State of Minnesota

HOUSE OF REPRESENTATIVES

NINETY-FIRST SESSION

H. F. No. 2346

03/11/2019 Authored by Baker
The bill was read for the first time and referred to the Committee on Commerce

A bill for an act

relating to health; modifying the prescription monitoring program; amending Minnesota Statutes 2018, section 152.126, subdivisions 1, 3, 4, 6.

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

Section 1. Minnesota Statutes 2018, section 152.126, subdivision 1, is amended to read:

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

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

(c) "Controlled substances" means those substances listed in section 152.02, subdivisions 3 to 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 butalbital and gabapentin.

(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.

(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.

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

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

Sec. 2. Minnesota Statutes 2018, section 152.126, subdivision 3, is amended to read:

Subd. 3. **Prescription Monitoring Program Advisory Task Force.** (a) The board shall appoint ~~an~~ a multidisciplinary advisory task force consisting of at least one ~~representative of~~ member from each of the following categories:

~~(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;~~

~~(9) a consumer or patient rights organization; and~~

~~(10) an association of medical examiners and coroners.~~

(1) prescribers in active practice, in good standing with their applicable licensing board, who specialize in each of the following:

(i) emergency medicine;

(ii) family practice;

(iii) pain management;

(iv) addiction medicine;

(v) obstetrics; or

(vi) dentistry;

(2) pharmacists in active practice and in good standing with the board;

(3) licensed substance abuse addiction counselors, in good standing with their applicable licensing board, who provide services for a state licensed substance abuse addiction treatment program;

(4) medical examiners or coroners, in active practice, who utilize the prescription monitoring program and are in good standing with their applicable licensing board or local appointing board;

(5) representatives of the Department of Human Services, including at least one individual with responsibility for substance abuse prevention and treatment policy;

(6) representatives of the Department of Health, including at least one individual with responsibility for injury and violence prevention policy; and

(7) law enforcement officials whose duty includes the enforcement of state controlled substances or prescription drug laws.

(b) The advisory task force shall ~~advise the board on the development and operation of the prescription monitoring program, including, but not limited to~~:

~~(1) technical standards for electronic prescription drug reporting;~~

~~(2) proper~~ (1) provide expertise in analysis and interpretation of prescription monitoring data;

~~(3) an evaluation process for the program; and~~

(2) provide recommendations for program evaluation and improvements;

(3) assist in defining content for monthly, quarterly, and annual program reports;

(4) recommend criteria for the unsolicited provision of prescription monitoring data by the board to prescribers and dispensers.

(c) The task force is governed by section 15.059. Notwithstanding any other provisions of law to the contrary, the task force shall not expire.

Sec. 3. Minnesota Statutes 2018, section 152.126, subdivision 4, is amended to read:

Subd. 4. **Reporting requirements; notice.** (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) 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) The dispenser must submit the required information no later than one business day after the prescription is dispensed. If no reportable prescriptions are dispensed on any day, a report indicating that fact must be filed with the board.

(d) The dispenser must submit accurate information to the database, and must correct errors identified during the submission process within seven calendar days.

(e) The dispenser must correct errors brought to its attention by the subject of the data within seven calendar days, unless the dispenser verifies that an error did not occur and the data was correctly submitted. The dispenser must notify the subject of the data that either the error was corrected or that no error occurred. For the purposes of this paragraph, "subject of the data" means the individual reported as being the patient, the practitioner reported as being the prescriber, the client when an animal is reported as being the patient, or an authorized agent of these individuals.

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

(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, part 203, subpart D~~.~~; and

(3) individuals whose prescriptions are being mailed, shipped, or delivered from Minnesota to another state, so long as the data is reported to the prescription monitoring program of that state.

~~(d)~~ (g) A dispenser must provide notice to the patient for whom the prescription was written ~~a conspicuous notice~~, or to the patient's authorized representative, of the reporting requirements of this section and notice that the information may be used for program administration purposes.

Sec. 4. Minnesota Statutes 2018, section 152.126, subdivision 6, is amended to read:

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;

(iii) providing care, and the prescriber has reason to believe, based on clinically valid indications, that the patient is potentially abusing a controlled substance; or

(iv) providing other medical treatment for which access to the data may be necessary for a clinically valid purpose 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) a licensed pharmacist who is providing pharmaceutical care for which access to the data may be necessary to the extent that the information relates specifically to a current patient for whom the pharmacist is providing pharmaceutical care: (i) if the patient has consented to access to the submitted data; or (ii) if the pharmacist is consulted by a prescriber who is requesting data in accordance with clause (1);

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

(5) personnel or designees of ~~a~~ other health-related licensing ~~board~~ boards listed in section 214.01, subdivision 2, or of the Emergency Medical Services Regulatory Board, assigned to conduct a bona fide investigation of a complaint received by that board that alleges that a specific licensee is impaired by use of a drug for which data is collected under subdivision 4, has engaged in activity that would constitute a crime as defined in section 152.025, or has engaged in the behavior specified in subdivision 5, paragraph (a);

(6) 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;

(7) authorized personnel of a vendor under contract with the state of Minnesota who are engaged in the design, implementation, operation, and maintenance of the 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);

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

(9) personnel of the Minnesota health care programs assigned to use the data collected under this section to identify and manage recipients whose usage of controlled substances

may warrant restriction to a single primary care provider, a single outpatient pharmacy, and a single hospital;

(10) personnel of the Department of Human Services assigned to access the data pursuant to paragraph ~~(i)~~ (j);

(11) 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 (4), access by an individual includes persons in the definition of an individual under section 13.02; and~~

(12) personnel or designees of ~~a~~ other health-related licensing ~~board~~ boards listed in section 214.01, subdivision 2, assigned to conduct a bona fide investigation of a complaint received by that board that alleges that a specific licensee is inappropriately prescribing controlled substances as defined in this section~~.~~; and

(13) personnel of the board specifically assigned to conduct a bona fide investigation of a specific licensee or registrant.

(c) The commissioner of health shall have access to de-identified data for statistical, research, or educational purposes related to public health and safety.

~~By July 1, 2017,~~ (d) Every prescriber licensed by a health-related licensing board listed in section 214.01, subdivision 2, practicing within this state who is authorized to prescribe controlled substances for humans and who holds a current registration issued by the federal Drug Enforcement Administration, and every pharmacist licensed by the board and practicing within the state, shall register and maintain a user account with the prescription monitoring program. Data submitted by a prescriber, pharmacist, or their delegate during the registration application process, other than their name, license number, and license type, is classified as private pursuant to section 13.02, subdivision 12.

~~(d)~~ (e) Only permissible users identified in paragraph (b), clauses (1), (2), (3), (6), (7), (9), and (10), may directly access the data electronically. No other permissible users may directly 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.

~~(e)~~ (f) The board shall not release data submitted under subdivision 4 unless it is provided with evidence, satisfactory to the board, that the person requesting the information is entitled to receive the data.

~~(f)~~ (g) 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)~~ (d) prior to attaining direct access to the data.

~~(g)~~ (h) 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.

~~(h)~~ (i) 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.

~~(i)~~ (j) 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, section 2.34, paragraph (c), prior to implementing this paragraph.

~~(j)~~ (k) The board shall review the data submitted under subdivision 4 on at least a quarterly basis and shall establish criteria, in consultation with the advisory task force, for referring information about a patient to prescribers and dispensers who prescribed or dispensed the prescriptions in question if the criteria are met.