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House of Representatives, February 23, 2011

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

Received by the Clerk of the House on February 18, 2011. Referred to the Committee on Health and Human Services pursuant to Joint Rule 308.2 and ordered printed pursuant to Joint Rule 401.

A handwritten signature in cursive script that reads "Heather J.R. Priest".

HEATHER J.R. PRIEST
Clerk

Presented by Representative STRANG BURGESS of Cumberland.
Cosponsored by Senator McCORMICK of Kennebec and
Representatives: FOSSEL of Alna, O'CONNOR of Berwick, PETERSON of Rumford,
SIROCKI of Scarborough, Senators: RECTOR of Knox, SNOWE-MELLO of Androscoggin,
SULLIVAN of York.

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

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

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

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

10 ~~(2) Reporting of a broad array of prescription drug marketing costs under section~~
11 ~~2698-A and subsequent reporting by the department to the Legislature and the~~
12 ~~Attorney General;~~

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

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

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

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

20 **5. Funding.** The program may be funded from the General Fund, from federal funds
21 and from other special revenue funds. ~~One half of the funds collected under section~~
22 ~~2700-A, subsection 4 annually must be allocated to the costs of the program.~~ The
23 program may accept funds from nongovernmental health access foundations, the Tobacco
24 Manufacturers Act under chapter 263, subchapter 3, undesignated funds associated with
25 pharmaceutical marketing and pricing practices acquired through litigation or action of
26 the Office of the Attorney General and fees from subscriptions, contracts and agreements
27 with private payors as established by rule. Savings achieved as a result of the program
28 may be retained for operation of the program or paid into the General Fund, at the option
29 of the department.

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

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

33 **Sec. 5. 22 MRSA §2700-A**, as amended by PL 2007, c. 327, §§2 and 3 and c. 362,
34 §§1 and 2, is further amended to read:

35 **§2700-A. Prohibitions**

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

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

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

12 B-1. "Prescriber" means a person who is licensed, registered or otherwise authorized
13 in the appropriate jurisdiction to prescribe and administer drugs in the course of
14 professional practice.

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

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

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

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

23 **2. Regulated advertisement requirement.** Beginning October 15, 2005, a
24 manufacturer may not present or cause to be presented in the State a regulated
25 advertisement, unless that advertisement meets the requirements concerning misbranded
26 drugs and devices and prescription drug advertising of federal law and regulations under
27 21 United States Code, Sections 331 and 352(n) and 21 Code of Federal Regulations, Part
28 202 and state rules.

29 **2-A. Software prohibition.** Beginning January 1, 2008, a person may not sell or
30 distribute in the State computer software that influences or attempts to influence a
31 prescribing decision of a prescriber to prescribe a certain drug or that directs a patient to a
32 certain pharmacy. Features of computer software that are prohibited include, but are not
33 limited to, pop-up and other advertisements, instant messages and economic incentives
34 that are triggered by or in specific response to a selection, act or other input or
35 designation of pharmacy by the prescriber or an agent of the prescriber. This subsection
36 does not apply to in-house equipment provided within a hospital for use by prescribers
37 and the hospital pharmacy or to information provided to a prescriber about prescription
38 drug formulary compliance, patient care management or pharmacy reimbursement.

39 ~~**3. Disclosure of clinical trials of prescription drugs.** Beginning October 15, 2005,~~
40 ~~a manufacturer or labeler of prescription drugs that is required to report marketing costs~~
41 ~~for prescription drugs pursuant to section 2698 A shall post, with regard to those~~
42 ~~prescription drugs, on the publicly accessible Internet website of the federal National~~
43 ~~Institutes of Health or its successor agency or another publicly accessible website the~~

1 following information concerning any clinical trial that the manufacturer conducted or
2 sponsored on or after October 15, 2002:

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

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

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

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

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

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

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

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

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

34 SUMMARY

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