

SENATE No. 17

The Commonwealth of Massachusetts

In the Year Two Thousand Nine

An Act Relative to Data Mining.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

1 SECTION 1. Chapter 118G is hereby amended by inserting after section 33 the following
2 section:—

3 Section 34. It is the intent of the legislature to safeguard the confidentiality of
4 prescribing information, protect the integrity of the doctor-patient relationship, maintain the
5 integrity and public trust in the medical profession, combat vexatious and harassing sales
6 practices, restrain undue influence exerted by pharmaceutical industry marketing representatives
7 over prescribing decisions and further the state interest in improving the quality and lowering the
8 cost of health care. The legislature intends to regulate the monitoring of prescribing practices
9 only for commercial marketing purposes by companies selling prescribed products. The intent is
10 not to regulate monitoring for other uses, such as quality control, research unrelated to
11 marketing, or use by governments or other entities not in the business of selling health care
12 products.

13 (a) As used in this section the following words shall, unless the context clearly requires
14 otherwise, have the following meanings:—

“Bona-fide clinical trial”, 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 health outcome, has received approval from an appropriate Institutional Review Board, and has been registered at ClinicalTrials.gov prior to commencement.

“Identifying information”, information that can be used to directly or indirectly identify the patient or the prescriber, including, but not limited to, a person’s name, address, telephone number, facsimile number, electronic mail address, photograph or likeness, account, credit card, medical record, social security number, Drug Enforcement Agency (DEA) number, National Provider Identifier (NPI) or any other unique number, characteristic, code or information which is likely to lead to the identification of the patient or prescriber.

“Marketing purpose”, 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.

“Person”, any business, individual, corporation, union, association, firm, partnership, committee, or other organization or group of persons.

“Pharmacy”, a facility under the direction or supervision of a registered pharmacist which is authorized to dispense controlled substances, including but not limited to retail drug business as defined in Section 1 of Chapter 94C.

“Prescriber”, a person who is licensed, registered or otherwise authorized to prescribe and administer drugs in the course of professional practice.

“Prescribed product”, includes a biological product as defined in section 251 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.

“Regulated transaction”, a prescription for a drug that is written by a prescriber within the commonwealth or that is dispensed within the commonwealth. The commonwealth does not regulate activities that take place wholly outside of the commonwealth.

(b) No person shall license, use, sell, or transfer for any marketing purpose, prescribed product information related to a regulated transaction that has identifying

information. A record of a regulated transaction 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 commonwealth for marketing purposes

(c) Nothing in this section shall prohibit the collection use, transfer, or sale of prescribed product information for marketing purposes if:-- (i) the data is aggregated; (ii) the data does not contain identifying information; and (iii) the data cannot be used, directly or indirectly, to obtain identifying information.

(d) Nothing in this section shall prohibit the collection, use, transfer, or sale of prescribed product information for non-marketing purposes, including, but not limited to, pharmacy reimbursement, prescription drug formulary or prior authorization compliance, patient care, patient care management, utilization review, health care research, bona fide clinical trials, product safety studies, transfer of prescription records that may occur when a pharmacy's ownership is changed or transferred, transfer of information to the patient or patient's authorized representative, and as required by law.

(e) Nothing in this section shall be interpreted to regulate conduct that takes place wholly outside of the commonwealth.

(f) Nothing in this section 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.

(g) Whoever violates any provision of this section shall be punished by imprisonment for not more than two and one half years in a house of correction, or by a fine of not less than twenty thousand dollars, or by both such fine and imprisonment. Whoever violates any provision of this section after one or more prior convictions of a violation of this section shall be punished by imprisonment in the state prison for not more than 10 years, or by a fine of not more than thirty thousand dollars or by both such fine and imprisonment.

(h) A violation of this section shall also constitute an unfair or deceptive act or practice in the conduct of trade in violation of Section 2 of Chapter 93A. Any person whose rights under this section have been violated may institute and prosecute in his own name and on his own behalf, or the attorney general, acting on behalf of the commonwealth, may institute a civil action for injunctive and other equitable relief.

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 2. This act shall take effect upon passage.