPOUNDED DRUG PRODUCTS*, last updated January 28, 2003 (available at <http://www.fda.gov/cder/parhmcomp/survey.html>, visited November 26, 2004)).

(1) Pursuant to a prescription issued by a licensed health professional authorized to prescribe drugs;²

(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 State Board of Pharmacy 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

Authority to compound drugs

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 prescription drugs, 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

The board's rules permit pharmacists to compound drugs while employed with freestanding pharmacies, institutional pharmacies, and compounding

² "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 licensed to practice optometry under a therapeutic 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.

facilities authorized to compound parenteral or sterile product prescription drugs. Each facility must, however, meet certain standards regarding library resources, drug stocks, equipment, utilities, work areas, waste disposal, and storage facilities.⁷

For all compounded prescription drugs, 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 drug 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 Board's labeling standards for compounded drugs.⁸

The bill

(R.C. 4729.01(C))

The bill specifies an additional circumstance under which a pharmacist may compound drugs. Under this circumstance, pharmacists are given a limited authority to compound and provide drugs without patient-specific prescriptions.

Specifically, the bill provides that compounding may occur 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 all of the following apply:

(1) The drug is not commercially available;

(2) A limited quantity of the drug is compounded and provided to the professional;

(3) The drug is compounded and provided to the professional as an occasional exception to the normal practice of dispensing drugs pursuant to patient-specific prescriptions.

Technical corrections

(R.C. 4729.01(B) and (E))

The bill includes technical corrections in the definitions that are used in the statutes governing the practice of pharmacy.

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

⁸ OAC 4729-5-16.

COMMENT

There are some outstanding issues related to states' regulation of drug compounding by pharmacists. 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. (21 United States Code Annotated 353a.) The Act also contains limitations on solicitation and advertisement of drugs by pharmacists or pharmacies. This portion of the Act was 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 and invalidated the solicitation and advertisement portion of the Act. The government appealed to the United States Court of Appeals for the Ninth Circuit. That court declared 21 U.S.C.A. 353a invalid in its entirety. (*Western States Medical Center v. Shalala*, 238 F.3d 1090 (9th Cir. 2001).)

The government filed a petition for review to the United States Supreme Court. The Court upheld the decision of the circuit court, declaring the advertising and solicitation provisions to be unconstitutional. (*Thompson v. Western States Medical Center*, 535 U.S. 357 (2002).) The Court did not rule on, and therefore left in place, the Ninth Circuit's holding that the unconstitutional restrictions could not be severed from the rest of 21 U.S.C.A. 353a. Accordingly, that entire section is now invalid. As a result of this ruling, 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 kind 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."⁹

⁹ http://www.fda.gov/ora/compliance_ref/cpg/cpgdrg/cpg460-200.html. The Manual lists the types of activities that may lead the FDA to institute an enforcement action.

HISTORY

ACTION	DATE	JOURNAL ENTRY
Introduced	02-10-04	p. 1521
Reported, S. Health, Human Services & Aging	11-16-04	p. 2272
Passed Senate (31-0)	11-16-04	p. 2275

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