A bill for an act

relating to health; prohibiting the use of certain prescription information for marketing purposes; imposing administrative penalties; amending Minnesota Statutes 2008, section 151.50; proposing coding for new law in Minnesota Statutes, chapter 151.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. Minnesota Statutes 2008, section 151.50, is amended to read:

151.50 RULES.

The board shall adopt rules to carry out the purposes and enforce the provisions of ~~sections 151.42 to 151.51~~ this chapter. All rules adopted under this section shall conform to wholesale drug distributor licensing guidelines formally adopted by the United States Food and Drug Administration; and in case of conflict between a rule adopted by the board and a Food and Drug Administration wholesale drug distributor guideline, the latter shall control.

Sec. 2. **[151.60] PRESCRIPTION RECORD PRIVACY.**

Subdivision 1. **Intent; purpose.** 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 purpose of this legislation is 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.

Subd. 2. **Definitions.** For the purposes of this section, the terms defined in this subdivision have the meanings given.

(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, which directly or indirectly identifies a practitioner 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 an entity making or selling prescribed products or the entity's agent that is intended to influence prescribing or purchasing choices of the entity's 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; or

(6) advertising or promoting prescribed products directly to patients.

(d) "Nonmarketing purposes" include, but are not limited to:

(1) educational or quality assurance programs conducted by a health plan company or a benefits management program to ensure compliance with an independently established formulary based on evidence-based prescribing guidelines and cost-containment goals;

(2) communication by a pharmacist about patient safety or generic substitution, or in response to patient questions about a medication; or

(3) safety warnings, adverse event reporting, labeling changes, or Risk Evaluation and Management Strategy (REMS) compliance communications.

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

(f) "Pharmacy" means any individual or entity licensed or authorized under this chapter to dispense prescribed products.

(g) "Prescribed product" means a biological product as defined in section 351 of the Public Health Service Act, United States Code, title 42, section 262, or a drug as defined in section 201 of the federal Food, Drug, and Cosmetic Act, United States Code, title 21, section 321.

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

Subd. 3. **Privacy provisions.** (a) No person shall knowingly disclose or use regulated records in this state that include prescription information containing individual identifying information for the purpose of 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 entity, if there is satisfactory assurance in writing that the recipient of the record will safeguard the record from being disclosed or used in the state for any marketing purpose that is prohibited under this section.

(c) Regulated records containing individual identifying information may be disclosed, sold, transferred, exchanged, or used for nonmarketing purposes.

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

(1) the data are aggregated;

(2) the data do 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.

Subd. 4. **Enforcement.** (a) Any person who knowingly fails to comply with the requirements of this section by using or disclosing regulated records in a manner not authorized under this section 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 Board of Pharmacy. Each disclosure of a regulated record shall constitute a violation.

(b) The Office of the Attorney General shall take necessary action to enforce payment of penalties assessed under this subdivision.

Subd. 5. **Consumer fraud.** In addition to any other remedy provided by law, a violation of this section shall be an unfair or deceptive act in trade or commerce and an unfair method of competition and may be enforced under chapter 325F.

Subd. 6. **No extraterritorial effect.** Nothing in this section shall be interpreted to regulate conduct that takes place entirely outside of the state.

Subd. 7. **No effect on truthful speech of doctors or patients.** Nothing in this section shall be interpreted to regulate the content, time, place, or manner of any discussion between a practitioner and their patient, or a practitioner and any person representing a prescription drug manufacturer.

Subd. 8. **Statement of compliance.** Each pharmaceutical manufacturer, wholesale drug distributor, or pharmacy licensed under this chapter shall submit to the board with their annual registration or license renewal a statement on a form prescribed by the board indicating that they have complied with and will continue to comply with this section. The statement must be signed by owner, president, or chief executive owner of the manufacturer, distributor, or pharmacy.

Subd. 9. **Severability.** If any provision of this section or its application to any person or circumstance is held invalid, the remainder of the section or the application of the provisions to other persons or circumstances is not affected.