### **CHAPTER 603**

### PRESCRIPTION DRUG ACCESS

## **SUBCHAPTER 1**

### MAINE RX PLUS PROGRAM

## §2681. Maine Rx Plus Program established

The Maine Rx Plus Program, referred to in this subchapter as the "program," is established to reduce prescription drug prices and to improve the quality of health care for residents of the State. The program is administered by the department and must utilize manufacturer rebates and pharmacy discounts to reduce prescription drug prices. [PL 2003, c. 494, §3 (AMD).]

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 take steps 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, and to integrate the program as part of any statewide program for the uninsured. 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.

[PL 2003, c. 494, §4 (AMD).]

- **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. [PL 1999, c. 786, Pt. A, §3 (NEW).]
  - A-1. "Covered drugs" means drugs that are on the MaineCare preferred drug list established and revised from time to time by the department pursuant to its authority to operate the MaineCare program. [PL 2003, c. 494, §4 (NEW).]
  - B. "Initial discounted price" for a drug means the amount that participating retail pharmacies may charge qualified residents participating in the program for that drug, as established by the department through rulemaking. [PL 2003, c. 513, Pt. G, §1 (AMD).]
  - C. "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). [PL 1999, c. 786, Pt. A, §3 (NEW).]
  - 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. [PL 2003, c. 494, §4 (AMD).]
  - E. [PL 2003, c. 494, §4 (RP).]
  - F. "Qualified resident" means a resident of the State who has a family income equal to or less than 350% of the federal poverty level and who is enrolled in the program. "Qualified resident" also means a resident of the State whose family incurs unreimbursed expenses for prescription drugs

that equal 5% or more of family income or whose total unreimbursed medical expenses equal 15% or more of family income. For purposes of this paragraph, the cost of drugs provided under this subchapter is considered an expense incurred by the family for eligibility determination purposes. [PL 2003, c. 494, §4 (AMD).]

- G. "Secondary discounted price" means the initial discounted price minus any further discounts paid for out of the fund. [PL 2003, c. 494, §4 (AMD).] [PL 2003, c. 513, Pt. G, §1 (AMD).]
- **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-D 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. [PL 2005, c. 401, Pt. C, §3 (AMD).]
- **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. [PL 1999, c. 786, Pt. A, §3 (NEW).]
  - 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 MaineCare program pursuant to 42 United States Code, Section 1396r-8. [PL 2003, c. 494, §4 (AMD).]
  - C. With respect to the rebate taking effect no later than October 1, 2004, 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. [PL 2003, c. 494, §4 (AMD).]

[PL 2003, c. 494, §4 (AMD).]

- **5. Discounted prices for qualified residents.** Each participating retail pharmacy shall sell covered drugs to qualified residents at the lower of the initial discounted price and the secondary discounted price as such prices are determined by the department pursuant to this subchapter.
  - 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. [PL 1999, c. 786, Pt. A, §3 (NEW).]
  - B. Beginning January 1, 2004, a participating retail pharmacy shall offer the initial discounted price. [PL 2003, c. 494, §4 (AMD).]
  - C. No later than October 1, 2004, a participating retail pharmacy shall offer the secondary discounted price if available. [PL 2003, c. 494, §4 (AMD).]
- D. [PL 2003, c. 494, §4 (RP).] [PL 2003, c. 494, §4 (AMD).]
- **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 2-A. [PL 2003, c. 494, §4 (AMD).]

- B. The department may not impose transaction charges under this program on retail pharmacies that submit claims or receive payments under the program. [PL 1999, c. 786, Pt. A, §3 (NEW).]
- C. A participating retail pharmacy shall submit claims to the department to verify the amount charged to qualified residents under subsection 5. [PL 1999, c. 786, Pt. A, §3 (NEW).]
- D. On a weekly or biweekly basis, the department must reimburse a participating retail pharmacy for the difference between the initial discounted price and the secondary discounted price provided to qualified residents under subsection 5. [PL 2003, c. 494, §4 (AMD).]
- E. [PL 2003, c. 494, §4 (RP).]
- F. The department shall conduct ongoing quality assurance activities similar to those used in the MaineCare program. [PL 2003, c. 494, §4 (NEW).]

[PL 2003, c. 494, §4 (AMD).]

- 7. Action with regard to nonparticipating manufacturers and labelers. [PL 2003, c. 494, §5 (RPR); MRSA T. 22 §2681, sub-§7 (RP).]
- 7-A. Action with regard to nonparticipating manufacturers and labelers. The names of manufacturers and labelers who do and do not enter into rebate agreements pursuant to this subchapter are public information. The department shall release this information to health care providers and the public on a regular basis and shall publicize participation by manufacturers and labelers that is of particular benefit to the public. The department shall impose prior authorization requirements in the MaineCare program, as permitted by law, to the extent the department determines it is appropriate to do so in order to encourage manufacturer and labeler participation in the program and so long as the additional prior authorization requirements remain consistent with the goals of the MaineCare program and the requirements of the federal Social Security Act, Title 19.

This subsection takes effect on the date that the department begins offering prescription drug benefits under the program.

[PL 2003, c. 494, §6 (NEW).]

- 8. Discrepancies in rebate amounts. [PL 2003, c. 494, §7 (RP).]
- **9. Dedicated fund.** The Maine Rx Plus 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 including pharmacy claims processing fees, administrative and associated computer costs and other reasonable program costs; and to benefit the elderly low-cost drug program under section 254-D. 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-D.

[PL 2005, c. 401, Pt. C, §4 (AMD).]

- **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. [PL 1999, c. 786, Pt. A, §3 (NEW).]
- 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.

[PL 1999, c. 786, Pt. A, §3 (NEW).]

- **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.
- [PL 1999, c. 786, Pt. A, §3 (NEW).]
- 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. [PL 1999, c. 786, Pt. A, §3 (NEW).]
- **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.

[PL 1999, c. 786, Pt. A, §3 (NEW).]

- 15. Waivers. The department may seek any waivers of federal law, rule or regulation necessary to implement the provisions of this subchapter. [PL 1999, c. 786, Pt. A, §3 (NEW).]
- **16. Fee imposed.** Beginning July 1, 2011, a fee is imposed on all enrollees in the program established under this section. The amount of the fee must be determined by rule adopted by the department to cover the administrative and other operating costs of the program. Rules adopted pursuant to this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A. IPL 2011, c. 380, Pt. SS, §1 (NEW).]

## SECTION HISTORY

PL 1999, c. 786, §A3 (NEW). PL 2001, c. 358, §Q6 (AMD). PL 2001, c. 405, §2 (AMD). PL 2001, c. 405, §3 (AFF). PL 2003, c. 494, §§2-8 (AMD). PL 2003, c. 513, §G1 (AMD). PL 2005, c. 401, §§C3,4 (AMD). PL 2011, c. 380, Pt. SS, §1 (AMD).

### §2682. Display of Maine Rx Plus Program participation information

A drug dispensed pursuant to prescription, including a drug dispensed without charge to the consumer, must be accompanied by program participation information in a manner approved by the commissioner and as permitted by law. [PL 2001, c. 471, Pt. E, §5 (AMD); PL 2001, c. 471, Pt. E, §8 (AFF).]

- **1. Exceptions.** The requirements of this section do not apply to:
- A. A drug dispensed to a consumer who has health coverage that pays part or all of the retail cost of the drug; [PL 2001, c. 379, §1 (NEW).]
- B. A generic drug; or [PL 2001, c. 379, §1 (NEW).]
- C. A drug of a manufacturer or labeler that has entered into an agreement with the department pursuant to section 2681, subsection 3. [PL 2001, c. 379, §1 (NEW).] [PL 2001, c. 379, §1 (NEW).]
- **2. Rulemaking.** The commissioner shall adopt rules to implement this section. Rules adopted pursuant to this section are routine technical rules as defined by Title 5, chapter 375, subchapter II-A. [PL 2001, c. 379, §1 (NEW).]

- 3. Program participation information.
- [PL 2001, c. 471, Pt. E, §6 (RP); PL 2001, c. 471, Pt. E, §8 (AFF).]
- **3-A. Program participation information.** The rules must provide for the disclosure of program participation information, including, but not limited to, the following:
  - A. Notification that the manufacturer or labeler has not entered into an agreement with the Department of Health and Human Services pursuant to section 2681, subsection 3; and [PL 2001, c. 471, Pt. E, §7 (NEW); PL 2001, c. 471, Pt. E, §8 (AFF); PL 2003, c. 689, Pt. B, §6 (REV).]
- B. Advice to consult a health care provider or pharmacist about access to drugs at lower prices. [PL 2001, c. 471, Pt. E, §7 (NEW); PL 2001, c. 471, Pt. E, §8 (AFF).] [PL 2001, c. 471, Pt. E, §7 (NEW); PL 2001, c. 471, Pt. E, §8 (AFF); PL 2003, c. 689, Pt. B, §6 (REV).]
- **4. Separate writing.** The requirements of this section may be met by the distribution of a separate writing that is approved by or produced and distributed by the department. [PL 2001, c. 379, §1 (NEW).]
- **5. Waivers.** The rules must provide for waivers to the requirements of this section, particularly when the manufacturer or labeler is negotiating with the commissioner pursuant to section 2681, subsection 3.

[PL 2001, c. 379, §1 (NEW).]

SECTION HISTORY

PL 2001, c. 379, §1 (NEW). PL 2001, c. 471, §§E5-7 (AMD). PL 2001, c. 471, §E8 (AFF). PL 2003, c. 494, §9 (AMD). PL 2003, c. 689, §B6 (REV).

# **SUBCHAPTER 1-A**

### PRESCRIPTION DRUG ACADEMIC DETAILING

# §2685. Prescription drug academic detailing program

By January 1, 2008, the department shall establish a prescription drug academic detailing program, referred to in this section as "the program," to enhance the health of residents of the State, to improve the quality of decisions regarding drug prescribing, to encourage better communication between the department and health care practitioners participating in publicly funded health programs and to reduce the health complications and unnecessary costs associated with inappropriate drug prescribing. [PL 2007, c. 327, §1 (NEW).]

- 1. **Program design.** The department shall design the program after consultation with prescribers and dispensers of drugs, carriers and health plans, hospitals, pharmacy benefit managers, consumers, the MaineCare Advisory Committee and the MaineCare drug utilization review committee under section 3174-M, subsection 2-A.
- [PL 2007, c. 327, §1 (NEW).]
- **2. Definitions.** As used in this subchapter, unless the context otherwise indicates, the following terms have the following meanings.
  - A. "Academic detailing" means the provision of information regarding prescription drugs based on scientific and medical research, including information on therapeutic and cost-effective use of prescription drugs. [PL 2007, c. 327, §1 (NEW).]

- B. "Carrier" has the same meaning as in Title 24-A, section 4301-A, subsection 3. [PL 2007, c. 695, Pt. A, §25 (AMD).]
- C. "Dirigo Health insurance" means the program of health coverage provided under Title 24-A, section 6910. [PL 2007, c. 327, §1 (NEW).]
- D. "Dispenser" means a licensed mail order prescription pharmacy as defined in Title 32, section 13702-A, subsection 17; a licensed pharmacy as defined in Title 32, section 13702-A, subsection 24; and any other person or entity licensed to dispense prescription drugs under Title 32, chapter 117. [PL 2007, c. 695, Pt. C, §8 (AMD).]
- E. "Elderly low-cost drug program" means the elderly low-cost drug program provided under section 254-D. [PL 2007, c. 327,  $\S1$  (NEW).]
- F. "Health plan" means a health plan providing prescription drug coverage as authorized under the federal Medicare Prescription Drug, Improvement and Modernization Act of 2003, Public Law 108-173. [PL 2007, c. 327, §1 (NEW).]
- G. "MaineCare program" means the MaineCare program administered under chapter 855. [PL 2007, c. 327, §1 (NEW).]
- H. "Maine Rx Plus Program" means the Maine Rx Plus Program established under section 2681. [PL 2007, c. 327, §1 (NEW).]
- I. "Prescriber" means a person who is licensed, registered or otherwise authorized in the appropriate jurisdiction to prescribe and administer drugs in the course of professional practice. [PL 2007, c. 327, §1 (NEW).]
- J. "State employee health insurance program" means the state employee health insurance program provided under Title 5, section 285. [PL 2007, c. 327, §1 (NEW).] [PL 2007, c. 695, Pt. A, §25 (AMD); PL 2007, c. 695, Pt. C, §8 (AMD).]
- 3. Program components. Program components must include outreach and education regarding the therapeutic and cost-effective use of prescription drugs as issued in peer-reviewed scientific, medical and academic research publications and made available to prescribers and dispensers of drugs in the State, including through written information and through personal visits from program staff. To the extent possible, program components must also include information regarding clinical trials, pharmaceutical efficacy, adverse effects of drugs, evidence-based treatment options and drug marketing approaches that are intended to circumvent competition from generic and therapeutically equivalent drugs. Academic detailers shall observe standards of conduct in their educational materials and written and oral presentations as established by rules adopted by the department that are consistent with the following federal regulations regarding labeling and false and misleading advertising: the Food and Drug Administration labeling requirements of 21 Code of Federal Regulations, Part 201 (2007) and prescription drug advertising provisions of 21 Code of Federal Regulations, Part 202 (2007) and the Office of the Inspector General's Compliance Program Guidance for Pharmaceutical Manufacturers issued in April 2003, as amended. The rules must require academic detailers to disclose evidencebased information about the range and cost of appropriate drug treatment options and the health benefits and risks of all appropriate drugs.

[PL 2007, c. 327, §1 (NEW).]

**4. Program coverage.** The program must provide outreach and education to prescribers and dispensers who participate in, contract with or are reimbursed by state-funded health care programs, including but not limited to the MaineCare program, the Maine Rx Plus Program, Dirigo Health insurance, the elderly low-cost drug program and the state employee health insurance program. The program may provide outreach and education to carriers, health plans, hospitals, employers and other persons interested in the program on a subscription or fee-paying basis under rules adopted by the department.

[PL 2007, c. 327, §1 (NEW).]

**5. Funding.** The program may be funded from the General Fund, from federal funds and from other special revenue funds. Beginning April 1, 2012 each manufacturer of prescription drugs that are provided to Maine residents through the MaineCare program or the elderly low-cost drug program shall pay a fee of \$500 per calendar year to the department to provide funding for the program. The program may accept funds from nongovernmental health access foundations, the Tobacco Manufacturers Act under chapter 263, subchapter 3, undesignated funds associated with pharmaceutical marketing and pricing practices acquired through litigation or action of the Office of the Attorney General and fees from subscriptions, contracts and agreements with private payors as established by rule. Savings achieved as a result of the program may be retained for operation of the program or paid into the General Fund, at the option of the department.

[PL 2011, c. 461, §2 (AMD).]

**6. Annual report.** By April 1st each year the department shall provide to the Legislature an annual report on the operation of the program. The report must include information on the outreach and education components of the program; revenues, expenditures and balances; and savings attributable to the program in state-funded health care programs.

[PL 2007, c. 327, §1 (NEW).]

7. Rulemaking. The department shall adopt rules to implement the program. Rules adopted under this subsection are routine technical rules as defined by Title 5, chapter 375, subchapter 2-A. [PL 2007, c. 327, §1 (NEW).]

SECTION HISTORY

PL 2007, c. 327, §1 (NEW). PL 2007, c. 695, Pt. A, §25 (AMD). PL 2007, c. 695, Pt. C, §8 (AMD). PL 2011, c. 461, §2 (AMD).

#### **SUBCHAPTER 1-B**

#### MAXIMUM ALLOWABLE COST LIST

### §2687. Maximum allowable cost list

- 1. Comment period. The Department of Health and Human Services, office of MaineCare services shall establish a 17-day written comment period on any proposed change to the state maximum allowable cost list if the change results in a reduction in payment to pharmacies. The written comment period must be held in compliance with the Maine Administrative Procedure Act. A change in the maximum allowable cost list that will result in a reduction in payment to pharmacies may not take effect for at least 30 days and not until 30 days after the office of MaineCare services has completed its response to any written comments. For the purposes of this section, "maximum allowable cost list" means a list of prescription drugs that bases reimbursement on the cost of the generic product. [PL 2011, c. 323, §1 (NEW).]
- 2. Report. The Department of Health and Human Services, office of MaineCare services shall prepare an annual report that summarizes the number of drugs affected by changes made to the maximum allowable cost list under subsection 1 and the percentage change in payment for those drugs that resulted from changes to the list during the calendar year. The office of MaineCare services shall file the report annually by December 31st with the joint standing committee of the Legislature having jurisdiction over health and human services matters.

[PL 2011, c. 323, §1 (NEW).]

**3. Rulemaking.** The Department of Health and Human Services, office of MaineCare services shall amend its rules to implement the provisions of this subchapter. Rules adopted pursuant to this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

[PL 2011, c. 323, §1 (NEW).]

SECTION HISTORY

PL 2011, c. 323, §1 (NEW).

#### **SUBCHAPTER 2**

#### 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. [PL 1999, c. 786, Pt. A, §3 (NEW).]

SECTION HISTORY

PL 1999, c. 786, §A3 (NEW).

§2692. Prescription Drug Advisory Commission

(REPEALED)

SECTION HISTORY

PL 1999, c. 786, §A3 (NEW). PL 2007, c. 395, §25 (RP).

## §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. [PL 1999, c. 786, Pt. A, §3 (NEW).]

- 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, 2005, 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. [PL 2007, c. 395, §26 (AMD).]
  - B. By January 5, 2006, the commissioner shall determine whether the cost of prescription drugs provided to qualified residents under the Maine Rx Plus Program pursuant to subchapter 1 is reasonably comparable to the lowest cost paid for the same drugs delivered or dispensed in the State. In making this determination the following provisions apply.
    - (1) The commissioner shall review prescription drug use in the MaineCare 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 who are provided those drugs under the Maine Rx Plus 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) 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 Maine Rx Plus 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 Plus 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, 2006. [PL 2003, c. 494, §10 (AMD).]
- C. In establishing maximum retail prices under this paragraph, the commissioner shall follow procedures set forth by rules adopted by the department. [PL 2007, c. 395, §27 (AMD).]
- D. Rules adopted pursuant to this subsection are major substantive rules as defined in Title 5, chapter 375, subchapter II-A. [PL 1999, c. 786, Pt. A, §3 (NEW).] [PL 2007, c. 395, §§26, 27 (AMD).]
- 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.

[PL 1999, c. 786, Pt. A, §3 (NEW).]

- 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. [PL 1999, c. 786, Pt. A, §3 (NEW).]
- **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. [PL 1999, c. 786, Pt. A, §3 (NEW).]
- **5. Enforcement.** A violation of the maximum retail prices established under this section is a violation of the Maine Unfair Trade Practices Act.

[PL 1999, c. 786, Pt. A, §3 (NEW).]

**SECTION HISTORY** 

PL 1999, c. 786, §A3 (NEW). PL 2003, c. 494, §10 (AMD). PL 2007, c. 395, §§26, 27 (AMD).

### §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. [PL 1999, c. 786, Pt. A, §3 (NEW).]

SECTION HISTORY

PL 1999, c. 786, §A3 (NEW).

## **SUBCHAPTER 3**

### 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. [PL 1999, c. 786, Pt. A, §3 (NEW).]

- **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 and that has a labeler code from the federal Food and Drug Administration under 21 Code of Federal Regulations, 207.20 (1999). [PL 1999, c. 786, Pt. A, §3 (NEW).]
- B. "Manufacturer" means a manufacturer of prescription drugs and includes a subsidiary or affiliate of a manufacturer. [PL 1999, c. 786, Pt. A, §3 (NEW).] [PL 1999, c. 786, Pt. A, §3 (NEW).]
- **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; [PL 1999, c. 786, Pt. A, §3 (NEW).]
  - B. Exacts or demands prices or terms that lead to any unjust or unreasonable profit; [PL 1999, c. 786, Pt. A, §3 (NEW).]
  - C. Discriminates unreasonably against any person in the sale, exchange, distribution or handling of prescription drugs dispensed or delivered in the State; or [PL 1999, c. 786, Pt. A, §3 (NEW).]
- 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. [PL 1999, c. 786, Pt. A, §3 (NEW).] [PL 1999, c. 786, Pt. A, §3 (NEW).]
- **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.

[PL 1999, c. 786, Pt. A, §3 (NEW).]

- **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.
- [PL 1999, c. 786, Pt. A, §3 (NEW).]
- **5. Unfair trade practice.** A violation of this section is also a violation of the Maine Unfair Trade Practices Act.

[PL 1999, c. 786, Pt. A, §3 (NEW).]

**SECTION HISTORY** 

PL 1999, c. 786, §A3 (NEW).

§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. [PL 1999, c. 786, Pt. A, §3 (NEW).]

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. [PL 1999, c. 786, Pt. A, §3 (NEW).]

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. [PL 1999, c. 786, Pt. A, §3 (NEW).]

SECTION HISTORY

PL 1999, c. 786, §A3 (NEW).

§2698-A. Marketing costs

(REPEALED)

**SECTION HISTORY** 

RR 2003, c. 1, §17 (RAL). RR 2003, c. 1, §18 (AFF). PL 2003, c. 688, §C8 (AMD). PL 2005, c. 286, §§1,2 (AMD). PL 2011, c. 461, §3 (RP).

§2698-B. Actual price disclosure and certification

(REPEALED)

**SECTION HISTORY** 

PL 2003, c. 667, §1 (NEW). PL 2003, c. 667, §2 (AFF). PL 2005, c. 402, §§1-4 (AMD). PL 2011, c. 461, §4 (RP).

#### **SUBCHAPTER 4**

## PRESCRIPTION DRUG PRACTICES

§2699. Prescription drug practices

(REPEALED)

**SECTION HISTORY** 

RR 2003, c. 1, §17 (RAL). RR 2003, c. 1, §18 (AFF). PL 2003, c. 430, §1 (NEW). PL 2003, c. 430, §3 (AFF). PL 2003, c. 456, §1 (NEW). PL 2003, c. 673, §§FFF1,2 (AMD). PL 2003, c. 688, §\$C9,10 (AMD). PL 2003, c. 688, §C11 (AFF). PL 2007, c. 431, §\$1, 2 (AMD). PL 2007, c. 431, §3 (AFF). PL 2009, c. 581, §\$1, 2 (AMD). PL 2011, c. 443, §2 (RP).

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