

**CREATE PRESCRIPTION DRUG FAIR
PRICING ACT**

House Bill 4151
Sponsor: Rep. David Woodward
Committee: Health Policy

Complete to 2-13-03

A SUMMARY OF HOUSE BILL 4151 AS INTRODUCED 2-5-03

House Bill 4151 would create the "Prescription Drug Fair Pricing Act" to establish within the Department of Community Health an "Rx program" to provide discounted prescription drug prices to eligible state residents who are uninsured, underinsured, or state Medicaid recipients. The bill would allow a manufacturer or labeler that sells prescription drugs that are ultimately dispensed to patients through any state funded or state operated program to enter into a rebate agreement with the Department of Community Health (DCH). Participation in the program would be voluntary, but the DCH would release to the public the name of any manufacturer or labeler that did not enter into a rebate agreement. The director of the DCH (or his or her designee) would negotiate the amount of the rebate required under the agreement, in accordance with guidelines set forth in the bill, and a dedicated fund would be created within the DCH to receive revenue from manufacturers and labelers who paid rebates. The DCH would use the fund to reimburse "participating retail pharmacies"--i.e., pharmacies and other retail dispensers of prescription drugs that either participated in the state Medicaid program or voluntarily agreed to discount the price of covered prescriptions--for discounted prices provided to program participants. Participating pharmacies would be required to discount the price of a covered prescription sold to a program participant.

The bill would provide guidelines for a process for resolving a discrepancy in a rebate amount paid under a rebate agreement. Beginning the year after the act took effect, and each year thereafter, the DCH would have to report the enrollment and financial status of the program to the legislature. Finally, the bill would authorize the DCH to coordinate with other governmental programs and to take actions to enhance efficiency, reduce the cost of prescription drugs, and maximize the benefits of the Rx program and other governmental programs. The act would take effect January 1, 2004. A more detailed summary of the bill's key provisions follows below.

Rx program. A manufacturer or labeler that sold prescription drugs that were ultimately dispensed through any state funded or state operated program could voluntarily elect to enter into a rebate agreement with the DCH for the Rx program. The rebate agreement would require the manufacturer or labeler to make rebate payments to the state each calendar quarter beginning July 1, 2004. In negotiating the amount of the rebate with a manufacturer or labeler, the DCH would have to take into consideration the rebate calculated under the Medicaid rebate program pursuant to section 1927 of Title XIX of the Social Security Act, the average wholesale price of prescription drugs, and any other relevant information on prescription drug prices and price discounts. The DCH would have to attempt to obtain an initial rebate amount equal to or greater than the rebate calculated under the section 1927 Medicaid rebate program. The bill would also

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direct the DCH to try 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.

The name of any manufacturer and labeler who chose not to enter into a rebate agreement with the DCH would be considered public information, and the DCH would have to release the information to the public. If the DCH and a drug manufacturer or labeler failed to reach agreement on the terms of a rebate, the DCH would 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. The bill specifies that the DCH could allow prior authorization of a prescription drug only if safety, efficacy, and disease management considerations would not be compromised by substitution with an equivalent prescription drug.

A participating retail pharmacy would have to discount the price of a prescription covered by the Rx program and sold to an Rx program participant. In addition, the DCH and a participating pharmacy would have to satisfy several requirements. First, the DCH would have to establish discounted prices for drugs covered by a rebate agreement and would have to 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. Second, beginning July 1, 2004, a pharmacy would have to sell a prescription drug to a program participant at or below the "average wholesale price", minus six percent, plus the dispensing fee provided under the state Medicaid program. ("Average wholesale price" would mean the wholesale price charged on a specific prescription drug that was assigned by the manufacturer and was listed in a nationally recognized drug pricing file approved by the DCH.) The DCH would specify by rule both the initial and discounted price levels. Not later than October 1, 2004, a participating pharmacy would have to offer a prescription drug to a program participant at or below the initial price level, minus the amount of any rebate paid by the state to the pharmacy. In determining the discounted price level, the DCH would have to consider an average of all rebates weighted by sales of prescription drugs subject to rebates under the act over the most recent 12-month period for which information was available and the cost of administering the Rx program. The administration costs could not exceed one percent of the total rebates received.

Participant eligibility. A state resident would be eligible to participate in the program if he or she did not have prescription drug coverage under a public or private health care payment or benefits plan, was underinsured, or was a recipient of state Medicaid benefits. The DCH would be required to promulgate rules to establish simplified procedures for determining eligibility and issuing program enrollment cards to eligible residents, and to undertake outreach efforts to build public awareness of the program and maximize enrollment. The DCH could promulgate rules to adjust the requirements and terms of the program to accommodate any new federally funded prescription drug programs.

Pharmacies. The state board of pharmacy would promulgate rules requiring disclosure by a participating pharmacy to a program participant the amount of savings provided as a result of the program, and would have to consider and protect proprietary information in doing so. The DCH could not impose a transaction charge on a participating pharmacy that submitted a claim or

received a payment under the program. A participating pharmacy would have to submit a claim to the DCH to verify the amount charged to a program participant. On a weekly or biweekly basis, the DCH would reimburse a participating pharmacy for all of the discounted prices provided to program participants and dispensing fees set by the director. The DCH would collect from each pharmacy utilization data necessary to calculate the amount of the rebate and would have to protect the confidentiality of any information protected by state or federal law, rule, or regulation.

Discrepancy in rebate paid. Discrepancies in a rebate amount paid under a rebate agreement would be resolved as follows. In the case of a discrepancy in the manufacturer's or labeler's favor between the amount claimed by a participating pharmacy and the amount rebated, the DCH could hire, at its own expense, a mutually agreed-upon independent auditor. If the audit did not resolve the discrepancy, the manufacturer or labeler would have to justify the reason for the discrepancy or make payment to the DCH for any additional rebate amount due.

If there was a discrepancy against the interest of the manufacturer or labeler in the information provided by the DCH to the manufacturer or labeler regarding the negotiation of the rebate to be paid by the manufacturer or labeler, the manufacturer or labeler, at its own expense, could hire a mutually agreed-upon independent auditor to verify the accuracy of the information. If the discrepancy persisted following the audit, the DCH would have to justify the reason for the discrepancy or refund to the manufacturer or labeler any excess paid to the DCH by the manufacturer or labeler. After completion of these procedures, either party could request a hearing and would be required to submit supporting documentation along with the request. The hearing would be conducted as a contested case hearing under the Administrative Procedures Act of 1969.

Rx dedicated fund. The bill would establish the Rx dedicated fund in the state treasury to receive revenue from manufacturers and labelers who paid rebates to the DCH as well as any appropriations or allocations designated for the fund. The DCH would use the fund to reimburse participating retail pharmacies for discounted prices provided to Rx program participants and to reimburse itself for Rx program administration costs, including costs of contracted services, computer costs, professional fees paid to participating retail pharmacies, and other reasonable program costs. The state treasurer would be responsible for overseeing the investment of the fund. Interest earned on fund balances would accrue to the fund, and the unexpended balance remaining in the fund at the end of the fiscal year would remain in the fund rather than lapsing into the general fund.

DCH powers. The DCH could promulgate rules to implement the act and it could seek any waivers of federal law, rule, or regulation necessary to implement the act. In implementing the act, the DCH could coordinate with other governmental programs and could take actions to enhance efficiency, reduce the cost of prescription drugs, and maximize the benefits of the Rx program and other governmental programs.

Severability. If a portion of the act or the application of the act to any person or circumstances was found invalid by a court, the invalidity would not affect the remaining portions or applications of the act that could be given effect without the invalid portion or application.

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