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*Bill Analysis*  
*Legislative Service Commission*

## **S.B. 14**

125th General Assembly  
(As Introduced)

**Sens. Hagan, DiDonato, Miller, Herington, Mallory, Fingerhut, Dann, Fedor, Roberts, Brady, Prentiss**

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### **BILL SUMMARY**

- Creates the Rx Program in the Department of Job and Family Services to provide participants with discounts on prescription drugs.
- Requires the Director of Job and Family Services to adopt rules governing the Rx Program.
- Establishes the Rx Program Fund in the state treasury.
- If certain conditions are met, permits the Director to establish maximum amounts that terminal distributors of dangerous drugs may charge for any or all prescription drugs.
- Prohibits a manufacturer, wholesale distributor, or terminal distributor of dangerous drugs from taking certain actions with respect to the sale, exchange, distribution, or handling of a prescription drug dispensed or delivered in Ohio and establishes civil penalties for violations of these prohibitions.

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### **CONTENT AND OPERATION**

#### ***Establishment of Rx Program***

(secs. 329.043, 5110.02, 5110.10, and 5110.12)

The bill creates the Rx Program in the Ohio Department of Job and Family Services (ODJFS) to provide participants with discounts on prescription drugs. The bill establishes three eligibility requirements for participation in the Program:

- (1) The individual must be an Ohio resident;

(2) The individual must be ineligible for federal, state, or county programs that pay part or all of the cost of prescriptions;<sup>1</sup>

(3) The individual cannot have prescription drug coverage through a third-party payor.

An individual seeking to participate in the Rx Program may apply to the county department of job and family services of the county in which the individual resides. The bill gives these county departments authority to accept applications and determine eligibility for the Program. Participants are to be issued an enrollment card that must be presented to a terminal distributor of dangerous drugs to receive a discount on prescription drugs covered by the Program.<sup>2</sup>

### **Mechanics of Rx Program**

#### **Rebate agreements**

(secs. 5110.25, 5110.26, and 5110.27)

Under the bill, any manufacturer or wholesale distributor of dangerous drugs that sells prescription drugs through a state health program is required to participate in the Rx Program by entering into a rebate agreement with the ODJFS Director. Rebate payments must be made to the Director on either a quarterly basis or in accordance with a schedule established by the Director in rules. Rx Program prescription drug discounts are funded by rebate payments made by participating manufacturers and distributors. The Rx Program must cover a prescription drug if the drug is included in a rebate agreement entered into under the bill.

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<sup>1</sup> *This does not apply to the extent the Rx Program is coordinated with other programs as authorized by the bill.*

<sup>2</sup> *"Dangerous drug" means any of the following: (1) a drug that under the "Federal Food, Drug and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, as amended, is required to bear a label stating, "Caution: Federal law prohibits dispensing without a 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 upon a prescription, (2) a drug that under the Revised Code may be dispensed only upon a prescription, (3) a drug that contains a schedule V controlled substance, or (4) a drug intended for administration by injection into the human body.*

*"Terminal distributor of dangerous drugs," includes a pharmacy, hospital, nursing home, or other place where dangerous drugs are sold at retail or distributed to patients.*

The bill requires the Director to negotiate with each manufacturer or distributor the amount of the rebate to be paid to the Director under the Program. In the process of negotiations, the Director must (1) take into consideration any rebates provided for under federal Medicaid law, the average wholesale price of prescription drugs, and any other available information on prescription drug prices and price discounts, and (2) use the Director's best efforts to obtain a rebate amount that is at least as much as the amount of the rebate provided for under federal Medicaid law or that is not less than the amount that the federal government receives as a discount, rebate, or price reduction for prescription drugs.

### **Rx Program Fund**

(sec. 5110.04)

The bill creates the Rx Program Fund in the state treasury. The ODJFS Director must deposit into the Fund the rebate payments made by manufacturers and distributors of dangerous drugs pursuant to an Rx Program rebate agreement. The Director is to use the money in the Rx Fund in the following ways:

- (1) To reimburse a terminal distributor of dangerous drugs the amount of the discount provided by the distributor to an Rx Program participant;
- (2) To pay the terminal distributor the professional fee provided for in rules;
- (3) To pay the administrative costs of the Rx Program, including costs associated with contracted services, computers, and other reasonable administrative matters.

Investment earnings of the Fund are to be credited to the Fund.

### **Discounts for prescription drug purchases**

(secs. 5110.15 and 5110.16)

Each terminal distributor of dangerous drugs is required by the bill to discount the amount it charges an Rx Program participant for a prescription drug covered by the Program. Discounts are to be calculated by the Director and must be equal to the amount of the rebate minus a professional fee and administrative costs.

In accordance with rules adopted by the Director, a terminal distributor must disclose to each Rx Program participant the amount the program has saved



the participant on the cost of a prescription drug covered by the program and purchased from that distributor.

**Claims and reimbursements**

(secs. 5110.18, 5110.19, 5110.20, and 5110.21)

A terminal distributor of dangerous drugs that provides a discount on a prescription drug to an Rx Program participant must submit a claim to the Director verifying the amount that the terminal distributor charged the participant. The terminal distributor must use the claim form prescribed by the Director in rules.

The Director, using the claims submitted, must reimburse each terminal distributor the amount of the discount the distributor provided to an Rx Program participant on a prescription drug and pay the distributor the professional fee established by ODJFS in rules for each claim submitted. The Director must make Rx Program reimbursements and payments on either a weekly or biweekly basis.

The Director may not impose a transaction charge on a terminal distributor that submits a claim. The Director also may not release any information included on a claim that is subject to confidentiality protection under federal or state law.

**List of non-participating manufacturers and distributors**

(sec. 5110.28)

The bill requires the Director to maintain a list of manufacturers and distributors that do not enter into rebate agreements and make the list available to the public.

**Duties of the Director of Job and Family Services**

(secs. 5110.03, 5110.06, 5110.07, 5110.08, 5110.09, 5110.40, and 5110.50)

Under the bill, the Director of Job and Family Services must do all of the following:

(1) Adopt rules in accordance with the Administrative Procedure Act (Revised Code Chapter 119.) to implement the Rx Program that provide for all of the following:

(a) Simplified eligibility determination procedures;

(b) The manner in which a terminal distributor of dangerous drugs is to disclose to an Rx Program participant the amount the program has saved the participant on the cost of a prescription drug covered by the Rx Program that the

participant purchases from the terminal distributor. The rules must not require a terminal distributor to reveal any proprietary information.

(c) Claim forms to be used by a terminal distributor of dangerous drugs;

(d) The amount of the professional fee to be paid to terminal distributors of dangerous drugs. The fee is to be \$3 initially. The Director must review the amount periodically to determine whether it should be increased.

(e) A schedule for manufacturers and wholesale distributors of dangerous drugs to pay rebates to the Director pursuant to a rebate agreement entered into under the bill;

(f) Any adjustments to the requirements and terms of the Rx Program to accommodate any federally funded prescription drug programs created after the bill's effective date;

(2) Seek a waiver of federal law or regulation if necessary to the implementation of the Rx Program.

(3) Undertake outreach efforts to publicize the Rx Program and maximize enrollment in the program.

(4) Report enrollment in and the financial status of the Rx Program to the Speaker and Minority Leader of the House of Representatives and to the President and Minority Leader of the Senate not later than the second week of each January.

(5) No later than April 1, 2005:

(a) Review, using data from the most recent six-month period for which data is available, Medicaid recipients' use of prescription drugs and create a list of the 100 drugs most used by Medicaid recipients and the 100 prescription drugs for which the total cost was the highest.

(b) Determine the average amount terminal distributors of dangerous drugs charged Rx Program participants for each prescription drug included on the list on a date selected by the Director.

(c) Determine the average amount terminal distributors of dangerous drugs charged persons who are not Rx Program participants for each prescription drug included on the list on the date selected by the Director.

The Director is authorized by the bill to coordinate the Rx Program with state programs administered by the Director or, pursuant to an interagency agreement, directors of other state departments, to enhance efficiency, reduce the



cost of prescription drugs, and maximize the benefits of the Rx Program and other programs. Coordination may include making participants of other programs eligible for the Rx Program. In addition, if the Director determines that there is a severe shortage of prescription drugs in this state that could threaten the public health or welfare, the Director is authorized to take any action the Director determines is necessary.

**Maximum prices for prescription drugs**

(secs. 5110.42 and 5110.44)

If the Director determines that the average amount terminal distributors of dangerous drugs charged Rx Program participants for certain prescription drugs is not reasonably comparable to the average amount they charged persons other than Rx Program participants for the same prescription drug, the bill requires the Director to adopt rules that establish maximum amounts they may charge in Ohio for any or all prescription drugs.<sup>3</sup> The rules must be adopted in accordance with the Administrative Procedure Act not later than October 1, 2005. The rules must permit a terminal distributor of dangerous drugs to appeal the maximum price in accordance with the Administrative Procedure Act (Revised Code Chapter 119.).

The bill prohibits a terminal distributor of dangerous drugs from charging more for a prescription drug than the amount established by the rules. A violation of that restriction is an unfair or deceptive act under the Consumer Sales Practices Act.

**Prohibited actions**

(sec. 5110.60)

Under the bill, a manufacturer, wholesale distributor, or terminal distributor of dangerous drugs may not do any of the following:

- (1) Demand an unconscionable price for a prescription drug;
- (2) Demand prices or terms for a prescription drug that lead to an unjust or unreasonable profit;
- (3) Discriminate unreasonably against any person in the sale, exchange, distribution, or handling of a prescription drug dispensed or delivered in this state;

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<sup>3</sup> *The prescription drugs are those included on the list of 100 most costly drugs the bill requires the Director to create.*

A manufacturer, wholesale distributor, or terminal distributor that violates these restrictions is liable in a civil action for (1) three times the amount of the injury caused by the violation, (2) an amount not to exceed \$100,000, (3) the cost of bringing and prosecuting the civil action, including necessary and reasonable investigative costs, reasonable expert fees, and reasonable attorney fees, and (4) in the case of a willful violation or a determination that the manufacturer, wholesale distributor, or terminal distributor previously has been found liable for an action prohibited by the bill, punitive damages.

**Action by the Attorney General**

(sec. 5110.62)

The bill authorizes the Attorney General to bring an action against a manufacturer, wholesale distributor, or terminal distributor on behalf of a person, group of persons, state agency, or political subdivision injured by one of the prohibited actions described above. The bill specifies that there is a right to a jury trial in such an action and, in addition to the damages described above, the Attorney General may obtain injunctive relief. If punitive damages are awarded, the Attorney General is required to equitably distribute them to all injured parties, subtracting reasonable costs to the Attorney General for distributing the damages.

**Effective date**

(Section 3)

The bill specifies that its provisions take effect January 1, 2004.

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**COMMENT**

The bill is modeled on legislation establishing the Maine Rx Program. The Maine Rx Program would allow state residents who enroll in the program to purchase prescription drugs at a discounted price. The state would collect rebates from manufacturers in amounts it negotiates with them and, from those rebates, reimburse pharmacies for the discounts provided to the program's enrollees. The drugs of manufacturers that do not enter into rebate agreements with the state would be subject to prior authorization by Maine's Department of Human Services before the cost could be reimbursed under the state's Medicaid program. The Commissioner on Human Services could establish maximum retail prices effective July 2003 if prices paid under the Maine Rx Program for the most common drugs were not reasonably comparable to the lowest prices paid in the state.

Although the legislation creating it was enacted in May 2000, the Maine Rx Program has yet to be implemented. In August 2000, the Pharmaceutical

Research and Manufacturers of America (PhRMA), an association representing drug manufacturers that accounts for over 75% of brand-name sales in the United States, filed suit in federal court in Maine, arguing that the Maine Rx Program (1) interferes with the federal Medicaid program in violation of the Supremacy Clause of the Constitution, and (2) violates the Constitution's Commerce Clause, which prohibits states from regulating transactions outside their borders. The district court enjoined the program, but was subsequently reversed by the First Circuit Court of Appeals. On May 19, 2003, the United States Supreme Court affirmed the First Circuit's decision, concluding that PhRMA had not met the burden necessary for obtaining an injunction--probability of success on the merits of its claims.<sup>4</sup>

Despite its holding, the Court made clear that it had not decided the validity of the Maine Rx Program. The case will now return to the district court for an evidentiary hearing and resolution of the factual issues raised by the parties. Further, because of Medicaid implications of the program, it is subject to review by the United States Secretary of Health and Human Services. The district court or the Secretary could still terminate or require modification of the Maine Rx Program before it can be implemented.<sup>5</sup>

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## HISTORY

ACTION	DATE	JOURNAL ENTRY
Introduced	01-23-03	pp. 66-67

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<sup>4</sup> *Pharmaceutical Research and Manufacturers of America v. Walsh*, 01-188. 2003 U.S. LEXIS 4056 (May 19, 2003), aff'g *Pharmaceutical Research and Manufacturers of America v. Concannon*, 249 F.3d 66 (2001).

<sup>5</sup> *After the Supreme Court issued its decision, Maine Governor Baldacci convened a workgroup of legislators and other stakeholders who participated in the drafting and passage of the Maine Rx Program. On May 30, 2003, as a result of that workgroup's efforts, the Governor presented a redesigned program, Maine Rx Plus, to the Maine legislature.*