L.D. 2599

DATE: May 11, 2000 (Filing No. S-803)

Reproduced and distributed under the direction of the Secretary of the Senate.

STATE OF MAINE
SENATE
119TH LEGISLATURE
SECOND REGULAR SESSION

SENATE AMENDMENT "A" to S.P. 1026, L.D. 2599, Bill, "An Act to Establish Fairer Pricing for Prescription Drugs"

Amend the bill by striking out everything after the enacting clause and before the summary and inserting in its place the following:

'PART A

Sec. A-1. 5 MRSA §12004-I, sub-§47-E is enacted to read:

47-E. Human Services	Prescription Drug Advisory Commission	Expenses/ Legislative Per Diem for Nonsalaried or Nonpaid Public Members	22 MRSA §2692, sub-§6

Sec. A-2. 22 MRSA §254-B, as enacted by PL 1999, c. 431, §1, is repealed.

Sec. A-3. 22 MRSA c. 603 is enacted to read:

CHAPTER 603

PRESCRIPTION DRUG ACCESS

SUBCHAPTER I

MAINE RX PROGRAM

SENATE AMENDMENT

§2681. Maine Rx Program established

The Maine Rx Program, referred to in this subchapter as the "program," is established to reduce prescription drug prices for residents of the State. The program is designed for the State to utilize manufacturer rebates and pharmacy discounts to reduce prescription drug prices. In implementing the program, the State shall serve as a pharmacy benefit manager in establishing rebates and discounts on behalf of qualified residents.

1. Program goals. The Legislature finds that affordability is critical in providing access to prescription drugs for Maine residents. This subchapter is enacted by the Legislature to enable the State to act as a pharmacy benefit manager in order to make prescription drugs more affordable for qualified Maine residents, thereby increasing the overall health of Maine residents, promoting healthy communities and protecting the public health and welfare. 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 qualified Maine residents under this subchapter.

2. Definitions. As used in this subchapter, unless the context otherwise indicates, the following terms have the following meanings.

A. "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.

B. "Initial discounted price" means a price that is less than or equal to the average wholesale price, minus 6%, plus the dispensing fee provided under the Medicaid program under this Title.

C. "Labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale.

D. "Participating retail pharmacy" or "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 program and that provides discounted prices to residents as provided in subsection 5.

E. "Pharmacy benefit manager" means an entity that procures prescription drugs at a negotiated rate under a contract.

F. "Qualified resident" means a resident of the State who has obtained from the department a Maine Rx enrollment card.

G. "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.

3. Rebate agreement. A drug manufacturer or labeler that sells prescription drugs in this State through the elderly low-cost drug program under section 254 or any other publicly supported pharmaceutical assistance program shall enter into a rebate agreement with the department for this program. The rebate agreement must require the manufacturer or labeler to make rebate payments to the State each calendar quarter or according to a schedule established by the department.

4. Rebate amount. The commissioner shall negotiate the amount of the rebate required from a manufacturer or labeler in accordance with this subsection.

A. The commissioner shall take into consideration the rebate calculated under the Medicaid Rebate Program pursuant to 42 United States Code, Section 1396r-8, the average wholesale price of prescription drugs and any other information on prescription drug prices and price discounts.

B. The commissioner shall use the commissioner's best efforts to obtain an initial rebate amount equal to or greater than the rebate calculated under the Medicaid program pursuant to 42 United States Code, Section 1396r-8.

C. With respect to the rebate taking effect no later than October 1, 2001, the commissioner shall use the commissioner's best efforts 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.

5. Discounted prices for qualified residents. Any participating retail pharmacy that sells prescription drugs covered by a rebate agreement pursuant to subsection 3 shall discount the retail price of those drugs sold to qualified residents.

A. 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.

B. Beginning January 1, 2001, a participating retail pharmacy shall offer the initial discounted price.

C. No later than October 1, 2001, a participating retail pharmacy shall offer the secondary discounted price.

D. In determining the amount of discounted prices, the department shall consider an average of all rebates provided pursuant to subsection 4, weighted by sales of drugs subject to these rebates over the most recent 12-month period for which the information is available.

6. Operation of program. The requirements of this subsection apply to participating retail pharmacies.

A. The Maine Board of Pharmacy shall adopt rules requiring disclosure by participating retail pharmacies to qualified residents of the amount of savings provided as a result of the program. The rules must consider and protect information that is proprietary in nature. Rules adopted pursuant to this paragraph are routine technical rules as defined in Title 5, chapter 375, subchapter II-A.

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

C. A participating retail pharmacy shall submit claims to the department to verify the amount charged to qualified residents under subsection 5.

D. On a weekly or biweekly basis, the department must reimburse a participating retail pharmacy for discounted prices provided to qualified residents under subsection 5 and professional fees, which must be set by the commissioner. The amount of the initial professional fee must be set at $3 per prescription.

E. The department shall collect utilization data from the participating retail pharmacies submitting claims 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.

7. Action with regard to nonparticipating manufacturers and labelers. The names of manufacturers and labelers who do not enter into rebate agreements pursuant to this subchapter are public information. The department shall impose prior authorization requirements in the Medicaid program under this Title, as permitted by law, for the dispensing of prescription drugs provided by those manufacturers and labelers.

8. Discrepancies in rebate amounts. Discrepancies in rebate amounts must be resolved using the process established in this subsection.

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. 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.

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 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. 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 paragraph A or B, either the department or the manufacturer or labeler may request a hearing before the Administrative Hearings Unit. Supporting documentation must accompany the request for a hearing.

9. Dedicated fund. The Maine Rx Dedicated Fund, referred to in this section as the "fund," is established to receive revenue from manufacturers and labelers who pay rebates as provided in subsection 4 and any appropriations or allocations designated for the fund. The purposes of the fund are to: reimburse retail pharmacies for discounted prices provided to qualified residents pursuant to subsection 5; to reimburse the department for contracted services, administrative and associated computer costs, professional fees paid to participating retail pharmacies and other reasonable program costs; and to benefit the elderly low-cost drug program under section 254. The fund also

must be used in fiscal year 2002-03 to repay the working capital advance made to the program during fiscal year 2000-01 from the Trust Fund for a Healthy Maine, established in section 1512. The fund is a nonlapsing dedicated fund. Interest on fund balances accrues to the fund. Surplus funds in the fund must be used for the benefit of the program. Notwithstanding Title 5, section 1585, surplus funds may also be transferred to the elderly low-cost drug program established under section 254.

10. Annual summary report. The department shall report the enrollment and financial status of the program to the Legislature by the 2nd week in January each year.

11. Obligations of department. The department shall establish simplified procedures for determining eligibility and issuing Maine Rx enrollment cards to qualified residents and shall undertake outreach efforts to build public awareness of the program and maximize enrollment of qualified residents. The department may adjust the requirements and terms of the program to accommodate any new federally funded prescription drug programs.

12. Contracting. The department may contract with a 3rd-party or 3rd-parties to administer any or all components of the program, including, but not limited to, outreach, eligibility, claims, administration and rebate recovery and redistribution.

13. Medical assistance programs. The department shall administer the program and other medical and pharmaceutical assistance programs under this Title in a manner that is advantageous to the programs and to the enrollees in those programs. In implementing this subsection the department may coordinate the other programs and this program and may take actions to enhance efficiency, reduce the cost of prescription drugs and maximize the benefits to the programs and enrollees, including providing the benefits of this program to enrollees in other programs.

14. Rulemaking. The department may adopt rules to implement the provisions of this section. Rules adopted pursuant to this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter II-A.

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

SUBCHAPTER II

PRESCRIPTION DRUG PRICE REDUCTION ACT

§2691. Short title; purpose

This subchapter may be known and cited as the "Prescription Drug Price Reduction Act." The Legislature finds that affordability is critical in providing access to prescription drugs for Maine residents. This subchapter is enacted by the Legislature as a positive measure to make prescription drugs more affordable for qualified Maine residents, thereby increasing the overall health of Maine residents, promoting healthy communities and protecting the public health and welfare of Maine residents.

§2692. Prescription Drug Advisory Commission

The Prescription Drug Advisory Commission, referred to in this subchapter as the "commission," is established to review access to and the pricing of prescription drugs for residents of the State, to advise the commissioner on prescription drug pricing and to provide periodic reports to the commissioner, the Governor and the Legislature.

1. Membership. The commission consists of the following 12 members:

A. Three members of the public, appointed by the President of the Senate, one of whom must represent the interests of senior citizens. Of the initial appointees, one must be appointed for a 2-year term and 2 for 3-year terms;

B. Three members of the public, appointed by the Speaker of the House, one of whom must represent the interests of senior citizens. Of the initial appointees, one must be appointed for a 2-year term and 2 for 3-year terms;

C. Two members of the health care community who are authorized by the laws of this State to prescribe drugs, appointed by the Governor. Of the initial appointees, one must be appointed for a 2-year term and one for a 3-year term;

D. Two pharmacists, appointed by the Governor. Of the initial appointees, one must be appointed for a 2-year term and one for a 3-year term. To be appointed to and remain on the commission, each pharmacist must:

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

(2) Have at least 5 years of experience in this State as a licensed pharmacist; and

(3) Be a resident of this State; and

E. The Director of the Bureau of Medical Services and the Commissioner of Professional and Financial Regulation, or their designees, who shall serve as ex officio, nonvoting members.

2. Terms. With the exception of the initial appointees, all members of the commission serve for terms of 3 years and may be reappointed. 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.

3. Meetings; chair. The commission shall meet at least 4 times per year. The members shall select a chair from among the members. Additional meetings may be called by the chair.

4. Duties. The duties of the commission include the following:

A. To review access to prescription drugs for residents of the State, including, but not limited to, pricing and affordability information;

B. To advise the commissioner on access to prescription drugs and prescription drug prices, including, but not limited to, insurance and 3rd-party payments for prescription drugs, the need for maximum retail prices, and, if maximum retail prices are established, 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;

C. To advise the commissioner on the adoption of rules necessary to implement this subchapter; and

D. To report to the commissioner, the Legislature and the Governor by April 1, 2001, and annually thereafter by the 2nd week in January, including in the report any recommendations for action regarding access to and the pricing of prescription drugs.

5. Staffing. The department shall provide staffing for the commission.

6. Compensation. Public members not otherwise compensated by their employers or other entities whom they represent are entitled to receive reimbursement of necessary expenses and a per diem equal to the legislative per diem for their attendance at authorized meetings of the commission.

7. Cooperation. In performing its duties, the commission shall work with the department, the Maine Board of Pharmacy and the Department of Professional and Financial Regulation.

§2693. Emergency drug pricing

In order to achieve the public health purposes listed in section 2691, maximum retail prices for prescription drugs sold in Maine may be established pursuant to this section.

1. 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.

A. By July 1, 2002, 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. Prior to adopting rules pursuant to this paragraph, the commissioner shall consult with and consider the recommendations of the commission regarding the rules.

B. By January 5, 2003, the commissioner shall determine whether the cost of prescription drugs provided to qualified residents under the Maine Rx Program pursuant to subchapter I is reasonably comparable to the lowest cost paid for the same drugs for delivery or dispensation in the State. In making this determination the following provisions apply.

(1) The commissioner shall review prescription drug use in the Medicaid program using data from the most recent 6-month period for which data is available.

(2) Using the data reviewed in subparagraph (1), the commissioner shall determine the 100 drugs for which the most units were provided and the 100 drugs for which the total cost was the highest.

(3) For each prescription drug listed in subparagraph (2), the commissioner shall determine the cost for each

drug for qualified residents provided those drugs under the Maine Rx Program on a certain date. The average cost for each such drug must be calculated.

(4) For each prescription drug listed in subparagraph (2), the commissioner shall determine the lowest cost for each drug paid by any purchaser on the date that is used for subparagraph (3) for delivery or dispensation 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 Maine Rx Program. The average cost for each such drug must be calculated.

(5) If the average cost for one or more prescription drugs under the Maine Rx Program as determined in subparagraph (3) is not reasonably comparable to the average lowest cost for the same drug or drugs as determined in subparagraph (4), the commissioner shall establish maximum retail prices for any or all prescription drugs sold in the State. Maximum prescription drug prices established under this subparagraph must take effect July 1, 2003.

C. In establishing maximum retail prices under this paragraph, the commissioner shall consider the advice of the commission and shall follow procedures set forth by rules adopted by the department.

D. Rules adopted pursuant to this subsection are major substantive rules as defined in Title 5, chapter 375, subchapter II-A.

2. Select prescription drugs. In making a determination under this section the commissioner 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.

3. Public health or welfare. The commissioner may take actions that the commissioner 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.

4. Appeals. A retailer of prescription drugs may appeal the maximum retail price of a prescription drug established pursuant to this section in accordance with the Maine Administrative Procedure Act.

5. Enforcement. A violation of the maximum retail prices established under this section is a violation of the Maine Unfair Trade Practices Act.

§2694. Rulemaking

With the exception of rules designated in this subchapter as major substantive rules, rules adopted pursuant to this subchapter are routine technical rules as defined by Title 5, chapter 375, subchapter II-A.

SUBCHAPTER III

PROFITEERING IN PRESCRIPTION DRUGS

§2697. Profiteering in prescription drugs

Prescription drugs are a necessity of life. Profiteering in prescription drugs is unlawful and is subject to the provisions of this section. The provisions of this section apply to manufacturers, distributors and labelers of prescription drugs.

1. Definitions. As used in this subchapter, unless the context otherwise indicates, the following terms have the following meanings.

A. "Labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale.

B. "Manufacturer" means a manufacturer of prescription drugs and includes a subsidiary or affiliate of a manufacturer.

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

A. Exacts or demands an unconscionable price;

B. Exacts or demands prices or terms that lead to any unjust or unreasonable profit;

C. Discriminates unreasonably against any person in the sale, exchange, distribution or handling of prescription drugs dispensed or delivered in the State; or

D. Intentionally prevents, limits, lessens or restricts the sale or distribution of prescription drugs in this State in retaliation for the provisions of this chapter.

3. Right of action and damages. The State may bring a civil action in District Court or Superior 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 subchapter. There is a right to a jury trial in any action brought in Superior Court under this section. If the State prevails, the defendant shall pay 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. For a willful or repeated violation of this section, punitive damages may be awarded. After deduction of the costs of distribution, the damages must be equitably distributed by the State to all injured parties.

4. Civil violation. Each violation of this section is a civil violation for which the Attorney General may obtain, in addition to other remedies, injunctive relief and a civil penalty in an amount not to exceed $100,000, plus the costs of suit, including necessary and reasonable investigative costs, reasonable expert fees and reasonable attorney's fees.

5. Unfair trade practice. A violation of this section is also a violation of the Maine Unfair Trade Practices Act.

§2698. Investigation by Attorney General

The Attorney General, upon the Attorney General's own initiative or upon petition of the commissioner or of 50 or more residents of the State, shall investigate suspected violations of this subchapter.

The Attorney General may require, by summons, the attendance and testimony of witnesses and the production of books and papers before the Attorney General related to any such matter under investigation. The summons must be served in the same manner as summonses for witnesses in criminal cases, and all provisions of law related to criminal cases apply to summonses issued under this section so far as they are applicable. All investigations or hearings under this section to which witnesses are summoned or called upon to testify or to produce books, records or correspondence are public or private at the choice of the person summoned and must be held in the county where the act to be investigated is alleged to have been committed, or if the investigation is on petition, it must be held in the county in which the petitioners reside. The expense of the investigation

must be paid from the appropriation provided in Title 5, section 203.

A Justice of the Superior Court may by order, upon application of the Attorney General, compel the attendance of witnesses, the production of books and papers, including correspondence, and the giving of testimony before the Attorney General in the same manner and to the same extent as before the Superior Court. Any failure to obey such an order may be punishable by that court as a contempt.

Sec. A-4. Agreements with governments of other jurisdictions and other 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.

Sec. A-5. Findings; intent; purpose.

1. Findings. The Legislature makes the following findings.

A. Pharmaceutical companies are charging the citizens of Maine excessive prices for prescription drugs, denying Maine citizens access to medically necessary health care and thereby threatening their health and safety. Many Maine citizens are admitted to or treated at hospitals each year because they can not afford the drugs prescribed for them that could have prevented the need for hospitalization. Many others must enter expensive institutional care settings because they can not afford their necessary prescription drugs that could have supported them outside of an institution. All Maine 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.

B. Citizens of Maine and other Americans pay the highest prices in the world for prescription drugs, prices that result in extremely high profits for pharmaceutical companies.

C. Prescription drug costs represent the fastest growing item in health care and are a driving force in rapidly increasing hospital costs and insurance rates.

D. Excessive pricing for prescription drugs threatens Maine's ability to assist with the health care costs of Maine citizens, undermines the financial capacity of Maine communities to meet the educational needs of Maine children,

hurts the ability of the Maine business community to provide health insurance coverage to Maine's work force and has a negative effect on Maine's economy. The Legislature finds that affordability is critical in providing access to prescription drugs for Maine residents.

2. Intent. It is the intent of the Legislature to provide access for all Maine citizens to medically necessary prescription drugs at the lowest possible prices.

3. Purpose. This law is enacted by the Legislature as a positive measure to make prescription drugs more affordable for Maine 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.

Sec. A-6. Appointments; first meeting of Prescription Drug Advisory Commission. All appointments must be completed no later than 30 days following the effective date of this Act. The appointing authorities shall notify the Executive Director of the Legislative Council upon making their appointments. The Chair of the Legislative Council shall call the first meeting of the commission within 30 days after notification that appointments have been completed. At the first meeting of the commission, the members shall select a chair from among the members.

Sec. A-7. Working capital advance. Notwithstanding the Maine Revised Statutes, Title 22, section 1511, subsection 3 and section 1512, the State Controller is authorized to advance to the Maine Rx Dedicated Fund in the Department of Human Services $4,582,500 from the Trust Fund for a Healthy Maine no later than January 1, 2001. These funds may be allotted by financial order upon the recommendation of the State Budget Officer and approval of the Governor. These funds must be returned to the Trust Fund for a Healthy Maine from the Maine Rx Dedicated Fund no later than June 30, 2005.

Sec. A-8. Appropriation. The following funds are appropriated from the General Fund to carry out the purposes of this Part.

	2000-01
HUMAN SERVICES, DEPARTMENT OF	
Maine Rx Program	
Positions - Legislative Count	(6.000)
Personal Services	$148,330

All Other	502,750

Provides for the one-time appropriation of funds to establish the Maine Rx Program, including the establishment of 6 additional positions and related operating costs, for outreach activities, to contract for claims management services and for costs associated with the issuance of prescription cards.

DEPARTMENT OF HUMAN SERVICES TOTAL	$651,080

ATTORNEY GENERAL, DEPARTMENT OF THE

Administration - Attorney General

Positions - Legislative Count	(1.000)
Personal Services	$46,745
All Other	5,340
TOTAL	52,085

Provides one-time funds for one Assistant Attorney General position and related operating costs due to the establishment of the Maine Rx Program.

Fair Drug Pricing Contingent Account

All Other	$130,000

Provides one-time funds to support litigation costs associated with the Maine Rx Program. Any balance remaining at the end of each fiscal year may not lapse but must be carried forward to be used for the same purpose.

DEPARTMENT OF THE ATTORNEY GENERAL	
TOTAL	$182,085
TOTAL APPROPRIATIONS	$833,165

Sec. A-9. Allocation. The following funds are allocated from the Other Special Revenue funds to carry out the purposes of this Part.

2000-01

PROFESSIONAL AND FINANCIAL REGULATION, DEPARTMENT OF

Licensing and Enforcement

All Other	$2,500

Provides for the allocation of funds for the costs associated with the Maine Board of Pharmacy to adopt rules associated with the Maine Rx Program.

PART B

Sec. B-1. 22 MRSA §254, sub-§8, as corrected by RR 1999, c. 1, §27, is amended to read:

8. Drug rebate program. Effective May 1, 1992, payment must be denied for drugs from manufacturers that do not enter into a rebate agreement with the department for prescription drugs included in the list of approved drugs under this program. Each agreement must provide that the pharmaceutical manufacturer make rebate payments for both the basic and supplemental components of the program to the department according to the following schedule.

~~A. For the period beginning May 1, 1992 and ending September 30, 1992, the rebate percentage is equal to 11% of the manufacturer's wholesale price for the total number of dosage units of each form and strength of a prescription drug that the department reports as reimbursed to providers of prescription drugs, provided payments are not due until 30 days following the manufacturer's receipt of utilization data supplied by the department, including the number of dosage units reimbursed to providers of prescription drugs during the period for which payment is due.~~

B. For the quarters beginning October 1, 1992, the rebate percentage is equal to the percentage recommended by the federal Health Care Financing Administration of the manufacturer's wholesale price for the total number of dosage units of each form and strength of a prescription drug that the department reports as reimbursed to providers of prescription drugs, provided payments are not due until 30 days following the manufacturer's receipt of utilization data supplied by the department, including the number of dosage units reimbursed to providers of prescription drugs during the period for which payments are due.

C. Beginning October 1, 1998, the department shall seek to achieve an aggregate rebate amount from all rebate agreements that is 6 percentage points higher than that required by paragraph B of this subsection, provided such rebates result in a net increase in the rebate revenue available to the elderly low-cost drug program. In the event the department is not able to achieve the rebate amount required by this paragraph without compromising the best interest of recipients of the elderly low-cost drug program, it shall report to the joint standing committee of the Legislature having jurisdiction over health and human services matters and the joint standing committee of the Legislature having jurisdiction over appropriations and financial affairs in the First Regular Session of the 119th Legislature.

Upon receipt of data from the department, the pharmaceutical manufacturer shall calculate the quarterly payment. If a discrepancy is discovered, the department may, at its expense, hire a mutually agreed-upon independent auditor to verify the pharmaceutical manufacturer's calculation. If a discrepancy is still found, the pharmaceutical manufacturer shall justify its calculation or make payment to the department for any additional amount due. The pharmaceutical manufacturer may, at its expense, hire a mutually agreed-upon independent auditor to verify the accuracy of the utilization data provided by the department. If a discrepancy is discovered, the department shall justify its data or refund any excess payment to the pharmaceutical manufacturer.

If the dispute over the rebate amount is not resolved, a request for a hearing with supporting documentation must be submitted to the Administrative Hearings Unit. Failure to resolve the dispute may be cause for terminating the drug rebate agreement and denying payment to the pharmaceutical manufacturer for any drugs.

~~All--prescription--drugs--of--a--pharmaceutical--manufacturer--who enters--into--an--agreement--pursuant--to--this--subsection--that--appear on--the--approved--list--of--drugs--must--be--immediately--available--and the--cost--of--the--drugs--must--be--reimbursed--and--is--not--subject--to any--restrictions--or--prior--authorization--requirements.~~ Any prescription drug of a manufacturer that does not enter into an agreement is not reimbursable unless the department determines the prescription drug is essential~~;~~ .

All prescription drugs of a pharmaceutical manufacturer that enters into an agreement pursuant to this subsection that appear on the list of approved drugs under this program must be immediately available and the cost of the drugs must be reimbursed and is not subject to any restrictions or prior authorization requirements, except as provided in this paragraph. If the commissioner establishes maximum retail prices for prescription drugs pursuant to section 2693, the department shall adopt rules for the elderly low-cost drug program requiring the use of a drug formulary and prior authorization for the dispensing of certain drugs to be listed on a formulary. Rules adopted pursuant to this paragraph are routine technical rules as defined in Title 5, chapter 375, subchapter II-A.

Sec. B-2. 22 MRSA §254, sub-§8-A is enacted to read:

8-A. Participation requirement. Beginning January 1, 2001, all manufacturers and labelers of drugs that participate in the Medicaid program under this Title must participate in the drug rebate program under subsection 8. For the purposes of this subsection, "labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale.

Sec. B-3. 22 MRSA §3174-Y is enacted to read:

§3174-Y. Prior authorization in Medicaid program

If the commissioner establishes maximum retail prices for prescription drugs pursuant to section 2693, the department shall adopt rules for the Medicaid program requiring additional prior authorization for the dispensing of drugs determined to be priced above the established maximum retail prices. The department shall adopt rules for the Medicaid program requiring additional prior authorization for the dispensing of drugs provided from manufacturers and labelers who do not enter into agreements with the department under section 2681, subsection 3. For the purposes of this section, "labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale.'

SENATE AMENDMENT "A" to S.P. 1026, L.D. 2599

FISCAL NOTE

This bill includes one-time General Fund appropriations totaling $833,165 and an Other Special Revenue funds allocation of $2,500 in fiscal year 2000-01 for the costs associated with establishing and operating the Maine Rx Program. Included in this amount is a one-time General Fund appropriation of $651,080 in fiscal year 2000-01 for the Department of Human Services to implement the Maine Rx Program. Of this amount, $172,330 is provided to fund 6 additional positions requested by the Department of Human Services, including one Social Services Program Manager position, one Comprehensive Health Planner I position, 2 Provider Relations Specialist positions, one Medical Care Coordinator position and one Planning and Research Associate I position and related operating costs. The specific responsibilities of these positions have not been identified. Whether these additional positions are sufficient to fulfill the required duties can not be determined at this time. Funds in the amount of $478,750 are also included in the All Other line category to contract for claims management services, outreach activities and the costs associated with the issuance of prescription drug cards. This amount is based on the assumption that the department's estimate of 325,000 eligible Maine residents will participate in the program by July 1, 2001. The actual number of "qualified residents" will be determined by routine technical rules adopted by the department. Whether the number of eligible participants will be 325,000 can not be determined at this time.

A one-time General Fund appropriation of $182,085 in fiscal year 2000-01 is included for the Department of the Attorney General for one Assistant Attorney General position and related costs, including a one-time appropriation of $130,000 to establish a nonlapsing contingent account to cover the costs of litigation.

The estimated future costs of the additional positions, related operating costs and program costs to be funded from the Maine Rx Dedicated Fund will be approximately $1,448,018 beginning in fiscal year 2001-02. Additional allocations from the fund may also be required for future litigation expenses if the $130,000 is expended by the Department of the Attorney General from the Fair Drug Pricing Contingent Account.

The estimated amount of dedicated revenue that will be collected by the Department of Human Services from rebates can not be determined at this time. Whether the revenue ultimately collected will be sufficient to support ongoing obligations associated with this program also can not be determined at this time.

The future costs associated with emergency drug pricing procedures beginning in fiscal year 2002-03 and the impact on the Maine Rx Dedicated Fund can not be determined at this time.

This bill also includes an Other Special Revenue funds allocation of $2,500 in fiscal year 2000-01 for the Maine Board of Pharmacy within the Department of Professional and Financial Regulation for the costs associated with rulemaking.

The Department of Human Services may incur some minor additional costs to adopt rules and for the costs associated with the payment of per diem and expenses for public members of the Prescription Drug Advisory Commission not otherwise compensated by their employers. These costs can be absorbed within the department's existing budgeted resources.

This bill may increase the number of civil suits filed in the court system. The additional workload and administrative costs associated with the minimal number of new cases filed can be absorbed within the budgeted resources of the Judicial Department. The collection of additional filing fees may also increase General Fund revenue by minor amounts.

SUMMARY

This amendment replaces the bill. It does the following.

1. Part A enacts a new chapter on prescription drug access. Enacted in this chapter are the following:

A. Subchapter I contains the Maine Rx Program to reduce prescription drug prices for residents of the State. The program utilizes manufacturer rebates and pharmacy discounts to reduce prescription drug prices. The State will serve as a pharmacy benefit manager in negotiating rebates and discounts on behalf of qualified residents. The program depends on manufacturers and labelers of prescription drugs to pay rebates to the State that are used to provide discounted prices to qualifying Maine residents when they purchase prescription drugs.

B. It establishes the Maine Rx Dedicated Fund to receive revenue due to the program, to make payments to retail pharmacies as required by the program and to pay for contracted services, administrative costs and other program costs.

C. It authorizes the Department of Human Services to coordinate the Maine Rx Program with other medical and pharmaceutical assistance programs.

D. Subchapter II contains the Prescription Drug Price Reduction Act. This subchapter establishes the Prescription Drug Advisory Commission, a 12-member commission that advises the Commissioner of Human Services regarding access to prescription drugs and prescription drug prices. The commission advises the commissioner on major substantive rules regarding the procedures to be used in setting and reviewing maximum retail prices for prescription drugs. The commission is required to provide annual reports to the Commissioner of Human Services, the Governor and the Legislature by April 1, 2001 and by the 2nd week in January each succeeding year.

E. The Commissioner of Human Services is required by January 5, 2003 to undertake a process to determine the need for maximum retail prices for prescription drugs. If the process results in a requirement that maximum retail prices be established, those prices must take effect by July 1, 2003. An appeal mechanism is provided and also a mechanism for addressing situations that may threaten or endanger the public health or welfare. A violation of the maximum retail prices is an unfair trade practice.

F. Subchapter III contains a prohibition on profiteering in prescription drugs by manufacturers, their affiliates and subsidiaries, distributors and labelers of prescription drugs. Profiteering may be punished as a civil violation and may result in an award of triple damages, attorney's fees, punitive damages and costs. A violation of the subchapter is a violation of the Maine Unfair Trade Practices Act.

2. It authorizes the State to negotiate and enter into purchasing alliances and regional strategies with governments and public and private entities for the purpose of reducing prescription drug prices for residents of the State.

3. It provides statements of findings, intent and purpose.

4. It provides appropriations and allocations to fund the provisions of the amendment.

5. If the Commissioner of Human Services establishes maximum retail prices for prescription drugs under the Maine Revised Statutes, Title 22, section 2693, the amendment directs the commissioner to establish a drug formulary and prior

authorization for dispensing drugs in the elderly low-cost drug program. Beginning January 1, 2001, it requires manufacturers and labelers of drugs that participate in the Medicaid program to participate in the drug rebate program in the elderly low-cost drug program.

6. If the Commissioner of Human Services establishes maximum retail prices for prescription drugs under Title 22, section 2693, the amendment directs the commissioner to require prior authorization for the dispensing of drugs in the Medicaid program that would apply to drugs that are priced above the established maximum retail prices. It directs the department to require prior authorization for the dispensing of drugs in the Medicaid program that are provided from manufacturers and labelers who do not enter into rebate agreements with the State under the Maine Rx Program.

SPONSORED BY:
(Senator PINGREE)

COUNTY: Knox