



Ralph D. Clark

*Bill Analysis*  
Legislative Service Commission

## **H.B. 290**

124th General Assembly  
(As Introduced)

**Reps. D. Miller, Jerse, Patton, Barnes, Britton, Distel, Sykes, Allen, Cirelli, Jones, Strahorn, Barrett, Fedor, Beatty, Key, Krupinski, Metelsky, Sferra, Lendrum, S. Smith, Woodard, Boccieri, Rhine, Coates, Carano**

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### **BILL SUMMARY**

- ? Creates the Rx Program in the Department of Job and Family Services.
- ? Requires the Director of Job and Family Services to adopt rules governing the Rx Program.
- ? Establishes the Rx Fund in the state treasury.

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### **CONTENT AND OPERATION**

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

(secs. 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. Any resident of Ohio may apply to ODJFS to participate in the Rx 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>1</sup>

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<sup>1</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.

### **Rebate agreements**

(secs. 5110.25, 5110.26, and 5110.27)

Each manufacturer of dangerous drugs and wholesale distributor of dangerous drugs that sells prescription drugs through a state health plan may enter into a rebate agreement with the Director of ODJFS under which the manufacturer or wholesale distributor is to make rebate payments to the Director on a quarterly basis or in accordance with a schedule established by rules adopted by ODJFS.

The Director must negotiate with each manufacturer or distributor of dangerous drugs the amount of the rebate the manufacturer or distributor will pay to the Director under the Rx Program. In the process of negotiations, the Director must (1) take into consideration rebates provided for under federal Medicaid law, the average wholesale price of prescription drugs, and any other information on prescription drug prices and price discounts available, (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 not less than the amount the federal government receives as a discount, rebate, or price reduction for prescription drugs.

The Rx Program must cover a prescription drug if the prescription drug is included in a rebate agreement entered into under the bill.

### **Discounts for prescription 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. The amount of the discount must be the amount of the rebate a manufacturer or wholesale distributor of dangerous drugs pays the Director for the drug pursuant to their rebate agreement. In accordance with rules adopted by the Director, a terminal distributor must also disclose to an 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.

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*"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.*

### **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 of ODJFS verifying the amount that the terminal distributor charged the participant. The terminal distributor must use a claim form prescribed in rules adopted by the Director pursuant to the bill.

The Director, using the claims submitted, must reimburse a terminal distributor the amount of the discount provided to an Rx Program participant on a prescription drug under the bill and pay the professional fee established by rules adopted pursuant to the bill for each claim. The Director must make the reimbursements and payments on 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.

### **Manufacturers and distributors who do not enter into rebate agreements**

(sec. 5110.28)

The Director of ODJFS is required to do both of the following with respect to manufacturers and wholesale distributors of dangerous drugs that do not enter into rebate agreements with the Director:

(1) Maintain a list of those manufacturers and wholesale distributors and make it available to the public;

(2) Require all prescription drugs manufactured by those manufacturers and distributed by those distributors to receive prior authorization by the Department of ODJFS pursuant to federal Medicaid law before the costs of those drugs may be reimbursed under Medicaid.<sup>2</sup>

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<sup>2</sup> A drug subject to "prior authorization" must be approved by the state Medicaid program in each case it is prescribed before Medicaid reimbursements for the drug will be permitted.

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

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

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) 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.

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

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

(5) 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.

### **The Rx Program Fund**

(sec. 5110.04)

The bill establishes the Rx Program Fund in the state treasury, consisting of rebates made by manufacturers and wholesale distributors of dangerous drugs and money appropriated by the General Assembly. The Director of ODJFS is to use the money in the 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 established by ODJFS rules, and (3) to pay 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.

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## **COMMENT**

The bill is modeled on statutes establishing the Maine Rx Program. On May 16, 2001, the First Circuit Court of Appeals handed down a decision in the case of *Pharmaceutical Research and Manufacturers of America v. Concannon* that upheld certain provisions of those statutes.<sup>3</sup> The Maine program is to provide prescription drug discounts to Maine residents based on rebates negotiated by the state with drug manufacturers and labelers. Manufacturers and labelers who do not enter into rebate agreements are to have their drugs subjected to prior authorization by the Maine Department of Human Services under provisions of federal Medicaid law before the cost can be reimbursed under the state's Medicaid program. The court found that the Maine Rx Program provisions that apply the prior authorization requirements of federal law are not preempted by federal Medicaid law under the Supremacy Clause of the United States Constitution, and do not violate the Interstate Commerce Clause. The court also found that the rebate agreement provisions do not violate the Interstate Commerce Clause. A petition for certiorari was filed July 31, 2001 with the United States Supreme

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<sup>3</sup> *Pharmaceutical Research and Manufacturers of America v. Concannon*, 2001 U.S. App. LEXIS 9324 (1st Cir. Me., May 16, 2001).

Court requesting that the Court hear the case. As of October 2, 2001, the Court had not acted on the request.<sup>4</sup>

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## HISTORY

ACTION	DATE	JOURNAL ENTRY
Introduced	06-07-01	p. 635

H0290-I.124/jc

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<sup>4</sup> U.S. Supreme Court web site, [www.SupremeCourtUS.gov/docket](http://www.SupremeCourtUS.gov/docket), visited October 2, 2001.