Stricken language would be deleted from and underlined language would be added to the law as it existed prior to this session of the General Assembly.

State of Arkansas
83rd General Assembly
Regular Session, 2001

A Bill

HOUSE BILL 1925

By: Representative Trammell

For An Act To Be Entitled

AN ACT FOR PRESCRIPTION DRUG PRICE REDUCTION; AND FOR OTHER PURPOSES.

Subtitle

AN ACT FOR PRESCRIPTION DRUG PRICE REDUCTION.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:

SECTION 1. Findings; intent; purpose.

(a) Findings. The General Assembly makes the following findings:

(1)(A) Pharmaceutical companies are charging the citizens of Arkansas excessive prices for prescription drugs, thereby denying Arkansas citizens access to medically necessary health care, which threatens their health and safety.

(B) Many Arkansas citizens are admitted to or treated at hospitals each year because they cannot afford drugs prescribed for them that could have prevented the need for hospitalization.

(C) Many other people must enter expensive institutional care settings because they cannot afford necessary prescription drugs that could have supported them outside of an institution.

(D) All Arkansas citizens are threatened by the possibility that when they need medically necessary prescription drugs most, they may be unable to afford their doctor's recommended treatment;

(2) Citizens of Arkansas and other Americans pay the highest prices in the world for prescription drugs, prices that result in extremely high profits for pharmaceutical companies;

(3) Prescription drug costs represent the fastest growing item in health care and are a driving force in rapidly increasing hospital costs and insurance rates;

(4) Excessive pricing for prescription drugs threatens Arkansas' ability to assist with the health care costs of Arkansas citizens, undermines the financial capacity of Arkansas communities to meet the educational needs of Arkansas children, hurts the ability of the Arkansas business community to provide health insurance coverage to Arkansas' work force and has a negative effect on Arkansas' economy; and

(5) Affordability is critical to providing access to prescription drugs for Arkansas residents.

(b) Intent. It is the intent of the General Assembly to provide access for all Arkansas citizens to medically necessary prescription drugs at the lowest possible prices.

(c) Purpose. This act is enacted by the General Assembly as a positive measure to make prescription drugs more affordable for Arkansas residents, thereby increasing the overall health of our families, benefiting employers and employees and the fiscal strength of our society, promoting healthy communities, and increasing the public health and welfare.

SECTION 2. Arkansas Code Title 20 is amended to add the following additional chapter:

Chapter 65. Prescription Drug Fair Pricing.

Subchapter 1. Arkansas Rx Program.

20-65-101. Findings and Intent.

(a) The General Assembly finds that affordability is critical to providing access to prescription drugs for Arkansas residents.

(b)(1) This subchapter is enacted by the General Assembly to enable the state to act as a pharmacy benefit manager in order to make prescription drugs more affordable for enrolled Arkansas residents, thereby increasing the overall health of Arkansas residents, promoting healthy communities and protecting the public health and welfare.

(2) It is not the intention of the state to discourage employers

from offering or paying for prescription drug benefits for their employees or to replace employer-sponsored prescription drug benefit plans that provide benefits comparable to those made available to enrolled Arkansas residents under this subchapter.

20-65-102. Definitions.

As used in this subchapter, unless the context otherwise indicates:

(1) "Average wholesale price" means 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;

(2) "Department" means the Department of Human Services;

(3) "Director" means the Director of the Department of Human Services;

(4) "Enrolled resident" means a resident of the state who has obtained from the department an Arkansas Rx enrollment card;

(5) "Initial discounted price" means a price that is less than or equal to the average wholesale price, minus six percent (6%), plus the dispensing fee provided under the Arkansas Medicaid Program;

(6) "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 (1999);

(7) "Participating retail pharmacy " means a retail pharmacy located in this state, or another business licensed to dispense prescription drugs in this state, that participates in the Arkansas Rx Program and that provides discounted prices to residents under this subchapter;

(8) "Pharmacy benefit manager" means an entity that procures prescription drugs at a negotiated rate under a contract; and

(9) "Secondary discounted price" means a price that is equal to or less than the initial discounted price minus the amount of any rebate paid by the state to the participating retail pharmacy.

20-65-103. Arkansas Rx Program established.

(a)(1) The Arkansas Rx Program is established to reduce prescription drug prices for residents of the state.

(2) The Arkansas Rx Program is designed for the state to utilize manufacturer rebates and pharmacy discounts to reduce prescription drug

prices.

(b) In implementing the Arkansas Rx Program, the state shall serve as a pharmacy benefit manager in establishing rebates and discounts on behalf of enrolled residents.

20-65-104. Rebate agreement.

(a) A drug manufacturer or labeler who sells prescription drugs in this state through any publicly supported pharmaceutical assistance program shall enter into a rebate agreement with the department for participation in the Arkansas Rx Program.

(b) The rebate agreement must require the manufacturer or labeler to make rebate to the state each calendar quarter or according to a schedule established by the department.

20-65-105. Rebate amount.

(a) The director shall negotiate the amount of the rebate required from a manufacturer or labeler in accordance with this section.

(b) The director shall take into consideration the rebate calculated under the Medicaid Rebate program pursuant to 42 U.S.C. § 1396r-8, the average wholesale price of prescription drugs and any other information on prescription drug prices and price discounts.

(c) The director shall use his or her best efforts to obtain an initial rebate amount equal to or greater than the rebate calculated under the Medicaid program pursuant to 42 U.S.C. § 1396r-8.

(d) With respect to the rebate taking effect no later than October 1, 2002, the director shall seek to obtain an amount equal to or greater than the amount of any discount, rebate or price reduction for prescription drugs provided to the federal government.

20-65-106. Discounted prices for enrolled residents.

(a) Any participating retail pharmacy that sells prescription drugs covered by a rebate agreement pursuant to this subchapter shall discount the retail price of those drugs sold to enrolled residents.

(b)(1) 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.

(2) Beginning January 1, 2002, a participating retail pharmacy shall offer the initial discounted price.

(3) No later than October 1, 2002, a participating retail pharmacy shall offer the secondary discounted price.

(4) In determining the amount of discounted prices, the department shall consider an average of all rebates provided pursuant to § 20-65-105, weighted by sales of drugs subject to these rebates over the most recent twelve-month period for which the information is available.

20-65-107. Operation of program.

(a) This section applies to participating retail pharmacies.

(b)(1) The department shall adopt rules requiring participating retail pharmacies to disclose to enrolled residents the amount of savings provided as a result of the Arkansas Rx Program.

(2) The rules must consider and protect information that is proprietary in nature.

(c) The department may not impose transaction charges under the Arkansas Rx Program on participating retail pharmacies that submit claims or receive payments under the Arkansas Rx Program.

(d) A participating retail pharmacy shall submit claims to the department to verify the amount charged to enrolled residents under § 20-65-106.

(e)(1) On a weekly or biweekly basis, the department must reimburse a participating retail pharmacy for discounted prices provided to enrolled residents under § 20-65-106 and for professional fees, which must be set by the director.

(2) The amount of the initial professional fee must be set at three dollars ($3.00) per prescription.

(f)(1) The department shall collect utilization data from the participating retail pharmacies which submit claims necessary to calculate the amount of the rebate from the manufacturer or labeler.

(2) The department shall protect the confidentiality of all information subject to confidentiality protection under state or federal law, rule or regulation.

20-65-108. Action with regard to nonparticipating manufacturers and labelers.

(a)(1) The names of manufacturers and labelers who do not enter into rebate agreements pursuant to this subchapter are public information.

(2) The department shall release this information to health care providers and the public.

(b) The department shall impose prior authorization requirements in the Arkansas Medicaid Program, as permitted by law, for the dispensing of prescription drugs provided by those manufacturers and labelers.

20-65-109. Discrepancies in rebate amounts.

(a) Discrepancies in rebate amounts must be resolved using the process established in this section.

(b)(1)(A) 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.

(B) 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.

(2)(A) 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 mutually agreed-upon independent auditor to verify the accuracy of the data supplied to the department.

(B) 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.

(c) Following the procedures established in subsection (b) of this section, either the department or the manufacturer or labeler may request administrative adjudication pursuant to § 25-15-208.

20-65-110. Arkansas Rx Trust Fund.

(a)(1) There is established on the books of the Treasurer of State, the

Auditor of State, and the Chief Fiscal Officer of the State a trust fund to be known as the "Arkansas Rx Trust Fund".

(2) In addition to all moneys appropriated by the General Assembly to the fund, there shall be deposited in the fund all payments collected by the state from manufacturers and labelers who pay rebates as provided in § 20-65-105, and all interest earned upon moneys deposited in the fund.

(3) All moneys received into the fund shall be utilized for:

(A) Reimbursing participating retail pharmacies for discounted prices provided to enrolled residents pursuant to § 20-65-106; and

(B) Reimbursing the department for contracted services, administrative and associated computer costs, professional fees paid to participating retail pharmacies, and other reasonable program costs.

(b) All expenditures from the fund must be authorized by the department according to the provisions of this subchapter.

20-65-111. Annual summary report.

The department shall report the enrollment and financial status of the Arkansas Rx Program to the Speaker of the House and the President Pro Tempore of the Senate by the second week in January each year.

20-65-112. Obligations of department.

(a) The department shall:

(1) Establish simplified procedures for determining eligibility and issuing Arkansas Rx enrollment cards to qualified residents; and

(2) Undertake outreach efforts to build public awareness of the Arkansas Rx Program and to maximize enrollment of qualified residents.

(b) The department may adjust the requirements and terms of the Arkansas Rx Program to accommodate any new federally funded prescription drug programs.

20-65-113. Contracting.

The department may contract with a third-party or third-parties to administer any or all components of the Arkansas Rx Program, including, but not limited to, outreach, eligibility, claims, administration, and rebate recovery and redistribution.

20-65-114. Medical assistance programs.

(a) The department shall administer the Arkansas Rx Program and other medical and pharmaceutical assistance programs in a manner that is advantageous to the programs and to the enrollees in those programs.

(b) In implementing this section the department may coordinate other programs with the Arkansas Rx Program and may take action to enhance efficiency, reduce the cost of prescription drugs, and maximize the benefits to the programs and enrollees, including providing the benefits of the Arkansas Rx Program to enrollees in other programs.

20-65-115. Rulemaking.

The department may adopt rules to implement this subchapter.

20-65-116. Waivers.

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

20-65-117. Agreements with other governments and entities.

The state may negotiate and enter into purchasing alliances and regional strategies with the governments of other jurisdictions and with other public and private entities for the purpose of reducing prescription drug prices for residents of the state.

Subchapter 2. Prescription Drug Price Reduction Act.

20-65-201. Short title.

This subchapter shall be known and may be cited as the “Prescription Drug Price Reduction Act.”

20-65-202. Purpose.

(a) The General Assembly finds that affordability is critical in providing access to prescription drugs for Arkansas residents.

(b) This subchapter is enacted by the General Assembly as a positive measure to make prescription drugs more affordable, thereby increasing the overall health of Arkansas residents, promoting healthy communities and

protecting the public health and welfare of Arkansas residents.

20-65-203. Definitions.

For the purposes of this subchapter:

(1) "Commission" means the Prescription Drug Advisory Commission created by this subchapter;

(2) "Department" means the Department of Human Services; and

(3) "Director" means the Director of the Department of Human Services.

20-65-204. Prescription Drug Advisory Commission.

(a) The Prescription Drug Advisory Commission is established.

(b) The commission shall consist of eleven (11) members selected as follows:

(1)(A) Three (3) members of the public, appointed by the President Pro Tempore of the Senate, one (1) of whom must represent the interests of senior citizens;

(B) Of the initial appointees, one (1) must be appointed for a two-year term and two (2) for three-year terms;

(2)(A) Three (3) members of the public, appointed by the Speaker of the House, one (1) of whom must represent the interests of senior citizens;

(B) Of the initial appointees, one (1) must be appointed for a two-year term and two (2) for three-year terms;

(3)(A) Two (2) members of the health care community who are authorized by the laws of this state to prescribe drugs, appointed by the Governor;

(B) Of the initial appointees, one (1) must be appointed for a two-year term and one (1) for a three-year term.

(4)(A) Three (3) pharmacists, appointed by the Governor;

(B) Of the initial appointees, two (2) must be appointed for two-year terms and one (1) for a three-year term.

(C) To be appointed to and remain on the commission, each pharmacist must:

(i) Be licensed to practice pharmacy and be engaged in the practice of retail pharmacy in this state;

(ii) Have at least five (5) years of experience in this state as a licensed pharmacist; and

(iii) Be a resident of this state.

(c)(1) With the exception of the initial appointees, all members of the commission serve for terms of three (3) years and may be reappointed.

(2) With the exception of the pharmacist members, if the profession or qualifications of a commission member change during the term of commission membership, the member may continue to complete the term for which the appointment was made.

(d)(1) The members shall select a chair from among the members.

(2) The Governor shall designate a member who shall be responsible for calling and presiding at the first meeting until a chair is elected.

(e)(1) The commission shall meet at least four (4) times per year.

(2) Additional meetings may be called by the chair.

(f) The duties of the commission include the following:

(1) To review access to prescription drugs for residents of the state, including, but not limited to, pricing and affordability information;

(2) To advise the director about access to prescription drugs and prescription drug prices, including, but not limited to:

(A) Insurance and third-party payments for prescription drugs;

(B) The need for maximum retail prices, and, if maximum retail prices are established, the procedures for adoption and periodic review of maximum retail prices;

(C) The procedures for establishing maximum retail prices for new prescription drugs and for reviewing maximum retail prices of selected drugs; and

(D) The procedures for phasing out or terminating maximum retail prices;

(3) To advise the director on the adoption of rules necessary to implement this subchapter; and

(4) To report to the director, the Speaker of the House, the President Pro Tempore of the Senate, and the Governor by April 1, 2002, and annually thereafter by the second week in January, including in the report any recommendations for action regarding access to and the pricing of prescription drugs.

(g) The department shall provide staffing for the commission.

(h) Each member of the board may receive expense reimbursement in accordance with § 25-16-901 and stipends in accordance with § 25-16-903.

(i) In performing its duties, the commission shall work with the department and the Arkansas State Board of Pharmacy.

20-65-205. Emergency drug pricing.

(a) In order to achieve the purposes of this subchapter, maximum retail prices for prescription drugs sold in Arkansas may be established pursuant to this section.

(b) Emergency drug pricing procedures. The following provisions apply to determinations regarding maximum retail prices for prescription drugs and to the procedures for establishing those prices:

(1)(A) By July 1, 2003, the department shall adopt rules establishing the procedures for adoption and periodic review of maximum retail prices, the procedures for establishing maximum retail prices for new prescription drugs and for reviewing maximum retail prices of selected drugs and the procedures for phasing out or terminating maximum retail prices;

(B) Prior to adopting rules pursuant to this subdivision (b)(1), the director shall consult with and consider the recommendations of the commission regarding the rules; and

(2)(A) By January 1, 2004, the director shall determine whether the cost of prescription drugs provided to qualified residents under the Arkansas Rx Program pursuant to this chapter is reasonably comparable to the lowest cost paid for the same drugs delivered or dispensed in the state.

(B) In making this determination the following provisions apply:

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

(ii) Using the data reviewed in subdivision (b)(2)(B)(i), the director shall determine the one hundred (100) drugs for which the most units were provided and the one hundred (100) drugs for which the total cost was the highest.

(iii) For each prescription drug listed in subdivision (b)(2)(B)(ii), the director shall determine the cost for the drug to residents enrolled in the Arkansas Rx Program on a certain date. The

average cost for each such drug must be calculated.

(iv) For each prescription drug listed in subdivision (b)(2)(B)(ii), the director shall determine the lowest cost for each drug paid by any purchaser on the date that is used for subdivision (b)(2)(B)(iii) delivered or dispensed in the 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 Arkansas Rx Program. The average cost for each such drug must be calculated.

(v) If the average cost for one or more prescription drugs under the Arkansas Rx Program as determined in subdivision (b)(2)(B)(iii) is not reasonably comparable to the average lowest cost for the same drug or drugs as determined in subdivision (b)(2)(B)(iv), the director shall establish maximum retail prices for any or all prescription drugs sold in the state. Maximum prescription drug prices established under this subdivision (b)(2)(B)(v) must take effect July 1, 2004; and

(3) In establishing maximum retail prices under this subsection (b), the director shall consider the advice of the commission and shall follow procedures set forth by rules adopted by the department.

(c) Select prescription drugs. In making a determination under this section 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.

(d) Public health or welfare. 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.

(e) Appeals. A retailer of prescription drugs may appeal the maximum retail price of a prescription drug. The appeal shall be made pursuant to the Arkansas Administrative Procedure Act.

(f) Enforcement. A violation of the maximum retail prices established under this section shall constitute an unfair and deceptive act or practice, as defined by the Deceptive Trade Practices Act, which begins at § 4-88-101.

Subchapter 3. Profiteering In Prescription Drugs.

20-65-301. Definitions.

As used in this subchapter, unless the context otherwise indicates:

(1) “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 (1999); and

(2) “Manufacturer” means a manufacturer of prescription drugs and includes a subsidiary or affiliate of a manufacturer.

20-65-302. Profiteering in prescription drugs.

(a) Profiteering in prescription drugs by a manufacturer, distributor, or labeler is unlawful and is subject to the provisions of this section.

(b) Profiteering. A manufacturer, distributor or labeler of prescription drugs engages in illegal profiteering if that manufacturer, distributor or labeler:

(1) Exacts or demands an unconscionable price;

(2) Exacts or demands prices or terms that lead to any unjust or unreasonable profit;

(3) Discriminates unreasonably against any person in the sale, exchange, distribution or handling of prescription drugs dispensed or delivered in the state; or

(4) Intentionally prevents, limits, lessens or restricts the sale or distribution of prescription drugs in this state in retaliation for the provisions of this chapter.

(c) Right of action and damages.

(1) The state may bring a civil action in circuit court for a direct or indirect injury to any person, group of persons, the state or a political subdivision of the state caused by a violation of this section.

(2) If the state prevails, the defendant shall pay three (3) times the amount of damages and the costs of suit, including necessary and reasonable investigative costs, reasonable expert fees and reasonable attorney’s fees.

(3) Punitive damages may be awarded for a willful or repeated violation of this section.

(4) After deduction of the costs of distribution, the damages must be equitably distributed by the state to all injured parties.

(d) Civil violation. Each violation of this section is a civil violation for which the department may obtain, in addition to other remedies, injunctive relief and a civil penalty in an amount not to exceed one hundred thousand dollars, ($100,000).

(e) Unfair trade practice. A violation of this section shall constitute an unfair and deceptive act or practice, as defined by the Deceptive Trade Practices Act, which begins at § 4-88-101.