



H.B. 39

127th General Assembly
(As Introduced)

**Reps. Skindell, D. Stewart, Foley, Koziura, Ujvagi, Strahorn, Lundy,
R. Hagan, Bolon, Brady, Beatty**

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 penalties for failing to disclose gifts.

CONTENT AND OPERATION

Reporting requirements

(R.C. 3715.88 and 3715.89)

The bill requires manufacturers and labelers of dangerous drugs¹ to file an annual report with the Director of Health. The bill defines "labeler" as one who

¹ Ohio law defines "dangerous drug" as:

(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 law (Revised Code Chapter 3715. or 3719.), the drug may be dispensed only on a prescription.

"[r]eceives dangerous drugs from a manufacturer or wholesaler and repackages them for retail sale" and has a "labeler code from the United States food and drug administration under 21 C.F.R. 207.20." The report must disclose any gift made to a licensed health care professional authorized to prescribe drugs,² hospital, nursing home, residential care facility,³ adult care facility,⁴ 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."⁵ The report must describe the "value, nature, and purpose" of each gift

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- (2) Any drug that contains a schedule V controlled substance and is exempt from the chapter of the Revised Code pertaining to controlled substances (R.C. Chapter 3719.) or to which that chapter does not apply;
 - (3) Any drug intended for administration by injection into the human body other than through a natural orifice of the human body.

(R.C. 4729.01, not in the bill).

² Ohio law defines "licensed health professional authorized to prescribe drugs" as "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, and certain specialized nurses. (R.C. 4729.01, not in the bill.)

³ Ohio law defines "residential care facility" as a home that provides:

- (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 authorized by Ohio law (R.C. 3721.011).

(R.C. 3721.01, not in the bill).

⁴ Ohio law defines "adult care facility" as an adult family home or adult group home "that provides accommodations and supervision to three to sixteen unrelated adults, at least three of whom are provided personal care services." (R.C. 3722.01, not in the bill).

⁵ "Detailing" is defined in the bill as "the marketing or promotion of dangerous drugs by or on behalf of a manufacturer or labeler." "Marketer" is defined in the bill as "a person who, while employed by or under contract to represent a manufacturer or labeler, engages in pharmaceutical detailing or other marketing or promotion of dangerous drugs."



made in the prior calendar year and be filed by February 1 on the form and in the manner prescribed by the Director. Manufacturers and labelers must provide the name and address of the individual responsible for compliance to the Director by January 1 of each year.

By June 1 of each year, the Director must submit a report summarizing the disclosures to the Governor, President and Minority Leader of the Senate, and the Speaker and Minority Leader of the House of Representatives.

Exemptions

(R.C. 3715.88)

The bill provides four exemptions from the reporting requirement.

(1) Gifts valued at \$25 or less;

(2) Sample drugs given with the intent that they be distributed to patients;⁶

(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.

Rule-making

(R.C. 3715.89)

The bill requires the Director to adopt rules under Revised Code Chapter 119. (Ohio's Administrative Procedure Act) prescribing the form and manner of the report. The bill also requires the Director to adopt rules defining "bona fide clinical trial" and "bona fide educational, scientific, or policy-making conference."

⁶ The bill uses the existing definition of "sample drug": a drug or pharmaceutical preparation that would be hazardous to health or safety if used without the supervision of a licensed health 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. (R.C. 2925.01, not in the bill.)

Enforcement

(R.C. 3715.90 and 3715.99)

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.

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 attorneys' fees associated with the action.

HISTORY

ACTION	DATE
Introduced	02-20-07

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