HOUSE BILL No. 4529

March 22, 2005, Introduced by Reps. Donigan, Vagnozzi, Tobocman, Lipsey, Hopgood, Accavitti, Gillard, Gleason, Alma Smith, Kolb, Leland and Virgil Smith and referred to the Committee on Health Policy.

A bill to allow 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 allow certain retail pharmacies to offer certain discounts; to create certain funds; to prescribe certain powers and duties of certain state agencies and departments; and to provide for the promulgation of rules.

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

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community health or his or her designee.

(c) "Fund" means the Rx dedicated fund established in section 7.

(d) "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 CFR 207.20.

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

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

(g) "Participating retail pharmacy" means a pharmacy or other business 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, that participates in the state medicaid program or voluntarily agrees to dispense prescription drugs covered by a rebate agreement under the Rx program created in section 3.

(h) "Rx program participant" means an individual who is eligible to participate in the Rx program under section 4.

(i) "Underinsured" means an individual who is covered by an insurance policy that pays 80% or less of prescription drug costs.

Sec. 3. (1) The Rx program is established within the department to provide discounted prescription drug prices to uninsured and underinsured residents of this state and to residents of this state who are recipients of benefits under the state

medicaid program.

(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 may voluntarily elect to 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 USC 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 USC 1396r-8.

(c) 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.

(d) The director shall begin collecting rebates under this section on July 1, 2005.

(4) The name of a manufacturer or labeler that does not enter into a rebate agreement with the department under this section is public information, and the department shall release the information to the public. If the director and a drug manufacturer or labeler fail to reach agreement on the terms of a rebate, the director 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. In determining which prescription drugs are placed on the prior authorization list, the director shall only allow prior authorization of a prescription drug if safety, efficacy, and disease management considerations are not compromised by substitution with an equivalent prescription drug.

(5) A participating retail pharmacy shall discount the price of a prescription covered by the Rx program and sold to an Rx program participant. In addition, the department and a participating retail pharmacy shall meet all of the following requirements:

(a) The department shall establish discounted prices for drugs covered by a rebate agreement entered into under this section 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.

(b) Beginning July 1, 2005, a participating 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 subdivision shall be specified by the director by rule. The average wholesale price, for purposes of this subdivision, 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.

(c) Not later than October 1, 2005, a participating retail pharmacy shall offer a prescription drug to an Rx program participant at or below the initial price level specified in subdivision (b) minus the amount of any rebate paid by the state to the retail pharmacy. The discounted price level required by this subdivision 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 and the cost of administering the Rx program, not to exceed 1% of the total rebates received.

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 plan, is underinsured, or is a recipient of benefits under the state medicaid program. The department shall promulgate rules to

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) 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 participating 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 a transaction charge on a participating retail pharmacy that submits a claim or receives a payment under the Rx program.

(3) A participating 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 participating retail pharmacy for all of the discounted prices provided to Rx program participants and dispensing fees set by the director.

(5) The department shall collect from each participating retail pharmacy 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 and federal law, rule, and regulation.

Sec. 6. A discrepancy in a rebate amount paid under a rebate agreement entered into 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 participating 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 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) After completion of 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. 7. (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 participating retail pharmacies for discounted prices provided to Rx program participants and to reimburse the department for the costs of administering the Rx program, including, but not limited to, contracted services, computer costs, professional fees paid to participating retail pharmacies, and other reasonable Rx program costs.

(3) The state treasurer shall oversee the investment of the fund, and interest earned on 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. 8. Beginning with the year after the year in which this act takes effect, 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. 9. 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. 10. The department and board shall promulgate rules to implement this act under the administrative procedures act of 1969, 1969 PA 306, MCL 24.201 to 24.328.

Sec. 11. The department may seek any waivers of federal law, rule, or regulation necessary to implement this act.

Sec. 12. If a portion of this act or the application of this act to any person or circumstances is found by a court to be invalid, the invalidity does not affect the remaining portions or applications of the act that can be given effect without the invalid portion or application, if the remaining portions of the act are not determined by the court to be inoperable, and to this end this act is declared to be severable.