An Act To Make Certain Prescription Drug Disclosure Laws Consistent with Federal Law

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

Sec. 1. 22 MRSA §1711-E, sub-§1-B, ¶C, as enacted by PL 2007, c. 460, §1, is amended to read:

C. The provisions of this section are narrowly and carefully tailored to address the findings listed in subsection 1-A, to achieve the State's purposes listed in this subsection and in conjunction with the following efforts to advance the State's compelling interests:

(1) Prior authorization and drug utilization review in the MaineCare program under section 3174-M;

~~(2) Reporting of a broad array of prescription drug marketing costs under section 2698-A and subsequent reporting by the department to the Legislature and the Attorney General;~~

~~(3) Prescription drug price disclosure under section 2698-B;~~

(4) Generic and therapeutically equivalent substitution of prescription drugs under Title 32, section 13781; and

(5) Protection of patient prescription drug information held by health care practitioners under section 1711-C.

Sec. 2. 22 MRSA §2685, sub-§5, as enacted by PL 2007, c. 327, §1, is amended to read:

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.

Sec. 3. 22 MRSA §2698-A, as amended by PL 2005, c. 286, §§1 and 2, is repealed.

Sec. 4. 22 MRSA §2698-B, as amended by PL 2005, c. 402, §§1 to 4, is repealed.

Sec. 5. 22 MRSA §2700-A, as amended by PL 2007, c. 327, §§2 and 3 and c. 362, §§1 and 2, is further amended to read:

§ 2700-A.Prohibitions

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

~~A. "Clinical trial" means a clinical investigation as defined by the federal Food and Drug Administration that involves any trial to test the safety or efficacy of a drug or biological product with one or more human subjects and that is intended to be submitted to, or held for inspection by, the federal Food and Drug Administration as part of an application for a research or marketing permit.~~

B. "Manufacturer of prescription drugs" or "manufacturer" means a manufacturer of prescription drugs or biological products or an affiliate of the manufacturer or a labeler that receives prescription drugs or biological products from a manufacturer or wholesaler and repackages those drugs or biological products for later retail sale and that has a labeler code from the federal Food and Drug Administration under 21 Code of Federal Regulations, 2027.20 (1999).

B-1. "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.

C. "Regulated advertisement" means the presentation to the general public of a commercial message regarding a prescription drug or biological product by a manufacturer of prescription drugs that is:

(1) Broadcast on television or radio from a station that is physically located in the State;

(2) Broadcast over the Internet from a location in the State; or

(3) Printed in magazines or newspapers that are printed, distributed or sold in the State.

2. Regulated advertisement requirement. Beginning October 15, 2005, a manufacturer may not present or cause to be presented in the State a regulated advertisement, unless that advertisement meets the requirements concerning misbranded drugs and devices and prescription drug advertising of federal law and regulations under 21 United States Code, Sections 331 and 352(n) and 21 Code of Federal Regulations, Part 202 and state rules.

2-A. Software prohibition. Beginning January 1, 2008, a person may not sell or distribute in the State computer software that influences or attempts to influence a prescribing decision of a prescriber to prescribe a certain drug or that directs a patient to a certain pharmacy. Features of computer software that are prohibited include, but are not limited to, pop-up and other advertisements, instant messages and economic incentives that are triggered by or in specific response to a selection, act or other input or designation of pharmacy by the prescriber or an agent of the prescriber. This subsection does not

apply to in-house equipment provided within a hospital for use by prescribers and the hospital pharmacy or to information provided to a prescriber about prescription drug formulary compliance, patient care management or pharmacy reimbursement.

3. Disclosure of clinical trials of prescription drugs. Beginning October 15, 2005, a manufacturer or labeler of prescription drugs that is required to report marketing costs for prescription drugs pursuant to section 2698-A shall post, with regard to those prescription drugs, on the publicly accessible Internet website of the federal National Institutes of Health or its successor agency or another publicly accessible website the following information concerning any clinical trial that the manufacturer conducted or sponsored on or after October 15, 2002:

A. The name of the entity that conducted or is conducting the clinical trial;

B. A summary of the purpose of the clinical trial;

C. The dates during which the trial has taken place; and

D. Information concerning the results of the clinical trial, including potential or actual adverse effects of the drug.

In order to satisfy the requirements of this subsection, the publicly accessible website and manner of posting must be acceptable to the department.

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.

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.

6. Penalties. A violation of this section is a violation of the Maine Unfair Trade Practices Act. Each day a manufacturer is in violation of this chapter is considered a separate violation.

7. Rulemaking. The department may adopt rules to implement this section. Rules adopted pursuant to this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

SUMMARY

This bill strikes the laws related to the reporting of marketing costs, price reporting and the disclosure of clinical trials by manufacturers and labelers of prescription drugs.