State of Minnesota

HOUSE OF REPRESENTATIVES

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HOUSE FILE NO. 1041

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The bill was read for the first time and referred to the Committee on Health and Human Services

A bill for an act

relating to health; establishing a controlled substances prescription electronic reporting system; proposing coding for new law in Minnesota Statutes, chapter 152.

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

Section 1. **[152.126] SCHEDULE II CONTROLLED SUBSTANCES PRESCRIPTION ELECTRONIC REPORTING SYSTEM.**

Subdivision 1. **Definitions.** For purposes of this section, the terms defined in this subdivision have the meanings given.

(a) "Board" means the Minnesota State Board of Pharmacy established under chapter 151.

(b) "Controlled substances" means those substances listed in section 152.02, subdivision 3, and those substances defined by the board pursuant to section 152.02, subdivisions 7, 8, and 12.

(c) "Dispense" or "dispensing" has the meaning given in section 151.01, subdivision 30. Dispensing does not include the direct administering of a controlled substance to a patient by a licensed health care professional.

(d) "Dispenser" means a person authorized by law to dispense, pursuant to a valid prescription, a controlled substance. A dispenser does not include a licensed hospital pharmacy that distributes controlled substances for inpatient hospital care.

(e) "Prescriber" means a licensed health care professional who is authorized to prescribe a controlled substance under section 152.12, subdivision 1.

(f) "Prescription" has the meaning given in section 151.01, subdivision 16.

Subd. 2. **Prescription electronic reporting system.** (a) The board shall establish by January 1, 2009, an electronic system for reporting the information required under subdivision 4 for all controlled substances dispensed within the state. Data for controlled substance prescriptions that are dispensed in a quantity small enough to provide treatment to a patient for a period of 48 hours or less need not be reported.

(b) The board may contract with a vendor for the purpose of obtaining technical assistance in the design, implementation, and maintenance of the electronic reporting system. The vendor's role shall be limited to providing technical support to the board concerning the software, databases, and computer systems required to interface with the existing systems currently used by pharmacies to dispense prescriptions and transmit prescription data to other third parties.

Subd. 3. **Prescription Electronic Reporting Advisory Committee.** (a) The board may convene an advisory committee. If the board convenes a committee, the committee must include at least one representative of:

(1) the Department of Health;

(2) the Department of Human Services;

(3) each health-related licensing board that licenses prescribers;

(4) a professional medical association, which may include an association of pain management and chemical dependency specialists;

(5) a professional pharmacy association;

(6) a consumer privacy or security advocate; and

(7) a consumer or patient rights organization.

(b) The advisory committee shall advise the board on the development and operation of the electronic reporting system, including, but not limited to:

(1) technical standards for electronic prescription drug reporting;

(2) proper analysis and interpretation of prescription monitoring data; and

(3) an evaluation process for the program.

Subd. 4. **Reporting requirements.** (a) Each dispenser must submit the following data to the board or its designated vendor:

(1) name of the prescriber;

(2) national provider identifier of the prescriber;

(3) name of the dispenser;

(4) national provider identifier of the dispenser;

(5) name of the patient for whom the prescription was written;

(6) date of birth of the patient for whom the prescription was written;

(7) date the prescription was written;

(8) date the prescription was filled;

(9) name and strength of the controlled substance;

(10) quantity of controlled substance prescribed; and

(11) quantity of controlled substance dispensed.

(b) The dispenser must submit the required information by a procedure and in a format established by the board.

(c) A dispenser is not required to submit this data for those controlled substance prescriptions dispensed for individuals residing in licensed skilled nursing or intermediate care facilities.

Subd. 5. **Use of data by board.** (a) The board shall develop and maintain a database of the data reported under subdivision 4. The database may be used by permissible users identified under subdivision 6 for the identification of:

(1) individuals receiving prescriptions for controlled substances from prescribers who subsequently obtain controlled substances from dispensers in quantities or with a frequency inconsistent with generally recognized standards of dosage for those controlled substances; and

(2) individuals presenting forged or otherwise false or altered prescriptions for controlled substances to dispensers.

(b) No permissible user identified under subdivision 6 may access the database for the sole purpose of identifying prescribers of controlled substances for unusual or excessive prescribing patterns without a valid search warrant or court order.

Subd. 6. **Access to reporting system data.** (a) Except as indicated in this subdivision, the data submitted to the board under subdivision 4 is private data on individuals as defined in section 13.02, subdivision 12.

(b) The following persons shall be considered permissible users and may access the data submitted under subdivision 4 in the same or similar manner, and for the same or similar purposes, as those persons who are authorized to access similar private data on individuals under federal and state law:

(1) a prescriber, to the extent the information relates specifically to a current patient of the prescriber, to whom the practitioner is prescribing or considering prescribing any controlled substance;

(2) a dispenser to the extent the information relates specifically to a current patient to whom that dispenser is dispensing or considering dispensing any controlled substance;

(3) an individual who is the recipient of a controlled substance prescription for which data was submitted under subdivision 4;

(4) personnel of the board specifically assigned to conduct a bona fide investigation of a specific licensee;

(5) personnel of the board engaged in the collection of controlled substance prescription information as part of the assigned duties and responsibilities under this section;

(6) authorized personnel of a vendor under contract with the board who are engaged in the design, implementation, and maintenance of the electronic reporting system as part of the assigned duties and responsibilities of their employment, provided that access to data is limited to the minimum amount necessary to test and maintain the system databases;

(7) a designated representative of a health-related licensing board responsible for the licensure, regulation, or discipline of prescribers or dispensers, provided that the requested data relates to a bona fide investigation of a specific licensee;

(8) federal, state, and local law enforcement authorities engaged in a bona fide investigation of a specific person; and

(9) personnel of the medical assistance program assigned to use the data collected under this section to identify recipients whose usage of controlled substances may warrant restriction to a single primary care physician, a single outpatient pharmacy, or a single hospital.

(c) Any permissible user identified in paragraph (b), who directly accesses the data electronically, shall implement and maintain a comprehensive information security program that contains administrative, technical, and physical safeguards that are appropriate to the user's size and complexity, and the sensitivity of the personal information obtained. The permissible user shall identify reasonably foreseeable internal and external risks to the security, confidentiality, and integrity of personal information that could result in the unauthorized disclosure, misuse, or other compromise of the information and assess the sufficiency of any safeguards in place to control the risks.

(d) The board shall not release data submitted under this section unless it is provided with evidence, satisfactory to the board, that the person requesting the information is entitled to receive the data. Access to the data by law enforcement authorities must be accompanied by a valid search warrant.

(e) The board shall not release the name of a prescriber without the written consent of the prescriber or a valid search warrant or court order. The board shall provide a mechanism for a prescriber to submit to the board a signed consent authorizing the release of the prescriber's name when data containing the prescriber's name is requested.

(f) The board shall maintain a log of all persons who access the data and shall ensure that any permissible user complies with paragraph (c) prior to attaining direct access to the data.

Subd. 7. **Disciplinary action.** (a) A dispenser who knowingly fails to submit data to the board as required under this section is subject to disciplinary action by the appropriate health-related licensing board.

(b) A prescriber or dispenser authorized to access the data who knowingly discloses the data in violation of state or federal laws relating to the privacy of healthcare data shall be subject to disciplinary action by the appropriate health-related licensing board.

Subd. 8. **Evaluation and reporting.** (a) The board shall evaluate the prescription electronic reporting system to determine if the system is cost-effective and whether it is negatively impacting appropriate prescribing practices of controlled substances. The board may contract with a vendor to design and conduct the evaluation.

(b) The board shall submit the evaluation of the system to the legislature by January 15, 2010.

Sec. 2. **FEDERAL GRANTS.**

The Board of Pharmacy shall apply for any applicable federal grants or other nonstate funds to establish and fully implement the prescription electronic reporting system.

Sec. 3. **BOARD OF PHARMACY.**

The Board of Pharmacy shall not increase the license fees of pharmacists or pharmacies in order to adequately fund the prescription electronic reporting system under Minnesota Statutes, section 152.126, without specific authority from the legislature.

Sec. 4. **EFFECTIVE DATE.**

(a) Section 1 is effective July 1, 2007, or upon receiving sufficient nonstate funds to implement the prescription electronic funding program, whichever is later. In the event that nonstate funds are not secured by the Board of Pharmacy to adequately fund the implementation of the prescription electronic reporting program, the board is not required to implement section 1 without a subsequent appropriation from the legislature.

(b) Sections 2 and 3 are effective the day following final enactment.