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HOUSE BILL No. 4018

January 27, 2005, Introduced by Rep. Kahn 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.

- 1 (b) "Director" means the director of the department of
- 2 community health or his or her designee.
- 3 (c) "Fund" means the Rx dedicated fund established in section
- **4** 7.
- 5 (d) "Labeler" means an entity or person that receives
- 6 prescription drugs from a manufacturer or wholesaler and repackages
- 7 those drugs for later retail sale and that has a labeler code from
- 8 the federal food and drug administration under 21 CFR 207.20.
- 9 (e) "Manufacturer" means a manufacturer of prescription drugs
- 10 and includes a subsidiary or affiliate of a manufacturer.
- (f) "Medicaid" or "state medicaid program" means the program
- 12 for medical assistance administered by the department under the
- 13 social welfare act, 1939 PA 280, MCL 400.1 to 400.119b.
- 14 (g) "Participating retail pharmacy" means a pharmacy or other
- 15 business that dispenses prescription drugs at retail and is
- 16 licensed under article 15 of the public health code, 1978 PA 368,
- 17 MCL 333.16101 to 333.18838, that participates in the state medicaid
- 18 program or voluntarily agrees to dispense prescription drugs
- 19 covered by a rebate agreement under the Rx program created in
- 20 section 3.
- 21 (h) "Rx program participant" means an individual who is
- 22 eligible to participate in the Rx program under section 4.
- (i) "Underinsured" means an individual who is covered by an
- 24 insurance policy that pays 80% or less of prescription drug costs.
- 25 Sec. 3. (1) The Rx program is established within the
- 26 department to provide discounted prescription drug prices to
- 27 uninsured and underinsured residents of this state and to residents

- 1 of this state who are recipients of benefits under the state
- 2 medicaid program.
- 3 (2) A manufacturer or labeler that sells prescription drugs in
- 4 this state that are ultimately dispensed to patients through any
- 5 state funded or state operated program may voluntarily elect to
- 6 enter into a rebate agreement with the department for the Rx
- 7 program. The rebate agreement shall require the manufacturer or
- 8 labeler to make rebate payments to the state each calendar quarter
- 9 according to a schedule established by the department under
- 10 subsection (3).
- 11 (3) The director shall negotiate the amount of the rebate
- 12 required under a rebate agreement entered into pursuant to
- 13 subsection (2) from a manufacturer or labeler in accordance with
- 14 the following:
- 15 (a) The director shall take into consideration the rebate
- 16 calculated under the medicaid rebate program pursuant to section
- 17 1927 of title XIX of the social security act, 42 USC 1396r-8, the
- 18 average wholesale price of prescription drugs, and any other
- 19 information on prescription drug prices and price discounts
- 20 considered relevant by the director.
- 21 (b) The director shall attempt to obtain an initial rebate
- 22 amount equal to or greater than the rebate calculated under the
- 23 medicaid rebate program pursuant to section 1927 of title XIX of
- 24 the social security act, 42 USC 1396r-8.
- 25 (c) The director shall attempt to obtain a rebate in an amount
- 26 equal to or greater than the amount of any discount, rebate, or
- 27 price reduction for prescription drugs provided to the federal

- 1 government by manufacturers and labelers.
- 2 (d) The director shall begin collecting rebates under this
- 3 section on July 1, 2005.
- 4 (4) The name of a manufacturer or labeler that does not enter
- 5 into a rebate agreement with the department under this section is
- 6 public information, and the department shall release the
- 7 information to the public. If the director and a drug manufacturer
- 8 or labeler fail to reach agreement on the terms of a rebate, the
- 9 director shall impose the prior authorization requirements allowed
- 10 under the state medicaid program, as permitted by law, for the
- 11 dispensing of prescription drugs provided by a manufacturer or
- 12 labeler described in this section. In determining which
- 13 prescription drugs are placed on the prior authorization list, the
- 14 director shall only allow prior authorization of a prescription
- 15 drug if safety, efficacy, and disease management considerations are
- 16 not compromised by substitution with an equivalent prescription
- **17** drug.
- 18 (5) A participating retail pharmacy shall discount the price
- 19 of a prescription covered by the Rx program and sold to an Rx
- 20 program participant. In addition, the department and a
- 21 participating retail pharmacy shall meet all of the following
- 22 requirements:
- 23 (a) The department shall establish discounted prices for drugs
- 24 covered by a rebate agreement entered into under this section and
- 25 shall promote the use of efficacious and reduced-cost prescription
- 26 drugs, taking into consideration reduced prices for state and
- 27 federally capped drug programs, differential dispensing fees,

- 1 administrative overhead, and incentive payments.
- 2 (b) Beginning July 1, 2005, a participating retail pharmacy
- 3 shall offer a prescription drug to an Rx program participant at or
- 4 below the average wholesale price, minus 6%, plus the dispensing
- 5 fee provided under the state medicaid program. The initial price
- 6 level required under this subdivision shall be specified by the
- 7 director by rule. The average wholesale price, for purposes of this
- 8 subdivision, is the wholesale price charged on a specific
- 9 prescription drug that is assigned by the manufacturer and is
- 10 listed in a nationally recognized drug pricing file approved by the
- 11 director.
- 12 (c) Not later than October 1, 2005, a participating retail
- 13 pharmacy shall offer a prescription drug to an Rx program
- 14 participant at or below the initial price level specified in
- 15 subdivision (b) minus the amount of any rebate paid by the state to
- 16 the retail pharmacy. The discounted price level required by this
- 17 subdivision shall be specified by the director by rule. In
- 18 determining the discounted price level, the director shall consider
- 19 an average of all rebates weighted by sales of prescription drugs
- 20 subject to rebates under this act over the most recent 12-month
- 21 period for which the information is available and the cost of
- 22 administering the Rx program, not to exceed 1% of the total rebates
- 23 received.
- Sec. 4. A resident of this state is eligible to participate in
- 25 the Rx program if he or she does not have prescription drug
- 26 coverage under a public or private health care payment or benefits
- 27 plan, is underinsured, or is a recipient of benefits under the

- 1 state medicaid program. The department shall promulgate rules to
- 2 establish simplified procedures for determining eligibility and
- 3 issuing Rx program enrollment cards to eligible residents. The
- 4 department shall undertake outreach efforts to build public
- 5 awareness of the Rx program and maximize enrollment by eligible
- 6 residents. The department may promulgate rules to adjust the
- 7 requirements and terms of the Rx program to accommodate any new
- 8 federally funded prescription drug programs.
- 9 Sec. 5. (1) The Michigan board of pharmacy created in section
- 10 17721 of the public health code, 1978 PA 368, MCL 333.17721, shall
- 11 promulgate rules requiring disclosure by a participating retail
- 12 pharmacy to an Rx program participant of the amount of savings
- 13 provided as a result of the Rx program. In promulgating the rules,
- 14 the Michigan board of pharmacy shall consider and protect
- 15 information that is proprietary in nature.
- 16 (2) The department shall not impose a transaction charge on a
- 17 participating retail pharmacy that submits a claim or receives a
- 18 payment under the Rx program.
- 19 (3) A participating retail pharmacy shall submit a claim to
- 20 the department to verify the amount charged to an Rx program
- 21 participant.
- 22 (4) On a weekly or biweekly basis, the department shall
- 23 reimburse a participating retail pharmacy for all of the discounted
- 24 prices provided to Rx program participants and dispensing fees set
- 25 by the director.
- 26 (5) The department shall collect from each participating
- 27 retail pharmacy utilization data necessary to calculate the amount

- 1 of the rebate from the manufacturer or labeler. The department
- 2 shall protect the confidentiality of all information subject to
- 3 confidentiality protection under state and federal law, rule, and
- 4 regulation.
- 5 Sec. 6. A discrepancy in a rebate amount paid under a rebate
- 6 agreement entered into under section 3 shall be resolved using the
- 7 following process:
- 8 (a) If there is a discrepancy in the manufacturer's or
- 9 labeler's favor between the amount claimed by a participating
- 10 retail pharmacy and the amount rebated by the manufacturer or
- 11 labeler, the department, at the department's expense, may hire a
- 12 mutually agreed-upon independent auditor. If a discrepancy still
- 13 exists following the audit, the manufacturer or labeler shall
- 14 justify the reason for the discrepancy or make payment to the
- 15 department for any additional rebate amount due.
- 16 (b) If there is a discrepancy against the interest of the
- 17 manufacturer or labeler in the information provided by the
- 18 department to the manufacturer or labeler regarding the negotiation
- 19 under section 3 of the rebate to be paid by the manufacturer or
- 20 labeler, the manufacturer or labeler, at the manufacturer's or
- 21 labeler's expense, may hire a mutually agreed-upon independent
- 22 auditor to verify the accuracy of the information supplied by the
- 23 department. If a discrepancy still exists following the audit, the
- 24 department shall justify the reason for the discrepancy or refund
- 25 to the manufacturer or labeler any excess paid to the department by
- 26 the manufacturer or labeler pursuant to a rebate agreement entered
- 27 into under section 3.

- 1 (c) After completion of the procedures established in
- 2 subdivision (a) or (b), either the department or the manufacturer
- 3 or labeler may request a hearing. Supporting documentation must
- 4 accompany the request for a hearing. The hearing shall be conducted
- 5 as a contested case hearing under the administrative procedures act
- 6 of 1969, 1969 PA 306, MCL 24.201 to 24.328.
- 7 Sec. 7. (1) The Rx dedicated fund is established in the state
- 8 treasury to receive revenue from manufacturers and labelers who pay
- 9 rebates to the department under this act and any appropriations or
- 10 allocations designated for the fund.
- 11 (2) The department shall use the fund to reimburse
- 12 participating retail pharmacies for discounted prices provided to
- 13 Rx program participants and to reimburse the department for the
- 14 costs of administering the Rx program, including, but not limited
- 15 to, contracted services, computer costs, professional fees paid to
- 16 participating retail pharmacies, and other reasonable Rx program
- 17 costs.
- 18 (3) The state treasurer shall oversee the investment of the
- 19 fund, and interest earned on fund balances accrues to the fund.
- 20 (4) The unexpended balance remaining in the fund at the end of
- 21 the fiscal year remains in the fund and does not lapse to the
- 22 general fund.
- 23 Sec. 8. Beginning with the year after the year in which this
- 24 act takes effect, the department shall report the enrollment and
- 25 financial status of the Rx program to the legislature by the second
- 26 week in January each year.
- 27 Sec. 9. In implementing this act, the department may

- 1 coordinate with other governmental programs and may take actions to
- 2 enhance efficiency, reduce the cost of prescription drugs, and
- 3 maximize the benefits of this and other governmental programs,
- 4 including providing the benefits of the Rx program to the
- 5 beneficiaries of other programs.
- 6 Sec. 10. The department and board shall promulgate rules to
- 7 implement this act under the administrative procedures act of 1969,
- 8 1969 PA 306, MCL 24.201 to 24.328.
- 9 Sec. 11. The department may seek any waivers of federal law,
- 10 rule, or regulation necessary to implement this act.
- 11 Sec. 12. If a portion of this act or the application of this
- 12 act to any person or circumstances is found by a court to be
- 13 invalid, the invalidity does not affect the remaining portions or
- 14 applications of the act that can be given effect without the
- 15 invalid portion or application, if the remaining portions of the
- 16 act are not determined by the court to be inoperable, and to this
- 17 end this act is declared to be severable.