MISSISSIPPI LEGISLATURE REGULAR SESSION 2004

By: Representatives Evans, Watson

To: Public Health and Human Services; Appropriations

HOUSE BILL NO. 435

AN ACT TO BE KNOWN AS THE PRESCRIPTION DRUG FAIR-PRICING ACT; TO PROVIDE FOR LEGISLATIVE FINDINGS AND DEFINITIONS; TO ESTABLISH THE PRESCRIPTION DRUG FAIR-PRICING PROGRAM WITHIN THE STATE DEPARTMENT OF HEALTH TO LOWER PRESCRIPTION DRUG PRICES FOR UNINSURED AND UNDERINSURED RESIDENTS OF THE STATE; TO PROVIDE THAT A DRUG MANUFACTURER OR LABELER THAT SELLS PRESCRIPTION DRUGS IN THE STATE MAY VOLUNTARILY ELECT TO ENTER INTO A REBATE AGREEMENT WITH THE DEPARTMENT; TO PROVIDE THAT THE DIRECTOR OF THE DEPARTMENT SHALL NEGOTIATE THE TERMS OF THE REBATE; TO PROVIDE THAT IF A DRUG MANUFACTURER OR LABELER ELECTS NOT TO AGREE TO A REBATE, THE DIRECTOR MAY PLACE THEIR PRODUCTS ON THE PRIOR AUTHORIZATION LIST FOR THE MEDICAID PROGRAM; TO PROVIDE THAT THE DIRECTOR SHALL PUBLICIZE TO HEALTH CARE PROVIDERS INFORMATION ABOUT THE RELATIVE COSTS OF DRUGS PRODUCED BY THOSE THAT ENTER INTO REBATE AGREEMENTS COMPARED TO THOSE THAT DO NOT ENTER INTO REBATE AGREEMENTS; TO REQUIRE RETAIL PHARMACIES TO DISCOUNT THE PRICE OF PRESCRIPTION DRUGS SOLD TO PARTICIPANTS IN THE PROGRAM; TO PROVIDE THAT ALL RESIDENTS OF THE STATE ARE ELIGIBLE TO PARTICIPATE IN THE PROGRAM; TO PROVIDE THAT THE DEPARTMENT SHALL UNDERTAKE OUTREACH EFFORTS TO BUILD PUBLIC AWARENESS OF THE PROGRAM AND MAXIMIZE ENROLLMENT; TO DIRECT THE STATE BOARD OF PHARMACY TO ADOPT RULES REQUIRING DISCLOSURE BY RETAIL PHARMACIES TO PROGRAM PARTICIPANTS OF THE AMOUNT OF SAVINGS PROVIDED AS A RESULT OF THE PROGRAM; TO PROVIDE THAT THE DEPARTMENT SHALL REIMBURSE RETAIL PHARMACIES FOR DISCOUNTED PRICES PROVIDED TO PROGRAM PARTICIPANTS AND DISPENSING FEES; TO PROVIDE PROCEDURES FOR RESOLVING DISCREPANCIES IN REBATE AMOUNTS; TO ESTABLISH A SPECIAL FUND IN THE STATE TREASURY TO RECEIVE REBATE FUNDS FROM MANUFACTURERS AND ANY APPROPRIATED FUNDS FOR THE PROGRAM; AND FOR RELATED PURPOSES.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MISSISSIPPI:

SECTION 1. This act shall be known as the "Mississippi Prescription Drug Fair-Pricing Act."

SECTION 2. (1) The Legislature finds that:

(a) Approximately one (1) in four (4) residents of Mississippi have no or wholly inadequate prescription drug insurance coverage.

(b) These uninsured residents pay excessive prices for prescription drugs, far higher prices than are paid by managed care organizations, insurance companies and the federal government for the same medicines and dosages. In many cases, these

excessive drug prices have the effect of denying residents access to medically necessary care, thereby threatening their health and safety.

(c) Many residents require repeated doctor or medical clinic appointments, having gotten sicker because they cannot afford to take the prescriptions prescribed for them. Many residents are admitted to or treated at hospitals each year because they cannot afford the drugs prescribed for them that could have prevented the need for hospitalization. Many others enter expensive institutional care settings because they cannot afford their necessary prescription drugs that could have supported them outside of an institution. In each of these circumstances, state medical assistance programs, including the Medicaid program, literally pay the price.

(d) One major reason uninsured residents pay so much for prescription drugs is that, unlike insured residents, they have no prescription benefits manager negotiating a fair price with the drug companies on their behalf.

(e) The state government is the only agent that, as a practical matter, can play an effective role as a market participant on behalf of all residents who are uninsured or underinsured. The state can and should act as a prescription benefit manager, negotiating voluntary drug rebates and using these funds to reimburse retail pharmacies for offering lower drug prices.

(2) The Legislature is enacting this act to create a program in which the state acts as a participant in the prescription drug marketplace, negotiating voluntary rebates from drug companies and using the funds to make prescription drugs more affordable to Mississippi residents. Such a program will improve public health and welfare, promote the economic strength of our society, and substantially benefit state health assistance programs, including the Medicaid program.

SECTION 3. (1) As used in this section:

(a) "Board" means the State Board of Health.

(b) "Department" means the State Department of Health.

(c) "Director" means the Executive Director of the State Department of Health, or the executive director's designee(s).

(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 Code of Federal Regulations, 207.20.

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

(f) "Program" means the Prescription Drug Fair-Pricing Program established in this section.

(g) "Retail pharmacy" means a pharmacy or other facility or business that dispenses or delivers prescription drugs to consumers in this state and is registered with the State Board of Pharmacy under Section 73-21-105.

(2) (a) The Prescription Drug Fair-Pricing Program is established within the department to lower prescription drug prices for uninsured and underinsured residents of the state.

(b) A drug manufacturer or labeler that sells prescription drugs in the state may voluntarily elect to enter into a rebate agreement with the department.

(c) The director shall negotiate the terms of the rebate from a manufacturer or labeler, taking into consideration the rebate calculated under the Medicaid Rebate Program under 42 USCS, Section 1396r-8, the average wholesale price of prescription drugs, and any other available information on prescription drug prices and price discounts.

(d) If a drug manufacturer or labeler elects not to agree to a rebate, the director may place those manufacturer's or

labeler's products on the prior authorization list for the state Medicaid program, and take similar actions involving prior authorization or formularies for any other state funded prescription drug program. The board shall promulgate rules creating clear procedures for the implementation of this paragraph. The names of manufacturers and labelers that do not enter into rebate agreements are public information, and the department shall release this information to the public. The director also shall publicize to doctors, pharmacists, and other health professionals information about the relative cost of drugs produced by manufacturers and labelers that enter into rebate agreements compared to those who do not enter into rebate agreements.

(e) A retail pharmacy shall discount the price of prescription drugs sold to participants in the prescription drug program.

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

(ii) Beginning July 1, 2004, a retail pharmacy shall offer prescription drugs at or below the average wholesale price, minus six percent (6%), plus a dispensing fee designated by the director. These initial price levels shall be calculated by the director, and the dispensing fee shall not be less than that provided under the state Medicaid program. The average wholesale price is the wholesale price charged on a specific commodity that is assigned by the drug manufacturer and is listed in a nationally recognized drug pricing file.

(iii) No later than January 1, 2005, a retail pharmacy shall offer prescription drugs at or below the initial

price levels specified in subparagraph (ii) minus the amount of any rebate paid by the state to the retail pharmacy. These discounted price levels shall be calculated by the director. In determining the discounted price levels, the director shall consider an average of all rebates weighted by sales of drugs subject to these rebates over the most recent twelve-month period for which the information is available.

(f) All residents of the state are eligible to participate in the program. The department shall establish simplified procedures for issuing program enrollment cards to eligible residents. The department shall undertake outreach efforts to build public awareness of the program and maximize enrollment by eligible resident.

(g) (i) The State Board of Pharmacy shall adopt rules requiring disclosure by retail pharmacies to program participants of the amount of savings provided as a result of the program. The rules must protect information that is proprietary in nature.

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

(iii) A retail pharmacy shall submit claims to the department to verify the amount charged to program participants.

(iv) On a weekly or biweekly basis, the department shall reimburse a retail pharmacy for discounted prices provided to program participants and dispensing fees set by the direction.

(v) The department shall collect from the 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.

(h) Discrepancies in rebate amounts must be resolved using the process established in this paragraph.

(i) If there is a discrepancy in the manufacturer's or labeler's favor between the amount claimed by a 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 amount due.

(ii) 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 manufacturer's or labeler's rebate, the manufacturer or labeler, at the manufacturer's or labeler's expense, may hire a manually agreed-upon independent auditor to verify the accuracy of the data supplied to the department. If a discrepancy still exists following the audit, the department shall justify the reason for the discrepancy or refund to the manufacturer any excess payment made by the manufacturer or labeler.

(iii) Following the procedures established in subparagraph (i) or (ii), either the department or the manufacturer or labeler may request a hearing. Supporting documentation must accompany the request for a hearing.

(i) The Prescription Drug Fair-Pricing Program Fund is established as a special fund in the State Treasury to receive funds from manufacturers and labelers who pay rebates and any appropriations or allocations designated for the fund. The purposes of the fund are to reimburse retail pharmacies for discounted prices provided to program participants, and reimburse the department for the costs of administering the program, including contracted services, computer costs, professional fees paid to retail pharmacies and other reasonable program costs. Unexpended amounts remaining in the fund at the end of a fiscal year shall not lapse into the State General Fund, and any interest

earned on amounts in the fund shall be deposited to the credit of the fund.

(j) The department shall report the enrollment and financial status of the program to the Legislature by the first week in December.

(k) In implementing this section, the department shall coordinate with other governmental programs to increase efficiency and, where it is beneficial to another state program, combine drug pricing negotiations to maximize drug rebates for this and other programs, including the state Medicaid program.

(l) The board may adopt rules to implement the provisions of this section.

(m) The department may seek any waivers of federal law, rule or regulation necessary to implement the provisions of this section.

SECTION 4. This act shall take effect and be in force from and after July 1, 2004.