Ohio Legislative Service Commission

Bill Analysis

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S.B. 79

129th General Assembly
(As Introduced)

Sens. Skindell, Cafaro, Tavares, Smith

BILL SUMMARY

- Requires pharmaceutical manufacturers and labelers to disclose to the Director of Health, on an annual basis, gifts to health care professionals or hospitals and other health care facilities.
- Requires the Director to adopt rules to implement the reporting requirements.
- Establishes a fine of $10,000 for each failure to disclose gifts.

CONTENT AND OPERATION

Reporting requirements

The bill requires manufacturers and labelers of dangerous drugs to file an annual report with the Director of Health. The report must disclose any gift made to a licensed health care professional authorized to prescribe drugs, hospital, nursing home, residential care facility, adult care facility, pharmacist, or health plan administrator. The requirement applies to any gift, fee, payment, subsidy, or other economic benefit provided in connection with detailing, promotion, or other marketing activities by the manufacturer or labeler, directly or through a marketer. The report must describe the value, nature, and purpose of each gift made in the prior calendar year and be filed by February 1 on the form and in the manner prescribed by the Director in rules. In addition, when submitting the report, the manufacturer or labeler must pay a fee in an amount and in a manner prescribed by the Director in rules.[1] Manufacturers and

[1] R.C. 3715.93(B)(2).

labelers must provide the name and address of the individual responsible for compliance to the Director by January 1 of each year.[2]

By June 1 of each year, the Director must submit a report summarizing the disclosures to the Governor and members of the General Assembly.[3]

Exemptions

The bill provides four exemptions from the reporting requirement:[4]

(1) Gifts, fees, payments, subsidies, or other economic benefit valued at $25 or less;

(2) Sample drugs given with the intent that they be distributed to patients;

(3) Payment of reasonable compensation and reimbursement of expenses related to a bona fide clinical trial conducted in connection with a research study designed to answer specific questions about vaccines, new therapies, or new ways of using known treatments;

(4) Scholarships or other support for medical students, residents, and fellows to attend bona fide educational, scientific, or policy-making conferences of an established professional association if the recipients are selected by the association.

Rule-making

The bill requires the Director to adopt rules under the Administrative Procedure Act (R.C. Chapter 119.) to do all of the following:[5]

(1) Prescribe the form and manner of the report required by the bill that manufacturers and labelers must file annually with the Director;

(2) Prescribe the amount of the fee that must accompany the report when it is submitted to the Director, and the manner in which it must be submitted;

(3) Define the terms "bona fide clinical trial" and "bona fide educational, scientific, or policy-making conference," as these terms are used in the bill.

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[2] R.C. 3715.93(B)(1).

[3] R.C. 3715.93(D).

[4] R.C. 3715.93(E).

[5] R.C. 3715.93(F).

Enforcement

Manufacturers or labelers who fail to disclose gifts may be fined up to $10,000 per violation. Each failure to disclose constitutes a separate violation.[6]

The bill also authorizes the Attorney General to bring an action in the Franklin County Court of Common Pleas seeking injunctive relief. In addition to granting the injunction, the court may require a violator to pay costs and attorney's fees associated with the action.[7]

Definition

As used in the bill:[8]

"Adult care facility" means an adult family home or adult group home that provides accommodations and supervision to three to 16 unrelated adults, at least three of whom are provided personal care services.[9]

"Dangerous drug" means:[10]

(1) Any drug to which one of the following applies:

(a) Under the federal Food, Drug, and Cosmetic Act, the drug is required to bear a label containing the legend "Caution: Federal law prohibits dispensing without prescription" or "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian" or any similar restrictive statement, or the drug may be dispensed only on a prescription;

(b) Under Ohio drug laws,[11] the drug may be dispensed only on a prescription.

(2) Any drug that contains a schedule V controlled substance and is exempt from the laws pertaining to controlled substances or to which those laws do not apply;[12]

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[6] R.C. 3715.93(C) and 3715.99.

[7] R.C. 3715.93(G).

[8] R.C. 3715.93(A).

[9] R.C. 5119.70 (not in the bill).

[10] R.C. 4729.01 (not in the bill).

[11] R.C. Chapters 3715. and 3719. (not in the bill).

[12] R.C. Chapter 3719. (not in the bill).

(3) Any drug intended for administration by injection into the human body other than through a natural orifice of the human body.

"Detailing" means the marketing or promotion of dangerous drugs by or on behalf of a manufacturer or labeler.

"Labeler" means a person who receives dangerous drugs from a manufacturer or wholesaler and repackages them for retail sale and has a labeler code from the U.S. Food and Drug Administration pursuant to federal regulations.[13]

"Licensed health professional authorized to prescribe drugs" means an individual who is authorized by law to prescribe drugs or dangerous drugs or drug therapy related devices in the course of the individual's professional practice. This includes dentists, physicians, veterinarians, certain optometrists, physician assistants, and certain advanced practice nurses.[14]

"Marketer" means a person who, while employed by or under contract to represent a manufacturer or labeler, engages in pharmaceutical detailing or other manufacturing or promotion of dangerous drugs.

"Residential care facility" means a home that provides:[15]

(1) Accommodations for 17 or more unrelated individuals and supervision and personal care services for three or more of those individuals who are dependent on the services of others by reason of age or physical or mental impairment; or

(2) Accommodations for three or more unrelated individuals, supervision and personal care services for at least three of those individuals who are dependent on the services of others by reason of age or physical or mental impairment, and, to at least one of those individuals, any of the skilled nursing care that may be provided by the facility under current law.[16]

"Sample drug" means a drug or pharmaceutical preparation that would be hazardous to health or safety if used without the supervision of a licensed health

[13] 21 Code of Federal Regulations 207.20.

[14] R.C. 4729.01 (not in the bill).

[15] R.C. 3721.01 (not in the bill).

[16] R.C. 3721.011 (not in the bill).

professional authorized to prescribe drugs, or a drug of abuse, and that, at one time, had been placed in a container plainly marked as a sample by a manufacturer.[17]

"Wholesaler" means a person who, on official written orders other than prescriptions, supplies dangerous drugs that the person has not manufactured, produced, or prepared personally and includes a "wholesale distributor of dangerous drugs" regulated by the Ohio State Board of Pharmacy.

HISTORY

ACTION	DATE
Introduced	02-16-11

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[17] R.C. 2925.01 (not in the bill).