



February 6, 2009

# Model Legislation

## Prescription Record Privacy Act

*The Prescription Project promotes appropriate prescribing, free of conflicts of interest caused by pharmaceutical marketing and based on the best available medical evidence.*

*It is promoting policy change by working with*

- *State and Federal Policymakers*
- *Academic Medical Centers*
- *Professional Medical Societies*
- *Private Payers*

*Created with The Pew Charitable Trusts, the Project is led by Community Catalyst in partnership with the Institute on Medicine as a Profession.*

### Bill Summary

This act protects the confidentiality of prescription records identifying a doctor or other health care professional licensed to prescribe medications by prohibiting the use of such information for marketing purposes.<sup>i</sup> The act also includes sections on maintaining the confidentiality of prescription data held by state health care programs and ensures that the state is complying with federal restrictions on the transfer and use of Medicaid data.

### Section 1. Purpose.<sup>ii</sup>

It is the intent of the legislature to safeguard the confidentiality of prescribing information, protect the integrity of the doctor-patient relationship, maintain the integrity and public trust in the medical profession, combat vexatious and harassing sales practices, restrain undue influence exerted by pharmaceutical industry marketing representatives over prescribing decisions and further the state interest in improving the quality and lowering the cost of health care. The legislature intends to regulate the monitoring of prescribing practices only for commercial marketing purposes by companies selling prescribed products. The intent is not to regulate monitoring for other uses, such as quality control, research unrelated to marketing, or use by governments or other entities not in the business of selling health care products.<sup>iii</sup>

### Section 2. Prescription Privacy.<sup>iv</sup>

#### 2a. Definitions. For the purposes of this chapter:

- (a) "Bona fide clinical trial" means any research project that prospectively assigns human subjects to intervention and comparison groups to study the cause and effect relationship between a medical intervention and a health outcome, has received approval from an appropriate Institutional Review Board, and has been registered at ClinicalTrials.Gov prior to commencement.
- (b) "Individual identifying information" means information that directly or indirectly identifies a prescriber<sup>v</sup> or a patient in this state, where the information is derived from or relates to a prescription for any prescribed product.
- (c) "Marketing" means any activity by a company making or selling prescribed products, or such company's agent, intended to influence

prescribing or purchasing choices of its products, including but not limited to:

- (1) advertising, publicizing, promoting or sharing information about a product;
- (2) identifying individuals to receive a message promoting use of a particular product, including but not limited to an advertisement, brochure, or contact by a sales representative;
- (3) planning the substance of a sales representative visit or communication or the substance of an advertisement or other promotional message or document;
- (4) evaluating or compensating sales representatives;
- (5) identifying individuals to receive any form of gift, product sample, consultancy, or any other item, service, compensation or employment of value;
- (6) advertising or promoting prescribed products directly to patients.

(d) "Person" means a business, individual, corporation, union, association, firm, partnership, committee, or other organization or group of persons.

(e) "Pharmacy" means any individual or entity licensed under state law to dispense prescribed products.<sup>vi</sup>

(f) "Prescribed product" includes a biological product as defined in section 351 of the Public Health Service Act, 42 U.S.C. §262 and a device or a drug as defined in section 201 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §321.

(g) "Regulated record" means information or documentation from a prescription written by a prescriber doing business in this state or a prescription dispensed in this state.

## **2b. Privacy Provisions.**

(a) No person shall knowingly disclose or use regulated records in this state that include prescription information containing individual identifying information for marketing a prescribed product.

(b) A regulated record containing individual identifying information may be transferred to another entity, including to another branch or subsidiary of the same firm, only if it carries satisfactory assurance that the recipient will safeguard the records from being disclosed or used in the state for a marketing purpose prohibited under this section.

(c) Regulated records containing individual identifying information may be disclosed, sold, transferred, exchanged, or used for non-marketing purposes.<sup>vii</sup>

(d) This section does not prohibit conduct involving the collection, use, transfer, or sale of regulated records for marketing purposes if:

- (1) the data is aggregated,
- (2) the data does not contain individually identifying information, and
- (3) there is no reasonable basis to believe that the data can be used to obtain individually identifying information.

(e) This section shall not prevent any person from disclosing regulated records to the identified individual as long as the information does not include protected information pertaining to any other person.

**2c. Rulemaking.**

The [agency] may adopt rules as necessary to implement this chapter.

**2d. Enforcement.<sup>viii</sup>**

Any person who knowingly fails to comply with the requirements of this chapter or rules adopted pursuant to this chapter by using or disclosing regulated records in a manner not authorized by this chapter or its rules shall be subject to an administrative penalty of at least \$10,000 per violation and not more than \$50,000 per violation, as assessed by the [agency]. Each disclosure of a regulated record shall constitute a violation. The office of the attorney general shall take necessary action to enforce payment of penalties assessed under this section. Minimum statutory penalties shall be set at \$10,000 per violation.

**2e. Consumer Fraud.<sup>ix</sup>**

In addition to any other remedy provided by law, a violation of this chapter shall be an unfair or deceptive act in trade or commerce and an unfair method of competition and may be enforced through the state's consumer fraud act.

**Section 3. State Health Care Programs – Other than Medicaid.<sup>x</sup>**

(a) The intent of this section is to ensure the confidentiality of data held by a state agency or its agent, which could be used to directly or indirectly identify a patient or a health care professional licensed to prescribe drugs, biological products, or medical devices.

(b) For the purposes of this section,

(1) "Individual identifying information" shall have the same meaning as in Section 2a of this act.

(2) "Prescribed product" includes a biological product as defined in section 351 of the Public Health Service Act, 42 U.S.C. §262 and a device or a drug as defined in section 201 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §321.

(3) "State health care program" means a program for which the state purchases prescribed products, including, but not limited to, a state pharmaceutical assistance program, or a program for state employees and their dependants, individuals under the supervision of corrections, or state retirees and their dependants with the exception of the state medical assistance program (Medicaid).

(c) Records held by an agency administering a state health care program that include prescription information containing individual identifying information shall only be disclosed for the purposes allowed in Section 2b of this act.<sup>xi</sup>

(d) Any person who knowingly fails to comply with the requirements of this chapter

or rules adopted pursuant to this chapter by using or disclosing regulated records in a manner not authorized by this chapter or its rules shall be subject to an administrative penalty of not more than \$50,000 per violation, as assessed by the [agency]. Each disclosure of a regulated record shall constitute a violation. The office of the attorney general shall take necessary action to enforce payment of penalties assessed under this section.

**Section 4. Medicaid.** <sup>xii</sup>

(a) The intent of this section is to ensure compliance with federal Medicaid law and regulations prohibiting the disclosure and use of Medicaid data except to administer the Medicaid program, and to ensure that data held by the state agency or its agents that could directly or indirectly identify patients or health care professionals licensed to prescribe products be kept confidential.

(b) [An agency] administering a state medical assistance program (Medicaid) under 42 CFR Chapter IV, Subchapter C (Medicaid) or a Medicaid waiver approved by the Centers for Medicare and Medicaid Services shall disclose records that include prescription information only as provided for under 42 CFR Section 431 and the Privacy Act of 1974. The [agency] shall ensure that any agent or contractors with the [agency] are informed of the limitations on redisclosure or use of the data provided for under applicable federal regulations and shall have policies and procedures for insuring compliance with this statute and federal regulations.

(c) Any person who knowingly fails to comply with the requirements of this chapter or rules adopted pursuant to this chapter by using or disclosing regulated records in a manner not authorized by this chapter or its rules shall be subject to an administrative penalty of not more than \$50,000 per violation, as assessed by the [agency]. Each disclosure of a regulated record shall constitute a violation. The office of the attorney general shall take necessary action to enforce payment of penalties assessed under this section. <sup>xiii</sup>

**Section 5. Severability.** <sup>xiv</sup>

If any provision of this act or its application to any person or circumstance is held invalid, the remainder of the act or the application of the provision to other persons or circumstances is not affected.

**Section 6. No Extra-Territorial Effect.**

Nothing in this bill shall be interpreted to regulate conduct that takes place entirely outside of the state.

**Section 7. No Effect on Truthful Speech to Doctors or Patients.**

Nothing in this bill shall be interpreted to regulate the content, time, place or manner of any discussion between a prescriber and their patient, or a prescriber and any person representing a prescription drug manufacturer.

**APPENDIX A. FINDINGS***Why should the legislature make findings?*

In November 2008, the First Circuit Court of Appeals upheld the first-in-the-nation New Hampshire law banning the transfer of prescriber or patient identified medical records for marketing purposes as fully compliant with the First Amendment. Two judges on the panel held that banning the transfer of records for marketing purposes was a regulation of conduct. All three judges held that even if the law was subject to First Amendment “commercial speech” scrutiny, the law is adequately justified by the state’s interest in lowering medicine costs in the state.

The First Circuit, and other courts that have considered similar laws, look very closely at the legislative record indicating the purpose and intended effect of these laws. New Hampshire’s law was upheld in large part because of the strength of its legislative record supporting the bill. Other states acting in this area should ensure that there is sufficient evidence in their legislative record to fully support the purposes the bill intends to serve, including to hold down medicine costs, to promote the best evidence-based prescribing for patient health and to serve privacy interests of patients and doctors.

This appendix explains the intended purpose and scope of the bill, which the legislature may make clear through specific findings, legislative reports, or bill language. To further bolster the defense of the legislation, hearings should be held to create a legislative record on how prescription data is used by those selling prescribed products to give their marketers influence over prescribing practices in ways that subvert state interests in providing the best quality health care at reasonable costs.

*Suggested Findings*

Specifically, the legislature may seek to explore, and potentially make findings on:

1. The increased influence of marketers using prescription data to target messages, gifts and influence;
2. The links between access and use of prescription data and heightened trends in prescribing that is not based on the best available evidence and more rapid prescribing of new drugs and decreased use of older or generic medications that are more effective according to the best available evidence.
3. The use of prescribing data to exert influence by building relationships with prescribers and reinforcing observed prescribing behavior by granting or withholding gifts, consultancies, and finely calibrated messages of appreciation or disapproval.
4. The threats of prescription tracing to the confidentiality of patient information, including its potential use to re-identify patients in specific populations and the fact that, even with patient identities removed, companies can track specific patients with individual identification numbers and use prescriber identities for direct marketing aimed at convincing a prescriber to change a particular patient's treatment.
5. The use of prescription tracking to alter the relationship between patients and health care professionals by placing the pharmaceutical company in the

position of monitoring health care practices and tailoring “educational” interventions in the best interests of the company’s shareholders instead of that of the patient.

6. The interests of health care providers in maintaining standards and patient trust in the medical profession, as evidenced by numerous national statements and editorials of health care providers and organizations that do not financially benefit from the practice of data mining.
7. The conflict of interest of the American Medical Association (AMA) which receives over \$40 million a year from selling physician profiles to data mining companies.
8. The inadequacies of the AMA's physician data restriction program, e.g. because (i) many physicians do not know about the program; (ii) many physicians do not receive the notification for renewing or canceling their participation in the program; (iii) the program only restricts data access to the street level sales representatives; the information can still be sold to data mining companies and pharmaceutical marketers and used for marketing purposes by others, including the supervisors of sales representatives; (iv) the AMA could choose to end the program at any time; (v) the AMA dissuades physicians from using the program with messages warning doctors that its use may lead to halting of free samples and other perks from pharmaceutical marketers, (vi) the program only applies to prescribing information identifying physicians; other health care professionals who prescribe medicines and are the subject of targeted marketing cannot use the program, (vii) there is no enforcement of the program and no independent body to ensure compliance, and (viii) the program requires doctors to renew their participation every three years.
9. The links between access to prescriber identified prescription data and increased incidence of harassing and vexatious sales practices in this state and around the country, as evidenced by the numerous statements of doctors and medical associations.
10. The undue influence of pharmaceutical marketing, on which companies spend between \$30 billion and \$54 billion annually, over 80 percent of which is directed at prescribers.
11. The conflicts between marketing agendas, which are directed at shifting consumption to higher priced products, and the goals of evidence-based care policies.
12. Targeted marketing campaigns using prescriber data are only cost-effective for the most expensive medications. This skews the information market so that only the most expensive drugs are promoted to doctors with these sophisticated marketing techniques. Without an incentive for equal speech on the part of generic manufacturers, the current system shifts prescribing trends towards the most expensive medicines.
13. The extensive research and commentary in both scientific journals and national news media that supports the legitimate interests of states in regulating the uses of prescription data for marketing.

*Sources for Suggested Findings:*

- Jerry Avorn and Michael Fisher, *Economic Implications of Evidence-Based Prescribing for Hypertension: Can Better Care Cost Less?* 291 *Journal of the American Medical Association* 1850 (April 21, 2004)
- David Blumenthal, *Doctors and Drug Companies*, 351 *New England Journal of Medicine* 1885 (October 28, 2004)
- Sean Flynn, *The Constitutionality of State Regulation of Prescription Data Mining*, *Pharmaceutical Law and Indust. Report*, Vol. 5, No. 43 (Nov. 2, 2007).
- David Grande, *Prescriber Profiling: Time to Call It Quits*, 146 *Annals of Internal Medicine* 741 (May 15, 2007)
- Jeremy Greene, *Pharmaceutical Marketing Research and the Prescribing Physician*, 146 *Annals of Internal Medicine* 742 (
- Gardiner Harris, Benedict Carey, & Janet Roberts, *Psychiatrists, Children, and the Drug Industry's Role*, *NY Times*, May 10, 2007, at A1
- Gardiner Harris & Robert Pear, *Drug Maker's Efforts to Compete in Lucrative Insulin Market are Under Scrutiny*, *N.Y. Times*, January 28, 2006, at A14
- Paul Kallukaran & Jerry Kagan, *Data Mining at IMS HEALTH: How We Turned a Mountain of Data into a Few Information-rich Mole Hills*, *IMS Health* (1998)
- Dana Katz, et al., *All Gifts Large and Small: Towards an Understanding of the Ethics of Pharmaceutical Industry Gift-Giving*, 3 *American Journal of Bioethics* 39 (Summer 2003)
- Liz Kowalczyk, *Drug Companies' Secret Reports*, *Boston Globe*, May 25, 2003, at A1
- Christopher Lee, *Drugmakers, Doctors Get Cozier*, *Wash. Post*, Apr. 29, 2007, at A03
- Merck, *Basic Training: Participant Guide* (2002)<sup>xv</sup>
- Susan Neyhart, *Using Data Mining to Get Brand Switching*, *Medical Marketing & Media* (1998)
- James P. Orlowski & Leon Wateska, *The Effects of Pharmaceutical Firm Enticements on Physician Prescribing Practices: There is No Such Thing As a Free Lunch*, *Chest* 102:270-273 (1992)
- Stephanie Saul, *Drug Makers Pay for Lunch as They Pitch*, *N.Y. Times*, July 28, 2006, at A1
- Stephanie Saul, *Doctors Object as Drug Makers Learn Who's Prescribing What* (alternate title, *Doctors Object to Gathering of Drug Data*), *N.Y. Times*, May 4, 2006, at A1
- Sheryl Gay Stolberg & Jeff Gerth, *High Tech Stealth Being Used to Sway Doctor Prescriptions*, *N.Y. Times*, Nov. 16, 2000, at A1
- Jake Whitney, *How Drug Reps Know Which Doctor to Target. Big (Brother) Pharma*, *New Republic Online*, ¶7 (2006)
- Ashley Wazana, *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?* 283 *JAMA* 373 (January 19, 2001)

**APPENDIX B. NON-MARKETING PURPOSES.**

This bill is not intended to regulate the non-marketing uses of prescription data. The purposes of the act make this clear, and list some examples of specific non-marketing purposes that remain unregulated by the Act. The definition of “marketing” in the bill is sufficient to protect the many legitimate uses of prescription data that are unrelated to targeting commercial marketing. The legislature may wish to include more detailed legislative history, findings, or exceptions in the law detailing the many possible non-marketing purposes that are unregulated by the bill.

The following list contains model exceptions that may be inserted to Section 2b. at the end of subsection (b):

These non-marketing purposes include, but are not limited to:

- (1) Activities related to filling a valid prescription, including, but not limited to the dispensing of a prescribed product to a patient or to the patient’s authorized representative; the transmission of prescription information between an authorized prescriber and a pharmacy; the transfer of prescription information between pharmacies; the transfer of prescription records that may occur if pharmacy ownership is changed or transferred and pharmacy reimbursement;
- (2) law enforcement purposes as otherwise authorized or required by statute or court order;
- (3) research including, but not limited to, bona fide clinical trials, post-marketing surveillance research, product safety studies, population-based public health research, and research regarding the effects of health care practitioner prescribing practices, and statistical reports if personal information is not published, re-disclosed, or used to identify or contact individuals;
- (4) product safety evaluations, product recalls and specific risk management plans, as identified or requested by the federal food and drug administration, or its successor agency;
- (5) pharmacy reimbursement, formulary compliance, case management related to the diagnosis, treatment, or management of illness for a specific patient, including, but limited to, care management educational communications provided to a patient about the patient’s health condition, adherence to a prescribed course of therapy, or other information about the product being dispensed, treatment options, or clinical trials;
- (6) utilization review by the state, by a healthcare provider, or by the patient’s insurance provider for health care services, including, but not limited to, determining compliance with the terms of coverage or medical necessity;
- (7) the collection and analysis of product utilization data for health care quality improvement purposes, including, but not limited to, development of evidence-based treatment guidelines or health care performance effectiveness and efficiency measures, promoting compliance with evidence-based treatment guidelines or health care performance measures, and providing prescribers with information that details their practices relative to their peers to encourage prescribing consistent with evidence-based practice;
- (8) the collection and dissemination of product utilization data to promote transparency in evaluating performance related to the health care quality improvement measures;

(9) the transfer of product utilization data to and through secure electronic health record or personal health record systems;

(10) use by any government agency or government agency sponsored program in carrying out its functions, or by any private person acting on behalf of a Federal, State or local agency in carrying out its functions; and

(11) use in connection with any civil, criminal, administrative, or arbitral proceeding in any Federal, State, or local court or agency or before any self-regulatory body, including, but not limited to, the service of process, investigation in anticipation of litigation, and the execution or enforcement of judgments and orders, or pursuant to an order of a Federal, State, or local court.

The model legislation was prepared for the Prescription Project by Sharon Treat, Esq., Executive Director, National Legislative Association on Prescription Drug Prices and Robin Lunge, Esq., Policy Director, National Legislative Association on Prescription Drug Prices; with assistance from Sean Flynn, Esq., Associate Director, Program on Information Justice and Intellectual Property, American University, Washington College of Law;

## ENDNOTES

<sup>i</sup> The approach taken in this act is modeled after the New Hampshire law which prohibits any marketing uses of these records (N.H. REV. STAT. ANN. § 318:47 f (2006)); (IMS Health Inc. v. Ayotte, No. 07-1945 (1st Cir. Appeal docketed June 20, 2007)); (IMS Health Inc. v. Ayotte, 490 F. Supp. 2d 163 (D.N.H. 2007)). The Maine and Vermont laws take a different and less comprehensive approach. Like New Hampshire, Vermont prohibits sharing individual identifying prescriber information for marketing uses, but the law allows health care professionals to choose to waive these protections (to “opt out”) through an administrative process linked to licensure (VT. STAT. ANN tit. 18 § 4631 (2007)); (IMS Health Inc. v. Sorrell, No. 2:07-cv-188 (D. Vt. filed Aug. 29, 2007)). In Maine, such individual prescriber records may be used for marketing unless a health care professional chooses to invoke the protections (to “opt in”), also through an administrative process linked to licensure (ME. REV. STAT. ANN. tit. 22 § 1711-E (2007)); (IMS Health Inc. v. Rowe, 1:07-cv-00127 (D. Me. filed Aug. 29, 2007)). The New Hampshire approach is more likely to result in a comprehensive, statewide policy that is enforceable and clearly carries out the State’s multiple purposes in establishing the policy. For more information about using an opt-in or opt-out approach, please contact the National Legislative Association on Prescription Drug Prices, Sharon Treat at nlarx@gwi.net or Robin Lunge at rlunge@gmail.com.

<sup>ii</sup> States with evidence-based initiatives, such as an evidence-based preferred drug list in Medicaid or an evidence-based prescriber education program, may also want to add that it is the intent of the legislature to carry out the goals of the evidence-based program.

<sup>iii</sup> Additional examples of uses that are not regulated by this act are: bona fide educational activities, law enforcement, filling prescriptions or providing health care to a patient, safety research or notifications (including targeting information on recalls or labeling changes), pharmacy reimbursement, formulary compliance reviews or any other activity which is not related to the commercial marketing of prescribed products. See also footnote 7 and Appendix B for suggested exceptions.

<sup>iv</sup> It may be appropriate to make specific findings in the legislation, although many state legislatures do not do so as a matter of bill drafting policy. The failure to include findings was cited in the District Court’s decision, currently on appeal, in IMS v. Ayotte overturning the New Hampshire data mining restriction law as evidence that the legislature had not sufficiently considered the issues before acting. While that decision is not binding on any other state, a findings section may bolster the defense of the legislation in any court challenge. Findings

should be based on information available to the legislature, including information presented at public hearings, as well as related state policy and laws. Findings based on academic literature and other sources are included in Appendix A, but should be modified to reflect the information actually considered by the legislature.

<sup>v</sup> The model act does not include a definition of “prescriber” because which health care professionals are licensed to prescribe products is governed by state law. The intent is to cover all health care professionals who are licensed to prescribe products in the state.

<sup>vi</sup> A cross-reference to the state’s licensure statute applicable to pharmacies should be inserted in this definition.

<sup>vii</sup> This bill is not intended to regulate the non-marketing uses of prescription data. The purposes of the act make this clear, and list some examples of specific non-marketing purposes that remain unregulated by the Act. The definition of “marketing” is sufficient to protect the many legitimate uses of prescription data that are unrelated to targeting commercial marketing, however, if specific exceptions should be included model exceptions are include in Appendix B.

<sup>viii</sup> Other potential remedies include injunctive relief suspending the further use or disclosure of the regulated records obtained in violation of this act.

<sup>ix</sup> This section could be an amendment of the state’s existing consumer fraud or unfair trade practices act instead of a section in a new chapter. If the section is included in the chapter, a cross-reference to the state’s consumer fraud or unfair trade practices act should be added.

<sup>x</sup> This section could be an amendment to existing laws governing state health care programs. In the alternative, a state could limit the disclosure of information from the state health care program by inserting a similar restriction in any contract between the state health care program and a pharmacy benefits manager.

<sup>xi</sup> It may be more appropriate to provide enforcement through the attorney general’s office if the agency administering the state health care program does not have an existing enforcement unit. Other potential remedies could include injunctive relief suspending the further use or disclosure of the regulated records obtained in violation of this act or enforcement through the state’s existing consumer fraud or unfair trade practices act.

<sup>xii</sup> This section provides a model for complying with federal Medicaid law. Under existing regulations at 42 CFR part 431, state agencies are required to have a state statute providing for enforcement of the limitations on the use and disclosure of Medicaid information required by federal law. See 42 CFR section 432.301. State agencies administering the Medicaid program have stricter confidentiality standards than required by the privacy protections contained in Section 2 of this Model Act . Agencies may disclose Medicaid information to third parties for use in administering the program, however, the third parties may only use the information for that purpose. The Centers on Medicare and Medicaid Services (CMS) may disclose information for additional uses, such as research or law enforcement purposes. This section of the Act addresses the responsibilities of state entities.

<sup>xiii</sup> It may be more appropriate to provide enforcement through the attorney general’s office if the Medicaid agency does not have an existing enforcement mechanism. Other potential remedies could include injunctive relief suspending the further use or disclosure of the regulated records obtained in violation of this act or enforcement through the state’s existing consumer fraud or unfair trade practices act.

<sup>xiv</sup> Some states have freestanding law that governs severability which is automatically applied to all legislation. In those states, bill drafts will not include a severability clause, but the same standard would nonetheless be applied in the event of a legal challenge.

<sup>xv</sup> Available at: <http://dida.library.ucsf.edu/pdf/xib00a10>