Senate Language S3656-2

433.4ARTICLE 26433.5PRESCRIPTION MONITORING PROGRAM

433.6 Section 1. Minnesota Statutes 2016, section 151.065, is amended by adding a subdivision 433.7 to read:

433.8 Subd. 7. Deposit. Fees collected by the board under this section shall be deposited in 433.9 the state government special revenue fund.

433.10 Sec. 2. Minnesota Statutes 2016, section 152.126, subdivision 6, is amended to read:

433.11 Subd. 6. Access to reporting system data. (a) Except as indicated in this subdivision, 433.12 the data submitted to the board under subdivision 4 is private data on individuals as defined 433.13 in section 13.02, subdivision 12, and not subject to public disclosure.

433.14 (b) Except as specified in subdivision 5, the following persons shall be considered 433.15 permissible users and may access the data submitted under subdivision 4 in the same or 433.16 similar manner, and for the same or similar purposes, as those persons who are authorized 433.17 to access similar private data on individuals under federal and state law:

433.18 (1) a prescriber or an agent or employee of the prescriber to whom the prescriber has 433.19 delegated the task of accessing the data, to the extent the information relates specifically to 433.20 a current patient, to whom the prescriber is:

433.21 (i) prescribing or considering prescribing any controlled substance;

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

433.23 (iii) providing care, and the prescriber has reason to believe, based on clinically valid 433.24 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;

433.29 (2) a dispenser or an agent or employee of the dispenser to whom the dispenser has

433.30 delegated the task of accessing the data, to the extent the information relates specifically to

434.1 a current patient to whom that dispenser is dispensing or considering dispensing any

Senate Language S3656-2

434.2 controlled substance and with the provision that the dispenser remains responsible for the

434.3 use or misuse of data accessed by a delegated agent or employee;

434.4 (3) a licensed pharmacist who is providing pharmaceutical care for which access to the

- 434.5 data may be necessary to the extent that the information relates specifically to a current
- 434.6 patient for whom the pharmacist is providing pharmaceutical care: (i) if the patient has
- 434.7 consented to access to the submitted data; or (ii) if the pharmacist is consulted by a prescriber
- 434.8 who is requesting data in accordance with clause (1);

434.9 (4) an individual who is the recipient of a controlled substance prescription for which

434.10 data was submitted under subdivision 4, or a guardian of the individual, parent or guardian

434.11 of a minor, or health care agent of the individual acting under a health care directive under

434.12 chapter 145C. For purposes of this clause, access by individuals includes persons in the

434.13 definition of an individual under section 13.02;

434.14 (5) personnel or designees of a health-related licensing board listed in section 214.01, 434.15 subdivision 2, or of the Emergency Medical Services Regulatory Board, assigned to conduct

434.15 subdivision 2, of of the Emergency Medical Services Regulatory Board, assigned to condi-434.16 a bona fide investigation of a complaint received by that board that alleges that a specific

434.17 licensee is impaired by use of a drug for which data is collected under subdivision 4, has

- 434.18 engaged in activity that would constitute a crime as defined in section 152.025, or has
- 434.19 engaged in the behavior specified in subdivision 5, paragraph (a);

434.20 (6) personnel of the board engaged in the collection, review, and analysis of controlled 434.21 substance prescription information as part of the assigned duties and responsibilities under 434.22 this section;

434.23 (7) authorized personnel of a vendor under contract with the state of Minnesota who are

434.24 engaged in the design, implementation, operation, and maintenance of the prescription

- 434.25 monitoring program as part of the assigned duties and responsibilities of their employment,
- 434.26 provided that access to data is limited to the minimum amount necessary to carry out such
- 434.27 duties and responsibilities, and subject to the requirement of de-identification and time limit

434.28 on retention of data specified in subdivision 5, paragraphs (d) and (e);

434.29 (8) federal, state, and local law enforcement authorities acting pursuant to a valid search 434.30 warrant;

434.31 (9) personnel of the Minnesota health care programs assigned to use the data collected 434.32 under this section to identify and manage recipients whose usage of controlled substances 434.33 may warrant restriction to a single primary care provider, a single outpatient pharmacy, and 434.34 a single hospital;

Senate Language S3656-2

435.1 (10) personnel of the Department of Human Services assigned to access the data pursuant 435.2 to paragraph (i);

435.3 (11) personnel of the health professionals services program established under section

- 435.4 214.31, to the extent that the information relates specifically to an individual who is currently
- 435.5 enrolled in and being monitored by the program, and the individual consents to access to
- 435.6 that information. The health professionals services program personnel shall not provide this
- 435.7 data to a health-related licensing board or the Emergency Medical Services Regulatory
- 435.8 Board, except as permitted under section 214.33, subdivision 3-; and

435.9 For purposes of clause (4), access by an individual includes persons in the definition of 435.10 an individual under section 13.02; and

(12) personnel or designees of a health-related licensing board 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.

435.15 (c) By July 1, 2017, every prescriber licensed by a health-related licensing board listed 435.16 in section 214.01, subdivision 2, practicing within this state who is authorized to prescribe 435.17 controlled substances for humans and who holds a current registration issued by the federal

- 435.18 Drug Enforcement Administration, and every pharmacist licensed by the board and practicing
- 435.19 within the state, shall register and maintain a user account with the prescription monitoring 435.20 program. Data submitted by a prescriber, pharmacist, or their delegate during the registration
- 435.21 application process, other than their name, license number, and license type, is classified
- 435.22 as private pursuant to section 13.02, subdivision 12.

435.23 (d) Notwithstanding paragraph (b), beginning January 1, 2020, a prescriber or an agent

- 435.24 or employee of the prescriber to whom the prescriber has delegated the task of accessing
- 435.25 the data, must access the data submitted under subdivision 4 to the extent the information
- 435.26 relates specifically to the patient:
- 435.27 (1) before the prescriber issues an initial prescription order for a Schedule II through 435.28 Schedule IV opiate controlled substance to the patient; and

435.29 (2) at least once every three months for patients receiving an opiate for treatment of

435.30 chronic pain or participating in medically assisted treatment for an opioid addiction.

- 435.31 (e) Paragraph (d) does not apply if:
- 435.32 (1) the patient is receiving hospice care;

Senate Language S3656-2

435.33 (2) the patient is being treated for pain due to cancer or the treatment of cancer;	
436.1 (3) the prescription order is for a number of doses that is intended to last the patient five	
436.2 days or less and is not subject to a refill;	
436.3 (4) the prescriber and patient have an ongoing doctor/patient relationship of a duration 436.4 longer than one year;	
 436.5 (5) the prescription order is issued within 14 days following surgery or three days 436.6 following oral surgery; 	
436.7 (6) the controlled substance is prescribed or administered to a patient who is admitted	
436.8 to an inpatient hospital;	
436.9 (7) the controlled substance is lawfully administered by injection, ingestion, or any other	
436.10 means to the patient by the prescriber, a pharmacist, or by the patient at the direction of a 436.11 prescriber and in the presence of the prescriber or pharmacist;	
436.12 (8) due to a medical emergency, it is not possible for the prescriber to review the data	
436.13 before the prescriber issues the prescription order for the patient; or	
436.14 (9) the prescriber is unable to access the data due to operational or other technological	
436.15 <u>failure of the program so long as the prescriber reports the failure to the board.</u>	
436.16 (f) Only permissible users identified in paragraph (b), clauses (1), (2), (3), (6), (7), (9), (2), (12), (12), (13), (14), (
436.17 and (10), may directly access the data electronically. No other permissible users may directly 436.18 access the data electronically. If the data is directly accessed electronically, the permissible	
436.19 user shall implement and maintain a comprehensive information security program that	
436.20 contains administrative, technical, and physical safeguards that are appropriate to the user's	
436.21 size and complexity, and the sensitivity of the personal information obtained. The permissible	
436.22 user shall identify reasonably foreseeable internal and external risks to the security, 436.23 confidentiality, and integrity of personal information that could result in the unauthorized	
436.25 confidentiality, and integrity of personal information that could result in the unauthorized 436.24 disclosure, misuse, or other compromise of the information and assess the sufficiency of	
436.25 any safeguards in place to control the risks.	
10.25 any suregulates in place to control the fisks.	
436.26 (g) The board shall not release data submitted under subdivision 4 unless it is provided	
436.27 with evidence, satisfactory to the board, that the person requesting the information is entitled	
436.28 to receive the data.	

 $\begin{array}{ll} 436.29 & (f) (h) \\ 436.30 & at least three years and shall maintain a log of all persons who access the data for a period of \\ 436.31 & prior to attaining direct access to the data. \end{array}$

Senate Language S3656-2

(g) (i) Section 13.05, subdivision 6, shall apply to any contract the board enters into 437.1

- pursuant to subdivision 2. A vendor shall not use data collected under this section for any 437.2
- purpose not specified in this section. 437.3

(h) (j) The board may participate in an interstate prescription monitoring program data 437.4

- exchange system provided that permissible users in other states have access to the data only 437.5
- as allowed under this section, and that section 13.05, subdivision 6, applies to any contract 437.6
- or memorandum of understanding that the board enters into under this paragraph. 437.7

(i) (k) With available appropriations, the commissioner of human services shall establish 437.8

and implement a system through which the Department of Human Services shall routinely 437.9

437.10 access the data for the purpose of determining whether any client enrolled in an opioid

437.11 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 437.12

- program. When the commissioner determines there have been multiple prescribers or multiple 437.13
- 437.14 prescriptions of controlled substances, the commissioner shall:

437.15 (1) inform the medical director of the opioid treatment program only that the

- 437.16 commissioner determined the existence of multiple prescribers or multiple prescriptions of 437.17 controlled substances; and

(2) direct the medical director of the opioid treatment program to access the data directly, 437.18 437.19 review the effect of the multiple prescribers or multiple prescriptions, and document the 437.20 review.

437.21 If determined necessary, the commissioner of human services shall seek a federal waiver 437.22 of, or exception to, any applicable provision of Code of Federal Regulations, title 42, section 437.23 2.34, paragraph (c), prior to implementing this paragraph.

(i) (l) The board shall review the data submitted under subdivision 4 on at least a quarterly 437.24

437.25 basis and shall establish criteria, in consultation with the advisory task force, for referring

- 437.26 information about a patient to prescribers and dispensers who prescribed or dispensed the
- prescriptions in question if the criteria are met. 437.27

437.28 Sec. 3. Minnesota Statutes 2016, section 152.126, subdivision 10, is amended to read:

Subd. 10. Funding. (a) The board may seek grants and private funds from nonprofit 437.29

- 437.30 charitable foundations, the federal government, and other sources to fund the enhancement
- 437.31 and ongoing operations of the prescription monitoring program established under this section.
- 437.32 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 438.1

438.2 approval from the legislature.

Senate Language S3656-2

- (b) Notwithstanding any other section, the administrative services unit for the 438.3
- 438.4 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 438.5
- 438.6 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 438.7
- equal each board's share of the annual appropriation to the Board of Pharmacy from the 438.8 state government special revenue fund for operating the prescription monitoring program
- 438.9
- 438.10 under this section. Each board's apportioned share shall be based on the number of prescribers 438.11 or dispensers that each board identified in this paragraph licenses as a percentage of the
- 438.12 total number of prescribers and dispensers licensed collectively by these boards. Each
- 438.13 respective board may adjust the fees that the boards are required to collect to compensate
- 438.14 for the amount apportioned to each board by the administrative services unit.
- 438.15 (c) The board shall have the authority to modify its contract with its vendor as provided
- 438.16 in subdivision 2, to authorize that vendor to provide a service to prescribers and pharmacies
- that allows them to access prescription monitoring program data from within the electronic 438.17
- health record system or pharmacy software used by those prescribers and pharmacists. 438.18
- 438.19 Beginning July 1, 2018, the board has the authority to collect an annual fee from each
- 438.20 prescriber or pharmacist who accesses prescription monitoring program data through the
- 438.21 service offered by the vendor. The annual fee collected must not exceed \$50 per user. The fees collected by the board under this paragraph shall be deposited in the state government
- 438.22 special revenue fund and are appropriated to the board for the purposes of this paragraph. 438.23