State of Minnesota

HOUSE OF REPRESENTATIVES

EIGHTY-EIGHTH SESSION

H. F. No. 2527

02/27/2014 Authored by Liebling
The bill was read for the first time and referred to the Committee on Health and Human Services Policy
03/10/2014 Adoption of Report: Amended and re-referred to the Committee on Civil Law

A bill for an act

relating to health; making changes to the Minnesota prescription monitoring program; requiring a report; amending Minnesota Statutes 2012, section 152.126, as amended.

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

Section 1. Minnesota Statutes 2012, section 152.126, as amended by Laws 2013, chapter 113, article 3, section 3, is amended to read:

152.126 ~~CONTROLLED SUBSTANCES PRESCRIPTION ELECTRONIC REPORTING SYSTEM~~ PRESCRIPTION MONITORING PROGRAM.

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

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

~~(b)~~ (c) "Controlled substances" means those substances listed in section 152.02, subdivisions 3 to ~~5~~ 6, and those substances defined by the board pursuant to section 152.02, subdivisions 7, 8, and 12. For the purposes of this section, controlled substances includes tramadol and butalbital.

~~(c)~~ (d) "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)~~ (e) "Dispenser" means a person authorized by law to dispense a controlled substance, pursuant to a valid prescription. For the purposes of this section, a dispenser does not include a licensed hospital pharmacy that distributes controlled substances for inpatient hospital care or a veterinarian who is dispensing prescriptions under section 156.18.

~~(e)~~ (f) "Prescriber" means a licensed health care professional who is authorized to prescribe a controlled substance under section 152.12, subdivision 1 or 2.

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

Subd. 1a. **Treatment of intractable pain.** This section is not intended to limit or interfere with the legitimate prescribing of controlled substances for pain. No prescriber shall be subject to disciplinary action by a health-related licensing board for prescribing a controlled substance according to the provisions of section 152.125.

Subd. 2. **Prescription electronic reporting system.** (a) The board shall establish by January 1, 2010, an electronic system for reporting the information required under subdivision 4 for all controlled substances dispensed within the state.

(b) The board may contract with a vendor for the purpose of obtaining technical assistance in the design, implementation, operation, and maintenance of the electronic reporting system.

Subd. 3. **Prescription ~~Electronic Reporting~~ Monitoring Program Advisory ~~Committee~~ Task Force.** (a) The board ~~shall convene~~ shall appoint an advisory ~~committee. The committee must include~~ task force consisting of 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 professional nursing association;

(7) a professional dental association;

(8) a consumer privacy or security advocate; and

(9) a consumer or patient rights organization.

(b) The advisory ~~committee~~ task force shall advise the board on the development and operation of the ~~electronic reporting system~~ prescription monitoring program, 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.

(c) The task force is governed by section 15.059. Notwithstanding section 15.059, subdivision 5, the task force shall not expire.

Subd. 4. **Reporting requirements; notice.** (a) Each dispenser must submit the following data to the board or its designated vendor~~, subject to the notice required under paragraph (d)~~:

(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) prescription number;

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

(7) address of the patient for whom the prescription was written;

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

(9) date the prescription was written;

(10) date the prescription was filled;

(11) name and strength of the controlled substance;

(12) quantity of controlled substance prescribed;

(13) quantity of controlled substance dispensed; and

(14) number of days supply.

(b) The dispenser must submit the required information by a procedure and in a format established by the board. The board may allow dispensers to omit data listed in this subdivision or may require the submission of data not listed in this subdivision provided the omission or submission is necessary for the purpose of complying with the electronic reporting or data transmission standards of the American Society for Automation in Pharmacy, the National Council on Prescription Drug Programs, or other relevant national standard-setting body.

(c) A dispenser is not required to submit this data for those controlled substance prescriptions dispensed for:

~~(1) individuals residing in licensed skilled nursing or intermediate care facilities;~~

~~(2) individuals receiving assisted living services under chapter 144G or through a medical assistance home and community-based waiver;~~

~~(3) individuals receiving medication intravenously;~~

~~(4) individuals receiving hospice and other palliative or end-of-life care; and~~

~~(5) individuals receiving services from a home care provider regulated under chapter 144A.~~

(1) individuals residing in a health care facility as defined in section 151.58, subdivision 2, paragraph (b), when a drug is distributed through the use of an automated drug distribution system according to section 151.58; and

(2) individuals receiving a drug sample that was packaged by a manufacturer and provided to the dispenser for dispensing as a professional sample pursuant to Code of Federal Regulations, title 21, section 203, subpart D.

(d) A dispenser must ~~not submit data under this subdivision unless~~ provide to the patient for whom the prescription was written a conspicuous notice of the reporting requirements of this section ~~is given to the patient for whom the prescription was written~~ and notice that the information may be used for program administration purposes.

Subd. 5. **Use of data by board.** (a) The board shall develop and maintain a database of the data reported under subdivision 4. The board shall maintain data that could identify an individual prescriber or dispenser in encrypted form. Except as otherwise allowed under subdivision 6, 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 use for those controlled substances, including standards accepted by national and international pain management associations; 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.

(c) No personnel of a state or federal occupational licensing board or agency may access the database for the purpose of obtaining information to be used to initiate or substantiate a disciplinary action against a prescriber.

(d) Data reported under subdivision 4 shall be ~~retained by the board in the database for a 12-month period, and shall be removed from the database no later than 12 months from the last day of the month during which the data was received.~~ made available to permissible users for a 12-month period beginning the day the data was received and ending 12 months from the last day of the month in which the data was received, except that permissible users defined in subdivision 6, paragraph (b), clauses (5) and (6), may use all data collected under this section for the purposes of administering, operating, and maintaining the prescription monitoring program and conducting trend analyses and other studies necessary to evaluate the effectiveness of the program. Data retained beyond 12 months must be de-identified.

(e) The board shall not retain data reported under subdivision 4 for a period longer than five years from the date the data was received.

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, and not subject to public disclosure.

(b) Except as specified in subdivision 5, 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 or an agent or employee of the prescriber to whom the prescriber has delegated the task of accessing the data, to the extent the information relates specifically to a current patient, to whom the prescriber is:

(i) prescribing or considering prescribing any controlled substance;

(ii) providing emergency medical treatment for which access to the data may be necessary; or

(iii) providing other medical treatment for which access to the data may be necessary and the patient has consented to access to the submitted data, and with the provision that the prescriber remains responsible for the use or misuse of data accessed by a delegated agent or employee;

(2) a dispenser or an agent or employee of the dispenser to whom the dispenser has delegated the task of accessing the data, to the extent the information relates specifically to a current patient to whom that dispenser is dispensing or considering dispensing any controlled substance and with the provision that the dispenser remains responsible for the use or misuse of data accessed by a delegated agent or employee;

(3) an individual who is the recipient of a controlled substance prescription for which data was submitted under subdivision 4, or a guardian of the individual, parent or guardian of a minor, or health care agent of the individual acting under a health care directive under chapter 145C;

(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, review, and analysis 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~~ state of Minnesota who are engaged in the design, implementation, operation, and maintenance of the ~~electronic reporting system~~ prescription monitoring program as part of the assigned

duties and responsibilities of their employment, provided that access to data is limited to the minimum amount necessary to carry out such duties and responsibilities, and subject to the requirement of de-identification and time limit on retention of data specified in subdivision 5, paragraphs (d) and (e);

(7) federal, state, and local law enforcement authorities acting pursuant to a valid search warrant;

(8) personnel of the ~~medical assistance program~~ Minnesota health care programs 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~~ provider, a single outpatient pharmacy, ~~or~~ and a single hospital; ~~and~~

(9) personnel of the Department of Human Services assigned to access the data pursuant to paragraph (h); and

(10) personnel of the health professionals services program established under section 214.31, to the extent that the information relates specifically to an individual who is currently enrolled in and being monitored by the program, and the individual consents to access to that information. The health professionals services program personnel shall not provide this data to a health-related licensing board or the Emergency Medical Services Regulatory Board, except as permitted under section 214.33, subdivision 3.

For purposes of clause ~~(3)~~ (4), access by an individual includes persons in the definition of an individual under section 13.02.

(c) ~~Any~~ A permissible user identified in paragraph (b), ~~who~~ clauses (1), (2), (5), (6), and (8) may directly ~~accesses~~ access the data electronically~~;~~. If the data is directly accessed electronically, the permissible user 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~~ subdivision 4 unless it is provided with evidence, satisfactory to the board, that the person requesting the information is entitled to receive the data.

~~(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)~~ (e) The board shall maintain a log of all persons who access the data for a period of at least three years and shall ensure that any permissible user complies with paragraph (c) prior to attaining direct access to the data.

~~(g)~~ (f) Section 13.05, subdivision 6, shall apply to any contract the board enters into pursuant to subdivision 2. A vendor shall not use data collected under this section for any purpose not specified in this section.

(g) The board may participate in an interstate prescription monitoring program data exchange system provided that permissible users in other states have access to the data only as allowed under this section, and that section 13.05, subdivision 6, applies to any contract or memorandum of understanding that the board enters into under this paragraph.

(h) With available appropriations, the commissioner of human services shall establish and implement a system through which the Department of Human Services shall routinely access the data for the purpose of determining whether any client enrolled in an opioid treatment program licensed according to chapter 245A has been prescribed or dispensed a controlled substance in addition to that administered or dispensed by the opioid treatment program. When the commissioner determines there have been multiple prescribers or multiple prescriptions of controlled substances, the commissioner shall:

(1) inform the medical director of the opioid treatment program only that the commissioner determined the existence of multiple prescribers or multiple prescriptions of controlled substances; and

(2) direct the medical director of the opioid treatment program to access the data directly, review the effect of the multiple prescribers or multiple prescriptions, and document the review.

If determined necessary, the commissioner of human services shall seek a federal waiver of, or exception to, any applicable provision of Code of Federal Regulations, title 42, part 2.34, item (c), prior to implementing this paragraph.

(i) The board may provide de-identified data submitted under subdivision 4 for public research, policy, or education purposes, that does not involve information that is likely to reveal the identity of the patient, prescriber, or dispenser who is the subject of 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 health care data shall be subject to disciplinary action by the appropriate health-related licensing board, and appropriate civil penalties.

~~Subd. 8. **Evaluation and reporting.** (a) The board shall evaluate the prescription electronic reporting system to determine if the system 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 July 15, 2011.~~

Subd. 9. **Immunity from liability; no requirement to obtain information.** (a) A pharmacist, prescriber, or other dispenser making a report to the program in good faith under this section is immune from any civil, criminal, or administrative liability, which might otherwise be incurred or imposed as a result of the report, or on the basis that the pharmacist or prescriber did or did not seek or obtain or use information from the program.

(b) Nothing in this section shall require a pharmacist, prescriber, or other dispenser to obtain information about a patient from the program, and the pharmacist, prescriber, or other dispenser, if acting in good faith, is immune from any civil, criminal, or administrative liability that might otherwise be incurred or imposed for requesting, receiving, or using information from the program.

Subd. 10. **Funding.** (a) The board may seek grants and private funds from nonprofit charitable foundations, the federal government, and other sources to fund the enhancement and ongoing operations of the prescription ~~electronic reporting system~~ monitoring program established under this section. Any funds received shall be appropriated to the board for this purpose. The board may not expend funds to enhance the program in a way that conflicts with this section without seeking approval from the legislature.

(b) Notwithstanding any other section, the administrative services unit for the health-related licensing boards shall apportion between the Board of Medical Practice, the Board of Nursing, the Board of Dentistry, the Board of Podiatric Medicine, the Board of Optometry, the Board of Veterinary Medicine, and the Board of Pharmacy an amount to be paid through fees by each respective board. The amount apportioned to each board shall equal each board's share of the annual appropriation to the Board of Pharmacy from the state government special revenue fund for operating the prescription ~~electronic reporting system~~ monitoring program under this section. Each board's apportioned share shall be based on the number of prescribers or dispensers that each board identified in this paragraph licenses as a percentage of the total number of prescribers and dispensers licensed collectively by these boards. Each respective board may adjust the fees that the boards are required to collect to compensate for the amount apportioned to each board by the administrative services unit.

Sec. 2. **STUDY REQUIRED; PRESCRIPTION MONITORING PROGRAM DATABASE.**

The Board of Pharmacy, in collaboration with the Prescription Monitoring Program Advisory Task Force, shall report to the chairs and ranking minority members of the house of representatives and senate committees and divisions with jurisdiction over health and human services policy and finance, by December 15, 2014, with:

(1) recommendations on whether or not to require the use of the prescription monitoring program database by prescribers when prescribing or considering prescribing, and pharmacists when dispensing or considering dispensing, a controlled substance as defined in Minnesota Statutes, section 152.126, subdivision 1, paragraph (c);

(2) an analysis of the impact of the prescription monitoring program on rates of chemical abuse and prescription drug abuse; and

(3) recommendations on approaches to encourage access to appropriate treatment for prescription drug abuse, through the prescription monitoring program.