HOUSE BILL No. 5922

June 21, 2000, Introduced by Reps. Woodward, Daniels, Schauer, Spade, Bob Brown, Dennis, Mans, Switalski, Callahan, Basham, Cherry, Hale, Bogardus, Garza, Reeves, Rison, Neumann, Frank, Pestka, Kelly, Brewer, Lockwood, Clarke, Bovin, Hanley, Gieleghem, Wojno, Hansen, Rivet, Minore, Vaughn, Clark, LaForge, DeHart, Schermesser, Brater, Price, O'Neil, Jacobs, Prusi, Jamnick, Quarles, Scott, Martinez, Thomas, Stallworth, Sheltrown and Kilpatrick and referred to the Committee on Health Policy.

A bill to require certain prescription drug manufacturers and labelers to enter into rebate agreements with the department of community health; to establish a discount prescription drug program for certain individuals; to require retail pharmacies to offer certain discounts; to prescribe the powers and duties of certain state agencies and departments; to provide for the promulgation of rules; and to prescribe penalties and remedies.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

Sec. 1. This act shall be known and may be cited as the "Michigan prescription drug fair pricing act".

Sec. 2. As used in this act:

(a) "Department" means the department of community health.

(b) "Director" means the director of the department of community health or his or her designee.

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(c) "Labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and that has a labeler code from the federal food and drug administration under 21 C.F.R. 207.20.

(d) "Manufacturer" means a manufacturer of prescription drugs and includes a subsidiary or affiliate of a manufacturer.

(e) "Medicaid" means the program for medical assistance administered by the department under the social welfare act, 1939 PA 280, MCL 400.1 to 400.119b.

(f) "Retail pharmacy" means a pharmacy that dispenses prescription drugs at retail and is licensed under article 15 of the public health code, 1978 PA 368, MCL 333.16101 to 333.18838, and that dispenses prescription drugs covered by a rebate agreement under the Rx program created in section 3.

Sec. 3. (1) The Rx program is established within the department to provide discounted prescription drug prices to uninsured residents of this state.

(2) A manufacturer or labeler that sells prescription drugs in this state that are ultimately dispensed to patients through any state funded or state operated program shall enter into a rebate agreement with the department for the Rx program. The rebate agreement shall require the manufacturer or labeler to make rebate payments to the state each calendar quarter according to a schedule established by the department under subsection (3).

(3) The director shall negotiate the amount of the rebate required under a rebate agreement entered into pursuant to subsection (2) from a manufacturer or labeler in accordance with the following:

(a) The director shall take into consideration the rebate calculated under the medicaid rebate program pursuant to section 1927 of title XIX of the social security act, 42 U.S.C. 1396r-8, the average wholesale price of prescription drugs, and any other information on prescription drug prices and price discounts considered relevant by the director.

(b) The director shall attempt to obtain an initial rebate amount equal to or greater than the rebate calculated under the medicaid rebate program pursuant to section 1927 of title XIX of the social security act, 42 U.S.C. 1396r-8.

(c) The director shall begin collecting rebates under this section on January 1, 2002. The director shall attempt to obtain a rebate in an amount equal to or greater than the amount of any discount, rebate, or price reduction for prescription drugs provided to the federal government by manufacturers and labelers.

Sec. 4. A resident of this state is eligible to participate in the Rx program if he or she does not have prescription drug coverage under a public or private health care payment or benefits program. The department shall establish simplified procedures for determining eligibility and issuing Rx program enrollment cards to eligible residents. The department shall undertake outreach efforts to build public awareness of the Rx program and maximize enrollment by eligible residents. The department may

promulgate rules to adjust the requirements and terms of the Rx program to accommodate any new federally funded prescription drug programs.

Sec. 5. (1) A retail pharmacy shall discount the price of a prescription covered by the Rx program and sold to an Rx program participant.

(2) The department shall establish discounted prices for drugs covered by a rebate agreement entered into under section 3 and shall promote the use of efficacious and reduced-cost prescription drugs, taking into consideration reduced prices for state and federally capped drug programs, differential dispensing fees, administrative overhead, and incentive payments.

(3) Beginning July 1, 2001, a retail pharmacy shall offer a prescription drug to an Rx program participant at or below the average wholesale price, minus 6%, plus the dispensing fee provided under the state medicaid program. The initial price level required under this subsection shall be specified by the director by rule. The average wholesale price, for purposes of this subsection, is the wholesale price charged on a specific prescription drug that is assigned by the manufacturer and is listed in a nationally recognized drug pricing file approved by the director.

(4) Not later than January 1, 2002, a retail pharmacy shall offer a prescription drug to an Rx program participant at or below the initial price level specified in subsection (3) minus the amount of any rebate paid by the state to the retail pharmacy. The discounted price level required by this subsection

shall be specified by the director by rule. In determining the discounted price level, the director shall consider an average of all rebates weighted by sales of prescription drugs subject to rebates under this act over the most recent 12-month period for which the information is available.

Sec. 6. (1) The Michigan board of pharmacy created in section 17721 of the public health code, 1978 PA 368, MCL 333.17721, shall promulgate rules requiring disclosure by a retail pharmacy to an Rx program participant of the amount of savings provided as a result of the Rx program. In promulgating the rules, the Michigan board of pharmacy shall consider and protect information that is proprietary in nature.

(2) The department shall not impose transaction charges on retail pharmacies that submit claims or receive payments under the Rx program.

(3) A retail pharmacy shall submit a claim to the department to verify the amount charged to an Rx program participant.

(4) On a weekly or biweekly basis, the department shall reimburse a retail pharmacy for all of the discounted prices provided to Rx program participants and professional fees set by the director. For purposes of this subsection, the initial professional fee is $3.00 per prescription. The director may raise or lower the professional fee set by this subsection by the promulgation of a rule.

(5) The department shall collect from all retail pharmacies utilization data necessary to calculate the amount of the rebate from the manufacturer or labeler. The department shall protect

the confidentiality of all information subject to confidentiality protection under state or federal law, rule, or regulation.

Sec. 7. The name of a manufacturer or labeler that does not enter into a rebate agreement with the department as required under section 3 is public information, and the department shall release this information to the public. The department shall impose the prior authorization requirements allowed under the state medicaid program, as permitted by law, for the dispensing of prescription drugs provided by a manufacturer or labeler described in this section.

Sec. 8. A discrepancy in a rebate amount paid under a rebate agreement required under section 3 shall be resolved using the following process:

(a) If there is a discrepancy in the manufacturer's or labeler's favor between the amount claimed by a retail pharmacy and the amount rebated by the manufacturer or labeler, the department, at the department's expense, may hire a mutually agreed-upon independent auditor. If a discrepancy still exists following the audit, the manufacturer or labeler shall justify the reason for the discrepancy or make payment to the department for any additional rebate amount due.

(b) If there is a discrepancy against the interest of the manufacturer or labeler in the information provided by the department to the manufacturer or labeler regarding the negotiation under section 3 of the rebate required to be paid by the manufacturer or labeler, the manufacturer or labeler, at the manufacturer's or labeler's expense, may hire a mutually

agreed-upon independent auditor to verify the accuracy of the information supplied by the department. If a discrepancy still exists following the audit, the department shall justify the reason for the discrepancy or refund to the manufacturer or labeler any excess paid to the department by the manufacturer or labeler pursuant to a rebate agreement entered into under section 3.

(c) Following the procedures established in subdivision (a) or (b), either the department or the manufacturer or labeler may request a hearing. Supporting documentation must accompany the request for a hearing. The hearing shall be conducted as a contested case hearing under the administrative procedures act of 1969, 1969 PA 306, MCL 24.201 to 24.328.

Sec. 9. (1) The Rx dedicated fund is established in the state treasury to receive revenue from manufacturers and labelers who pay rebates to the department under this act and any appropriations or allocations designated for the fund.

(2) The department shall use the fund to reimburse retail pharmacies for discounted prices provided to Rx program participants and to reimburse the department for the costs of administering the Rx program, including contracted services, computer costs, professional fees paid to retail pharmacies, and other reasonable Rx program costs.

(3) The department shall oversee the investment of the fund, and interest earned on Rx dedicated fund balances accrues to the fund.

(4) The unexpended balance remaining in the fund at the end of the fiscal year remains in the fund and does not lapse to the general fund.

Sec. 10. The department shall report the enrollment and financial status of the Rx program to the legislature by the second week in January each year.

Sec. 11. In implementing this act, the department may coordinate with other governmental programs and may take actions to enhance efficiency, reduce the cost of prescription drugs, and maximize the benefits of this and other governmental programs, including providing the benefits of the Rx program to the beneficiaries of other programs.

Sec. 12. The department may adopt rules to implement the provisions of this act.

Sec. 13. The department may seek any waivers of federal law, rule, or regulation necessary to implement this act.

Sec. 14. (1) By April 1, 2003, the director shall determine whether the prices for prescription drugs purchased by Rx programs participants are reasonably comparable to the lowest cost paid for the same prescription drugs delivered or dispensed to patients under all other public or private health care payment or benefits programs. In making this determination, all of the following apply:

(a) The director shall review prescription drug use in the medicaid program using data from the most recent 6-month period for which data is available.

(b) Using the data reviewed under subdivision (a), the director shall determine and list the 100 prescription drugs for which the most units were provided and the 100 prescription drugs for which the total cost was the highest.

(c) For each prescription drug listed under subdivision (b), the director shall determine the cost for each prescription drug purchased by Rx program participants on a certain date. The department shall then calculate the average cost for each of the listed prescription drugs.

(d) For each prescription drug listed under subdivision (b), the director shall determine the lowest cost for each prescription drug paid by any purchaser on the date that is used for subdivision (c) delivered or dispensed in this state, taking into consideration the federal supply schedule and prices paid by pharmaceutical benefits managers and by large purchasers and excluding drugs purchased through the Rx program. The department shall then calculate the average cost for each of the listed prescription drugs described in this subdivision.

(e) If the average cost for 1 or more prescription drugs under the Rx program as determined in subdivision (c) is not reasonably comparable to the average lowest cost for the same drug or drugs as determined in subdivision (d), the director shall establish by rule maximum retail prices for some or all prescription drugs sold in this state. Maximum prescription drug prices established under this subdivision shall take effect October 1, 2003 or when the promulgated rules take effect, whichever occurs first.

(2) In making a determination under subsection (1), the director may rely on pricing information on a selected number of prescription drugs if that list is representative of the prescription drug needs of the residents of the state and is made public as part of the process of establishing maximum retail prices under subsection (1)(e).

(3) In addition to the emergency powers prescribed in section 2251 of the public health code, 1978 PA 368, MCL 333.2251, the director may take actions that the director determines necessary if there is a severe limitation or shortage of or lack of access to prescription drugs in the state that could threaten or endanger the public health or welfare.

(4) If a retail pharmacy contests the maximum retail price of a prescription drug established pursuant to this section, the retail pharmacy is entitled to a hearing in accordance with the administrative procedures act of 1969, 1969 PA 306, MCL 24.201 to 24.328.

(5) A violation of the maximum retail prices established under this section is a felony.

Sec. 15. (1) A manufacturer, labeler, or wholesaler of prescription drugs engages in illegal profiteering if that manufacturer, labeler, or distributor does 1 or more of the following:

(a) Exacts or demands an unconscionable price for a prescription drug.

(b) Exacts or demands prices or terms for a prescription drug that lead to an unjust or unreasonable profit.

(c) Discriminates unreasonably against a person in the sale, exchange, distribution, or handling of prescription drugs dispensed or delivered in this state.

(d) Intentionally prevents, limits, lessens, or restricts the sale or distribution of prescription drugs in this state in retaliation for being subject to this act.

(2) The attorney general may bring a civil action for a direct or indirect injury to any person, any group of persons, the state, or any political subdivision of the state caused by a violation of subsection (1). There is a right to a jury trial in any action brought under this section. If the state prevails in an action brought under this subsection, the defendant shall pay 3 times the amount of damages and the costs of the action, including, but not limited to, necessary and reasonable investigative costs, reasonable expert fees, and reasonable attorney fees. For a willful or repeated violation of subsection (1), exemplary damages may be awarded. After deduction of the costs of distribution, the court shall order the damages equitably distributed by the state to all injured parties.

(3) Each violation of subsection (1) is a civil violation for which the attorney general may obtain, in addition to other remedies, injunctive relief and a civil penalty in an amount not to exceed $100,000.00, plus the costs of bringing the action, including, but not limited to, necessary and reasonable investigative costs, reasonable expert fees, and reasonable attorney fees.

Sec. 16. This act takes effect January 1, 2001.