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L.D. 4

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**HEALTH AND HUMAN SERVICES**

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**STATE OF MAINE**

**HOUSE OF REPRESENTATIVES**

**123RD LEGISLATURE**

**FIRST REGULAR SESSION**

COMMITTEE AMENDMENT "A" to H.P. 5, L.D. 4, Bill, "An Act To Amend the Prescription Privacy Law"

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

'**Sec. 1. 22 MRSA §1711-E,** as enacted by PL 2005, c. 589, §1, is amended to read:

**§1711-E. Confidentiality of prescription drug information**

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

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

A-1. "Administrator" has the same meaning as in Title 24-A, section 1901, subsection 1.

A-2. "Detailing" means one-to-one contact with a prescriber or employees or agents of a prescriber for the purpose of increasing or reinforcing the prescribing of a certain drug by the prescriber.

B. "Electronic transmission intermediary" means an entity that provides the infrastructure that connects the computer systems or other electronic devices used by and between health care practitioners, prescribers, pharmacies, health care facilities ~~and~~, pharmacy benefit managers ~~to~~, carriers and administrators and agents and contractors of those ~~carriers and agents~~ persons and entities in order to facilitate the secure transmission of an individual's prescription drug order, refill, authorization request, claim, payment or other prescription drug information.

C. "Health care facility" has the same meanings as in section 1711-C, subsection 1, paragraph D.

D. "Health care practitioner" has the same meanings as in section 1711-C, subsection 1, paragraph F.

E. "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.

F. "Individual" means a natural person who is the subject of prescription drug information.

F-1. "Marketing" means any of the following activities undertaken or materials or products made available to prescribers or to their employees or agents related to the transfer of prescription drugs from the producer or seller to the consumer or buyer:

(1) Advertising, publicizing, promoting or selling a prescription drug;

(2) Activities undertaken for the purpose of influencing the market share of a prescription drug or the prescribing patterns of a prescriber, a detailing visit or a personal appearance;

(3) Activities undertaken to evaluate or improve the effectiveness of a professional detailing sales force; or

(4) A brochure, media advertisement or announcement, poster or free sample of a prescription drug.

"Marketing" does not include pharmacy reimbursement, formulary compliance, pharmacy file transfers in response to a patient request or as a result of the sale or purchase of a pharmacy, patient care management, utilization review by a health care provider or agent of a health care provider or the patient's health plan or an agent of the patient's health plan, and health care research.

F-2. "Pharmacy" means a mail order prescription pharmacy as defined in Title 32, section 13702, subsection 13 or a drug outlet as defined in Title 32, section 13702, subsection 10.

G. "Pharmacy benefits manager" has the same meaning as in section 2699, subsection 1, paragraph F.

G-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.

H. "Prescription drug information" means information concerning prescription drugs as defined in Title 32, section 13702, subsection 24 and includes prescription drug orders as defined in Title 32, section 13702, subsection 25.

I. "Prescription drug information intermediary" means a person or entity that communicates, facilitates or participates in the exchange of prescription drug information regarding an individual or a prescriber. "Prescription drug information intermediary" includes, but is not limited to, a pharmacy benefits manager, a health plan, an administrator and an electronic transmission intermediary and any person or entity employed by or contracted to provide services to that entity.

**1-A. Findings.** The Legislature finds that enactment of this section will assist the State to achieve the following compelling state interests: to improve the public health, to limit annual increases in the cost of health care and to protect the privacy of patients and prescribers in the health care system of this State.

A. The State has a duty to assist public and private payors and health care practitioners and consumers to maintain an effective and efficient health care system that is based on sound medical and scientific knowledge and the professional judgment of health care practitioners and that is trusted by the general public.

B. Patients and prescribers have requested that the Legislature provide a mechanism for protecting the confidentiality of identifying prescription drug information from use for marketing purposes. Joining them are payors of all types and the general public demanding from the health care system efficiency, effectiveness and increased access for all persons.

C. Across the nation data companies purchase for marketing purposes computerized prescription drug records from pharmacies and insurers that identify prescribers. These records are sold to prescription drug manufacturers that use personally identifying prescriber information to attempt to influence prescribers to prescribe higher priced drugs, thus increasing the market share and profitability of the manufacturers and driving up the cost of health care.

D. Restricting the use of prescriber identifying information will act to decrease drug detailing that targets the prescriber, thus increasing decisions to prescribe lower priced drugs and decisions made on the basis of medical and scientific knowledge and driving down the cost of health care.

E. With redirected drug detailing programs, manufacturers of prescription drugs will be able to increase their investments in new and more effective prescription drugs and savings will accrue to payors that can be used for increased access to health care and for other necessary public and private purposes.

F. The provisions of this section are narrowly and carefully tailored to address the findings listed in this subsection, to achieve the State's purposes listed in subsection 1-B and to advance the State's compelling interests.

**1-B. Purposes.** It is the intent of the Legislature in enacting this section to achieve the following compelling state interests: to improve public health, to limit annual increases in the cost of health care and to protect the privacy of patients and prescribers in the health care system of this State.

A. The establishment of a system to protect patient confidentiality is critical to patient trust in the integrity of the health care system of this State. It will protect prescribers' expectations of privacy, freeing them from pressure to prescribe based on comparisons among them and their peers and aiding them in making health care decisions based on the best interests of the patient and on medical and scientific evidence about prescription drugs and health care treatments. It will decrease the influence of drug representatives. This will build patient and prescriber confidence in the health care system.

B. Restrictions on the use of personally identifying information for marketing purposes will protect personal privacy rights, end the use of prescriber comparisons for purposes related to manufacturer profitability and decrease unnecessary marketing costs.

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.

**2. Confidentiality of prescription drug information that identifies the individual.** A carrier or prescription drug information intermediary may not license, use, sell, transfer or exchange for value, for any marketing purpose, prescription drug information that identifies directly or indirectly the individual ~~except if expressly permitted under section 1711-C, Title 24, Title 24-A or the federal Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, as amended~~.

**2-A. Confidentiality of prescription drug information that identifies the prescriber.** Beginning January 1, 2008, a carrier, pharmacy or prescription drug information intermediary may not license, use, sell, transfer or exchange for value, for any marketing purpose, prescription drug information that identifies a prescriber who has filed for confidentiality protection in accordance with subsection 4.

**3. Enforcement.** A violation of ~~this section~~ subsection 2 or 2-A is a violation of the Maine Unfair Trade Practices Act.

**4. Confidentiality protection procedures.** The procedures in this subsection apply to the protection of prescription drug information that identifies a prescriber.

A. Beginning October 1, 2007, a board of licensure of a prescriber shall provide as part of the application process for licensure and relicensure confidentiality protection information and procedures as set forth in this paragraph.

(1) The application materials must state that prescription drug information that identifies the prescriber is used for marketing purposes by carriers, pharmacies and prescription drug information intermediaries and that, with regard to that use of information, the confidentiality of the prescriber may be protected under this section in one of 3 ways:

(a) If the licensing procedure is done by regular mail, by signing and submitting to the Maine Health Data Organization the accompanying confidentiality protection form and addressed envelope;

(b) If the licensing procedure includes a check-off box on the application form or electronically, by completing the check-off box and submitting the form to the licensing board; or

(c) If the licensing procedure is done over the Internet and the licensing board has provided an electronic link over the Internet from the application materials, by use of the electronic link to the Maine Health Data Organization website.

(2) The licensing board shall submit to the Maine Health Data Organization on a monthly basis a list of all prescribers who have filed with the licensing board for confidentiality protection.

(3) The confidentiality protection information must inform the prescriber that filing for confidentiality protection is effective until it is revoked by the prescriber.

B. The boards of licensure may adopt rules to implement paragraph A. Rules adopted pursuant to this paragraph are routine technical rules as defined by Title 5, chapter 375, subchapter 2-A.

C. The department shall assess an annual fee payable by October 1st each year beginning in 2007 on manufacturers of prescription drugs whose drugs are dispensed to members of the MaineCare program under chapter 855 and enrollees in the elderly low-cost drug program under section 254-D. Fees collected under this paragraph must be deposited in a separate account and do not lapse at the end of the fiscal year. Eighty percent of the assessments must be used to cover the costs of the Maine Health Data Organization pursuant to paragraph A and section 8713 and 20% of the assessments must be used to cover the costs of the boards of licensure pursuant to paragraph A.

**5. Rules.** The department, after consultation with the Governor's Office of Health Policy and Finance, shall adopt rules to implement this section. Rules adopted pursuant to this subsection are routine technical rules as defined by Title 5, chapter 375, subchapter 2-A.

**Sec. 2. 22 MRSA §8704, sub-§4,** as amended by PL 1999, c. 127, Pt. B, §8, is further amended to read:

**4. Rulemaking.** The board shall adopt rules necessary for the proper administration and enforcement of the requirements of this chapter and to carry out the duties of the organization under section 1711-E, subsection 4 and section 8713. All rules must be adopted in accordance with Title 5, chapter 375 and unless otherwise provided are routine technical rules as defined in Title 5, chapter 375, subchapter ~~II-A~~ 2-A.

**Sec. 3. 22 MRSA §8704, sub-§7,** as amended by PL 2005, c. 565, §5, is further amended to read:

**7. Annual report.** The board shall prepare and submit an annual report on the operation of the organization and the Maine Health Data Processing Center as authorized in Title 10, section 681, including any activity contracted for by the organization or contracted services provided by the center, with resulting net earnings, to the Governor and the joint standing committee of the Legislature having jurisdiction over health and human services matters no later than February 1st of each year. The report must include an annual accounting of all revenue received and expenditures incurred in the previous year and all revenue and expenditures planned for the next year. The report must include a list of persons or entities that requested data from the organization in the preceding year with a brief summary of the stated purpose of the request.

As part of its annual report, the organization shall report on filings for confidentiality protection under section 1711-E, subsection 4, the disclosure of the names of prescribers who filed for confidentiality protection, funding through the assessment under section 1711-E, subsection 4, paragraph C and recommendations for legislation to improve operation of section 1711-E, subsection 4.

**Sec. 4. 22 MRSA §8713** is enacted to read:

**§8713. Confidentiality protection for certain health care practitioners**

The organization shall establish procedures to accept filings for confidentiality protection from health care practitioners who file with the organization under section 1711-E, subsection 4 and licensing boards that submit lists of names of practitioners who file for confidentiality protection. The procedures must provide for disclosure, upon request, of the names of practitioners who filed for confidentiality protection. The costs of the organization for performing the functions under this section must be met by funding provided under section 1711-E, subsection 4, paragraph C.

**Sec. 5. Transfer to the Maine Health Data Organization.** Notwithstanding any other provision of law, the State Controller after consultation with the Commissioner of Health and Human Services and the Director of the Maine Health Data Organization shall transfer funds as determined and available under section 1 of this Act in each of fiscal years 2007-08 and 2008-09 from the Bureau of Medical Services, Other Special Revenue Funds account in the Department of Health and Human Services to the Maine Health Data Organization, Other Special Revenue Funds account for costs incurred as a result of this Act.

**Sec. 6. Transfer to Department of Professional and Financial Regulation.** Notwithstanding any other provision of law, the State Controller after consultation with the Commissioner of Health and Human Services and the Commissioner of Professional and Financial Regulation shall transfer funds as determined and available under section 1 of this Act in each of fiscal years 2007-08 and 2008-09 from the Bureau of Medical Services, Other Special Revenue Funds account in the Department of Health and Human Services to the Administrative Services - Professional and Financial Regulation, Other Special Revenue Funds account in the Department of Professional and Financial Regulation for costs incurred under this Act.

**Sec. 7. Appropriations and allocations.** The following appropriations and allocations are made.

**HEALTH AND HUMAN SERVICES, DEPARTMENT OF (FORMERLY DHS)**

**Bureau of Medical Services 0129**

Initiative: Provides a base allocation for the costs of the prescription drug privacy program.

| OTHER SPECIAL REVENUE FUNDS | 2007-08 | 2008-09 |
|---|---|---|
| All Other | $500 | $500 |
| OTHER SPECIAL REVENUE FUNDS TOTAL | $500 | $500 |

## SUMMARY

This amendment replaces the bill and is the majority report of the committee. The amendment provides an opt-out mechanism by which prescribers of prescription drugs may protect from marketing uses prescription drug information that identifies the prescriber. The amendment:

1. Adds a definition of "marketing";

2. Adds to the definition of "prescription drug information intermediary" persons or entities employed by or under contract to a prescription drug information intermediary;

3. Provides a statement of findings:

A. That the Legislature finds that enactment of this legislation will: improve the public health, limit annual increases in the cost of health care and protect the privacy of patients and prescribers in Maine's health care system;

B. That the State has a duty to assist in the maintenance of an effective and efficient health care system;

C. That patients and prescribers have requested that the Legislature provide a mechanism for protecting confidentiality;

D. That data companies sell prescriber and patient information to drug manufacturers who use it to influence prescribers to prescribe higher priced drugs, thereby increasing the cost of health care;

E. That restricting the use of prescriber-identifying information will decrease drug detailing and increase the use of lower priced drugs, thus decreasing the cost of health care;

F. That the resulting savings may be used for increased investment in drugs and increased access to health care; and

G. That the legislation is a narrowly and carefully tailored approach to achieving compelling state interests and other purposes;

4. Provides a statement of purposes the Legislature intends to achieve, including improving the public health, limiting annual increases in the cost of health care and

protecting the privacy of patients and prescribers in Maine's health care system. Other purposes include protection of personal privacy rights, ending the use of prescriber comparisons and decreasing marketing costs.

In part as a reaction to a Journal of the American Medical Association article, "The Accuracy of Drug Information from Pharmaceutical Sales Representatives," vol. 273, no. 16, pp. 1296-98 (1995), which concluded that 11% of the in-person statements made to physicians by pharmaceutical sales representatives contradicted information that was readily available to them, the amendment also provides a mechanism to be used in conjunction with academic detailing that is being considered by the Legislature this year and details the efforts of the Legislature in prior years to address problems with cost and access to health care and confidentiality of health information.

It also provides a statement that the provisions of the amendment are narrowly and carefully tailored to address the findings listed in the amendment to achieve the State's purposes listed in the amendment and in conjunction with the following efforts to advance the State's compelling interests:

A. Prior authorization and drug utilization review in the MaineCare program under the Maine Revised Statutes, Title 22, section 3174-M;

B. Reporting of a broad array of prescription drug marketing costs under Title 22, section 2698-A and subsequent reporting by the Department of Health and Human Services to the Legislature and the Attorney General;

C. Prescription drug price disclosure under Title 22, section 2698-B;

D. Generic and therapeutically equivalent substitution of prescription drugs under Title 32, section 13781; and

E. Protection of patient prescription drug information held by health care practitioners under Title 22, section 1711-C;

5. Separates the confidentiality provisions applicable to the patient and the prescriber;

6. Beginning January 1, 2008, states that a carrier, pharmacy or prescription drug information intermediary may not license, use, sell, transfer or exchange for value for marketing purposes prescriber-identifying prescription drug information of a prescriber who has filed for confidentiality protection;

7. Establishes a mechanism for confidentiality protection through an opt-out procedure similar to the federal Do Not Call List utilizing the licensing and relicensing process for prescribers. The procedures include information for the prescriber and methods for filing with the Maine Health Data Organization to protect confidentiality of prescriber-identifying information;

8. Grants rule-making authority to the licensing boards and the Maine Health Data Organization, provides them funding through an assessment on manufacturers of prescription drugs dispensed through the MaineCare program and elderly low-cost drug program and requires a report on confidentiality protection activity within the Maine Health Data Organization under the law as part of the organization's annual report to the Legislature;

9. Provides authority to the Department of Health and Human Services to transfer funding to the Maine Health Data Organization and the Department of Professional and Financial Regulation to fund their costs for the mechanism to protect the confidentiality of prescriber-identifying prescription drug information; and

10. Adds an appropriations and allocations section.

**FISCAL NOTE REQUIRED**
**(See attached)**

Approved: 06/13/07 mac

# 123rd MAINE LEGISLATURE

**LD 4** **LR 22(02)**

**An Act To Amend the Prescription Privacy Law**

**Fiscal Note for Bill as Amended by Committee Amendment "A"**
**Committee: Health and Human Services**
**Fiscal Note Required: Yes**

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## Fiscal Note

Current biennium revenue increase - Other Special Revenue Funds
Current biennium cost increase - Other Special Revenue Funds
Minor cost increase - General Fund
Minor revenue increase - General Fund

| | 2007-08 | 2008-09 | Projections 2009-10 | Projecti 2010-11 |
|---|---|---|---|---|
| **Appropriations/Allocations** | | | | |
| Other Special Revenue Funds | $500 | $500 | $500 | $500 |

**Correctional and Judicial Impact Statements**

Establishes new civil violations.

The collection of additional fines may also increase General Fund revenue by minor amounts.

**Fiscal Detail and Notes**

Provides a base allocation for the Bureau of Medical Services in the Department of Health and Human Services for the costs of implementing the provisions of this bill to be funded utilizing existing budget resources including available balances of fees and assessments on manufacturers of prescription drugs.

Assumes additional costs to the Maine Health Data Organization to implement the provisions of this bill will be funded through the transfer of funds from an assessment on manufacturers of prescription drugs.

Assumes additional costs to the Department of Professional and Financial Regulation to implement the provisions of this bill will be funded through the transfer of funds from an assessment on manufacturers of prescription drugs.