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Public Law
123rd Legislature
First Regular Session

Chapter 327
H.P. 638 - L.D. 839

An Act To Establish a Prescription Drug Academic Detailing Program

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 22 MRSA c. 603, sub-c. 1-A is enacted to read:

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.

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.

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.

B. "Carrier" has the same meaning as in Title 24-A, section 4301-A, section 3.

C. "Dirigo Health insurance" means the program of health coverage provided under Title 24-A, section 6910.

D. "Dispenser" means a licensed mail order prescription pharmacy as defined in Title 32, section 13702, subsection 13; a licensed drug outlet as defined in Title 32, section 13702, subsection 10; and any other person or entity licensed to dispense prescription drugs under Title 32, chapter 117.

E. "Elderly low-cost drug program" means the elderly low-cost drug program provided under section 254-D.

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.

G. "MaineCare program" means the MaineCare program administered under chapter 855.

H. "Maine Rx Plus Program" means the Maine Rx Plus Program established under section 2681.

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.

J. "State employee health insurance program" means the state employee health insurance program provided under Title 5, section 285.

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 evidence-based information about the range and cost of appropriate drug treatment options and the health benefits and risks of all appropriate drugs.

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.

5. Funding. The program may be funded from the General Fund, from federal funds and from other special revenue funds. One half of the funds collected under section 2700-A, subsection 4 annually must be allocated to the costs of 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.

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.

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.

Sec. 2. 22 MRSA §2700-A, sub-§4, as amended by PL 2005, c. 683, Pt. B, §17, is further amended to read:

4. Fees. Beginning April 1, 2006, each manufacturer of prescription drugs that are provided to Maine residents through the MaineCare program under section 3174-G or the elderly low-cost drug program under section 254-D shall pay a fee of \$1,000 per calendar year to the State. Fees collected under this subsection must be used to cover the cost of overseeing implementation of this section, including but not limited to maintaining links to publicly accessible websites to which manufacturers are posting clinical trial information under subsection 3 and other relevant sites, assessing whether and the extent to which Maine residents have been harmed by the use of a particular drug and undertaking the public education initiative under subsection 5 and the prescription drug academic detailing program under section 2685. One half of the annual revenues from this subsection must be allocated to and used for the academic detailing program under section 2685. Revenues received under this subsection, with the exception of funding designated for the academic detailing program under section 2685, must be deposited into an Other Special Revenue Funds account to be used for the purposes of this subsection.

Sec. 3. 22 MRSA §2700-A, sub-§5, as enacted by PL 2005, c. 392, §1, is amended to read:

5. Public education initiative. The department shall undertake a public education initiative to inform residents of the State about clinical trials and drug safety information and shall coordinate the public education program with the prescription drug academic detailing program under section 2685.

Sec. 4. Initial program design. In planning for the design of the prescription drug academic detailing program under the Maine Revised Statutes, Title 22, section 2685, the Department of Health and Human Services shall investigate initially establishing the program collaboratively with the states of New Hampshire and Vermont. The department shall review and evaluate use of the educational and assessment materials developed by the Commonwealth of Pennsylvania for the prescription drug academic detailing program that involved the cooperative work of that state and Harvard Medical School and shall consider adopting the Pennsylvania program as a starting point for the program. The department shall include discussion of these aspects of initial program design in the first 2 annual reports to the Legislature.

Sec. 5. Appropriations and allocations. The following appropriations and allocations are made.

HEALTH AND HUMAN SERVICES, DEPARTMENT OF (FORMERLY DHS)

Prescription Drug Academic Detailing N026

Initiative: Provides a base allocation for the costs of the prescription drug academic detailing program to be funded from a share of the fees collected from prescription drug manufacturers under the Maine Revised Statutes, Title 22, section 2700-A, subsection 4.

| OTHER SPECIAL REVENUE FUNDS | 2007-08 | 2008-09 |
|--|----------------|----------------|
| All Other | \$500 | \$500 |
| | <hr/> | <hr/> |
| OTHER SPECIAL REVENUE FUNDS TOTAL | \$500 | \$500 |

Effective September 20, 2007