SENATE
STATE OF MINNESOTA
NINETIETH SESSION

S.F. No. 730

(SENATE AUTHORS: ROSEN, Eaton, Abeler, Lourey and Koran)

DATE	D-PG	OFFICIAL STATUS
02/06/2017	531	Introduction and first reading Referred to Health and Human Services Finance and Policy
03/09/2017	1271a	Comm report: To pass as amended and re-refer to State Government Finance and Policy and Elections
03/13/2017	1299a	Comm report: To pass as amended and re-refer to Health and Human Services Finance and Policy
03/19/2018	6548a	Comm report: To pass as amended and re-refer to Finance
05/01/2018		Comm report: To pass as amended and re-refer to Rules and Administration

A bill for an act

relating to health; establishing an opiate stewardship program; establishing an opiate manufacturer registration fee to fund the operation of the prescription monitoring program; authorizing the board of pharmacy to impose a user fee on prescribers and pharmacies who choose to integrate access to the prescription monitoring program; requiring a prescriber to access the prescription monitoring program before prescribing a controlled substance; limiting the quantity of opiates and narcotics that can be prescribed for acute pain at any one time; appropriating money; requiring a report; amending Minnesota Statutes 2016, sections 151.065, by adding subdivisions; 151.252, subdivision 1; 152.11, subdivisions 1, 2; 152.126, subdivisions 1, 6, 10; Laws 2017, First Special Session chapter 6, article 12, section 2, subdivision 4; proposing coding for new law in Minnesota Statutes, chapter 151.

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

ARTICLE 1

OPIATE PRODUCT STEWARDSHIP

Section 1. Minnesota Statutes 2016, section 151.252, subdivision 1, is amended to read:

Subdivision 1. **Requirements.** (a) No person shall act as a drug manufacturer without first obtaining a license from the board and paying any applicable fee specified in section 151.065.

(b) Application for a drug manufacturer license under this section shall be made in a manner specified by the board.

(c) No license shall be issued or renewed for a drug manufacturer unless the applicant agrees to operate in a manner prescribed by federal and state law and according to Minnesota Rules.

(d) No license shall be issued or renewed for a drug manufacturer that is required to be registered pursuant to United States Code, title 21, section 360, unless the applicant supplies the board with proof of registration. The board may establish by rule the standards for licensure of drug manufacturers that are not required to be registered under United States Code, title 21, section 360.

(e) No license shall be issued or renewed for a drug manufacturer that is required to be licensed or registered by the state in which it is physically located unless the applicant supplies the board with proof of licensure or registration. The board may establish, by rule, standards for the licensure of a drug manufacturer that is not required to be licensed or registered by the state in which it is physically located.

(f) The board shall require a separate license for each facility located within the state at which drug manufacturing occurs and for each facility located outside of the state at which drugs that are shipped into the state are manufactured.

(g) The board shall not issue an initial or renewed license for a drug manufacturing facility unless the facility passes an inspection conducted by an authorized representative of the board. In the case of a drug manufacturing facility located outside of the state, the board may require the applicant to pay the cost of the inspection, in addition to the license fee in section 151.065, unless the applicant furnishes the board with a report, issued by the appropriate regulatory agency of the state in which the facility is located or by the United States Food and Drug Administration, of an inspection that has occurred within the 24 months immediately preceding receipt of the license application by the board. The board may deny licensure unless the applicant submits documentation satisfactory to the board that any deficiencies noted in an inspection report have been corrected.

(h) The board shall not issue a renewed license for a drug manufacturer unless the manufacturer pays any stewardship fee it is required to pay under section 151.2521.

Sec. 2. **[151.2521] OPIATE PRODUCT STEWARDSHIP FEE.**

Subdivision 1. **Opiate product stewardship fee established.** (a) A manufacturer licensed under section 151.252 that holds a United States Food and Drug Administration approved new drug application or approved abbreviated new drug application for any products containing opium or opiates listed in section 152.02, subdivision 3, paragraphs (b) and (c), any products containing narcotics listed in section 152.02, subdivision 4, paragraph (e), or any products containing narcotic drugs listed in section 152.02, subdivision 5, paragraph (b), shall pay to the Board of Pharmacy a stewardship fee as specified in this section.

(b) Drugs approved by the United States Food and Drug Administration for the treatment of opioid dependence are not subject to the annual stewardship fee, but only when used for that purpose.

Subd. 2. **Reporting requirements.** (a) Effective December 1, 2018, a manufacturer licensed under section 151.252 must provide the board with data about each of its prescription products that contain controlled substances listed in section 152.02, subdivisions 3 to 6 that are sold within this state as of that date. The data shall include, for each product, the trade and generic names, strength, package size, and National Drug Code. A manufacturer required to report this data shall also report a billing address to which the board can send invoices and inquiries related to the product stewardship fee. A manufacturer must notify the board of any change to this data no later than 30 days after the change is made. The board may require a manufacturer to confirm the accuracy of the data on a quarterly basis. If a manufacturer fails to provide information required under this paragraph on a timely basis, the board may assess an administrative penalty of $100 per day. This penalty must not be considered a form of disciplinary action.

(b) Effective February 1, 2019, a manufacturer licensed under section 151.252 or a wholesaler licensed under section 151.47 must report to the board every sale, delivery, or other distribution within or into this state of any prescription controlled substance listed in section 152.02, subdivisions 3 to 6, that is made to any practitioner, pharmacy, hospital, veterinary hospital, or other person who is permitted by section 151.37 to possess controlled substances for administration or dispensing to patients. Reporting must be in the automation of reports and consolidated orders system format unless otherwise specified by the board, and must occur by the 15th day of each calendar month, for sales, deliveries, and other distributions that occurred during the previous calendar month, except that the first report submitted to the board must include data retroactive to July 1, 2018. If a manufacturer or wholesaler fails to provide information required under this paragraph on a timely basis, the board may assess an administrative penalty of $100 per day. This penalty must not be considered a form of disciplinary action.

(c) Effective February 1, 2019, any pharmacy licensed under section 151.19 and located outside of this state, including, but not limited to, community, long-term care, mail order, and compounding and central service pharmacies, must report to the board the dispensing of drugs listed in subdivision 1 that is made to patients located within this state. Reporting must be in the manner and format specified by the board, and must occur by the 15th day of each calendar month, for dispensing that occurred during the previous calendar month, except that the first report submitted to the board must include data retroactive to July 1,

2018. If a pharmacy fails to provide information required under this paragraph on a timely basis, the board may assess an administrative penalty of $100 per day. This penalty must not be considered a form of disciplinary action.

(d) Effective February 1, 2019, the owners of pharmacies that are located within this state must report to the board the intracompany delivery or distribution, into this state, of the drugs listed in subdivision 1, to the extent that those deliveries and distributions are not reported to the board by a licensed wholesaler owned by, under contract to, or otherwise operating on behalf of the owner of the pharmacies. Reporting must be in the manner and format specified by the board, and must occur by the 15th day of each calendar month, for deliveries and distributions that occurred during the previous calendar month, except that the first report submitted to the board must include data retroactive to July 1, 2018.

Subd. 3. **Invoicing and payment.** (a) The board, beginning January 1, 2019, and at least quarterly, must use the data submitted under subdivision 2 to prepare invoices for each manufacturer that is required to pay the opiate stewardship fee required by this section. The invoices for each quarter must be prepared and sent to manufacturers no later than 45 days after the end of each quarter, except that the first invoice prepared by the board shall be for the first three quarters of fiscal year 2019. Manufacturers must remit payment to the board by no later than 30 days after the date of the invoice. If a manufacturer fails to remit payment by that date, the board shall charge interest at the rate that manufacturers are charged interest for making late Medicaid rebate payments.

(b) A manufacturer may dispute the amount invoiced by the board no later than 30 days after the date of the invoice. However, the manufacturer must still remit payment for the amount invoiced as required by this section. The dispute must be filed with the board in the manner and using the forms specified by the board. A manufacturer must submit, with the required forms, data satisfactory to the board that demonstrates that the original amount invoiced was incorrect. The board must make a decision concerning a dispute no later than 60 days after receiving the required dispute forms. If the board determines that the manufacturer has satisfactorily demonstrated that the original fee invoiced by the board was incorrect, the board must reimburse the manufacturer for any amount that is in excess of the correct amount that should have been invoiced when the board notifies the manufacturer of its decision.

Subd. 4. **Calculation of fees.** (a) The board must calculate the fee that is to be paid by each manufacturer by using a base rate for all drugs listed in subdivision 1, and multipliers of the base rate for certain drugs and dosage forms as specified in this subdivision.

(b) The base rate shall be $0.01 per unit distributed or dispensed. A unit is each capsule, tablet, milliliter, gram, or other such amount, as defined by board.

(c) An active ingredient multiplier of 10 shall be applied to the base for Schedule II opium derivatives and opiates, as defined in section 152.02, subdivision 3, except as further defined below:

(1) oxycodone: 15;

(2) oxymorphone: 15;

(3) hydromorphone: 15;

(4) methadone: 20; and

(5) fentanyl: 20.

(d) In addition to the active ingredient multiplier, a dosage form multiplier shall be applied to the base as follows:

(1) liquid: 0.2; and

(2) patch: 20.

Sec. 3. **[151.255] OPIATE STEWARDSHIP ADVISORY COUNCIL.**

Subdivision 1. **Establishment of the advisory council.** (a) The Opiate Stewardship Advisory Council is established to develop and implement a comprehensive and effective statewide effort to address the opioid addiction and overdose epidemic in Minnesota. The council shall focus on:

(1) prevention and education, including public education and awareness for adults and youth, prescriber education, the development and sustainability of opioid overdose prevention and education programs, and providing financial support to local law enforcement agencies for opiate antagonist programs;

(2) treatment, including statewide access to effective treatment and recovery services that is aligned with Minnesota's model of care approach to promoting access to treatment and recovery services. This includes ensuring that individuals throughout the state have access to treatment and recovery services, including care coordination services; peer recovery services; medication-assisted treatment and office-based opioid treatment; integrative and multidisciplinary therapies; and culturally specific services; and

(3) innovation and capacity building, including development of evidence-based practices, using research and evaluation to understand which policies and programs promote efficient

and effective prevention, treatment, and recovery results. This also includes ensuring that there are qualified providers and a comprehensive set of treatment and recovery services throughout the state.

(b) The council shall:

(1) review local, state, and federal initiatives and funding related to prevention and education, treatment, and services for individuals and families experiencing and affected by opioid abuse, and promoting innovation and capacity building to address the opioid addiction and overdose epidemic;

(2) establish priorities to address the state's opioid addiction and overdose epidemic for the purpose of allocating funds and consult with the commissioner of management and budget to determine whether proposals are for evidence-based practices, promising practices, or theory-based practices;

(3) ensure that available funding under this section is allocated to align with existing state and federal funding to achieve the greatest impact and ensure a coordinated state effort to address the opioid addiction and overdose epidemic;

(4) develop criteria and procedures to be used in awarding grants and allocating available funds from the opiate stewardship account and select proposals to receive grant funding. The council is encouraged to select proposals that are promising practices or theory-based practices, in addition to evidence-based practices, to help identify new approaches to effective prevention, treatment, and recovery; and

(5) in consultation with the commissioner of management and budget, and within available appropriations, select from the awarded grants projects that include promising practices or theory-based activities for which the commissioner of management and budget shall conduct evaluations using experimental or quasi-experimental design. Grants awarded to proposals that include promising practices or theory-based activities and that are selected for an evaluation shall be administered to support the experimental or quasi-experimental evaluation and require grantees to collect and report information that is needed to complete the evaluation. The commissioner of management and budget, under section 15.08, may obtain additional relevant data to support the experimental or quasi-experimental evaluation studies.

(c) The commissioner of human services shall award grants from the opiate stewardship account under section 151.256. The grants shall be awarded to proposals selected by the advisory council that address the priorities in paragraph (a), clauses (1) to (3). No more than three percent of the grant amount may be used by the grantee for administration. The

commissioner of human services shall submit a report of grants to be awarded for the upcoming fiscal year to the chairs and ranking minority members of the legislative committees with jurisdiction over health and human services policy and finance, by March 1 of each year, beginning March 1, 2019.

Subd. 2. **Membership.** (a) The council shall consist of 18 members appointed by the commissioner of human services, except as otherwise specified:

(1) two members of the house of representatives, one from the majority party appointed by the speaker of the house and one from the minority party appointed by the minority leader;

(2) two members of the senate, one from the majority party appointed by the senate majority leader and one from the minority party appointed by the senate minority leader;

(3) one member appointed by the Board of Pharmacy;

(4) one member who is a medical doctor appointed by the Minnesota chapter of the American College of Emergency Physicians;

(5) one member representing opioid treatment programs or sober living programs;

(6) one member who is a medical doctor appointed by the Minnesota Hospital Association;

(7) one member who is a medical doctor appointed by the Minnesota Society of Addiction Medicine;

(8) one member representing a pain psychologist;

(9) one member appointed by the Steve Rummler Hope Network;

(10) one member appointed by the Minnesota Ambulance Association;

(11) one member representing the Minnesota courts who is a judge or law enforcement officer;

(12) one public member who is a Minnesota resident and who has been impacted by the opioid epidemic;

(13) one member representing a manufacturer of opiates;

(14) one member representing an Indian tribe;

(15) the commissioner of human services or designee; and

(16) the commissioner of health or designee.

(b) The commissioner shall coordinate appointments to provide geographic diversity and shall ensure that at least one-half of council members reside outside of the seven-county metropolitan area.

(c) The council is governed by section 15.059, except that members of the council shall receive no compensation other than reimbursement for expenses. Notwithstanding section 15.059, subdivision 6, the council shall not expire.

(d) The chair shall convene the council at least quarterly, and may convene other meetings as necessary. The chair shall convene meetings at different locations in the state to provide geographic access, and shall ensure that at least one-half of the meetings are held at locations outside of the seven-county metropolitan area.

(e) The commissioner of human services shall provide staff and administrative services for the advisory council.

(f) The council is subject to chapter 13D.

Subd. 3. **Conflict of interest.** Advisory council members must disclose to the council and recuse themselves from voting on any matter before the council if the member has a conflict of interest. A conflict of interest means a financial association that has the potential to bias or have the appearance of biasing a council member's decision related to the opiate stewardship grant decision process or other council activities under this section.

Sec. 4. **[151.256] OPIATE STEWARDSHIP ACCOUNT.**

Subdivision 1. **Establishment.** The opiate stewardship account is established in the special revenue fund in the state treasury. The fees collected by the Board of Pharmacy under section 151.2521 shall be deposited into the account.

Subd. 2. **Use of account funds.** (a) Beginning in fiscal year 2020, money in the account shall be appropriated each fiscal year as specified in this section.

(b) $..... is appropriated from the opiate stewardship account to the Board of Pharmacy for administrative costs related to collection of the stewardship fee established under section 151.2521.

(c) $..... is appropriated to the commissioner of management and budget for evaluation activities under section 151.255.

(d) $..... is appropriated from the opiate stewardship account to the commissioner of human services for the provision of administrative services to the Opiate Stewardship Advisory Council and for the administration of the grants awarded under paragraph (e).

(e) Money remaining in the opiate stewardship account after making the appropriations required in paragraphs (b) to (d) is appropriated to the commissioner of human services. The commissioner shall distribute the appropriation as follows:

(1) at least 50 percent of the amount appropriated shall be distributed by the commissioner to county social service agencies to provide child protection services to children and families who are affected by addiction. The commissioner shall distribute this money proportionally to counties based on the number of open child protection case management cases in the county using data from the previous calendar year; and

(2) the remaining money shall be awarded as specified by the Opiate Stewardship Advisory Council as grants under section 151.255, unless otherwise appropriated by the legislature.

Sec. 5. **OPIATE STEWARDSHIP ADVISORY COUNCIL FIRST MEETING.**

The commissioner of human services shall convene the first meeting of the Opiate Stewardship Advisory Council established under Minnesota Statutes, section 151.255, no later than October 1, 2018. The members shall elect a chair at the first meeting.

ARTICLE 2

PRESCRIPTION MONITORING PROGRAM FUNDING

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

Subd. 3a. **Annual opiate registration fees.** (a) By March 1 of each year beginning March 1, 2019, the board shall determine for each opiate drug manufacturer the number of dosage units of that manufacturer's Schedule II and III opiates that were reported to the board through the prescription monitoring program established under section 152.126 for the previous calendar year and inform the manufacturer of the amount of the registration fee to be paid in accordance with section 151.252, subdivision 1, paragraph (b).

(b) Based on the quantity of reported dosage units, the fee due on June 1, 2019, and each June 1 thereafter, shall be for:

(1) more than 15,000,000, $125,000;

(2) 5,000,001 to 15,000,000, $75,000;

(3) 1,000,001 to 5,000,000, $50,000;

(4) 100,000 to 1,000,000, $12,500; and

(5) less than 100,000, $625.

Sec. 2. Minnesota Statutes 2016, section 151.065, is amended by adding a subdivision to read:

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

Sec. 3. Minnesota Statutes 2016, section 151.252, subdivision 1, is amended to read:

Subdivision 1. **Requirements.** (a) No person shall act as a drug manufacturer without first obtaining a license from the board and paying any applicable fee specified in section 151.065.

(b) In addition to the license required under paragraph (a), a manufacturer of opiates must pay the registration fee required in accordance with section 151.065, subdivision 3a, by June 1 of each year, beginning June 1, 2019. In the event of the change of ownership of a manufacturer, or of a Schedule II or III opiate, the new owner must pay the registration fee required under section 151.065, subdivision 3a, that the original owner would have been assessed had it retained ownership. A manufacturer of opiates that has multiple facilities licensed under paragraph (g) is required to obtain and pay for only one registration.

~~(b)~~ (c) Application for a drug manufacturer license under this section shall be made in a manner specified by the board.

~~(c)~~ (d) No license shall be issued or renewed for a drug manufacturer unless the applicant agrees to operate in a manner prescribed by federal and state law and according to Minnesota Rules.

~~(d)~~ (e) No license shall be issued or renewed for a drug manufacturer that is required to be registered pursuant to United States Code, title 21, section 360, unless the applicant supplies the board with proof of registration. The board may establish by rule the standards for licensure of drug manufacturers that are not required to be registered under United States Code, title 21, section 360.

~~(e)~~ (f) No license shall be issued or renewed for a drug manufacturer that is required to be licensed or registered by the state in which it is physically located unless the applicant supplies the board with proof of licensure or registration. The board may establish, by rule, standards for the licensure of a drug manufacturer that is not required to be licensed or registered by the state in which it is physically located.

~~(f)~~ (g) The board shall require a separate license for each facility located within the state at which drug manufacturing occurs and for each facility located outside of the state at which drugs that are shipped into the state are manufactured.

~~(g)~~ (h) The board shall not issue an initial or renewed license for a drug manufacturing facility unless the facility passes an inspection conducted by an authorized representative of the board. In the case of a drug manufacturing facility located outside of the state, the board may require the applicant to pay the cost of the inspection, in addition to the license fee in section 151.065, unless the applicant furnishes the board with a report, issued by the appropriate regulatory agency of the state in which the facility is located or by the United States Food and Drug Administration, of an inspection that has occurred within the 24 months immediately preceding receipt of the license application by the board. The board may deny licensure unless the applicant submits documentation satisfactory to the board that any deficiencies noted in an inspection report have been corrected.

Sec. 4. 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 charitable foundations, the federal government, and other sources to fund the enhancement and ongoing operations of the prescription 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,~~ In the event that the opiate manufacturer registration fees collected under section 151.252, subdivision 1, paragraph (b), up to $500,000 per fiscal year, and any grants or funds received by the board under paragraph (a) are not sufficient to fund the appropriation to the board for the operation of the prescription monitoring program, 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 portion of the annual appropriation to the Board of Pharmacy from the state government special revenue fund for ~~operating~~ the operation of the prescription monitoring program ~~under this section~~ that is not covered by the opiate manufacturer registration fees collected under section 151.252, subdivision 1, paragraph (b), the user fees collected under paragraph (c), and any grants or funds received by the board under paragraph (a). Each board's apportioned

share shall be based on the number of prescribers or ~~dispensers~~ pharmacists that each board identified in this paragraph licenses as a percentage of the total number of prescribers and ~~dispensers~~pharmacists 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.

(c) The board shall have the authority to modify its contract with its vendor as provided 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 health record system or pharmacy software used by those prescribers and pharmacists. Beginning July 1, 2018, the board has the authority to collect an annual fee from each prescriber or pharmacist who accesses prescription monitoring program data through the 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 special revenue fund and is appropriated to the board for the purposes of this paragraph.

Sec. 5. **OPIATE MANUFACTURER LICENSE SURCHARGE.**

(a) In addition to the annual renewal license fees paid by an opiate manufacturer under Minnesota Statutes, section 151.065, subdivision 3, each opiate manufacturer shall pay a license surcharge for licenses renewed during fiscal year 2019 of $.....

(b) The surcharge collected under this section shall be deposited in the opiate stewardship account established under Minnesota Statutes, section 151.256, and is appropriated to the Board of Pharmacy for administrative costs related to the collection of the stewardship fee under Minnesota Statutes, section 151.2521, and the registration fee under Minnesota Statutes, section 151.252, subdivision 1, paragraph (b).

Sec. 6. **APPROPRIATION AND TRANSFER.**

(a) $..... in fiscal year 2019 is appropriated from the state government special revenue fund to the Board of Pharmacy for the operation of the prescription monitoring program.

(b) Any amount over $500,000 collected under Minnesota Statutes, section 151.252, subdivision 1, paragraph (b), shall be transferred annually from the state government special revenue fund to the opiate stewardship account established under Minnesota Statutes, section 151.256.

ARTICLE 3

OTHER OPIATE PROVISIONS

Section 1. Minnesota Statutes 2016, section 152.11, subdivision 1, is amended to read:

Subdivision 1. **General prescription requirements for controlled substances.** (a) A written prescription or an oral prescription reduced to writing, when issued for a controlled substance in Schedule II, III, IV, or V, is void unless (1) it is written in ink and contains the name and address of the person for whose use it is intended; (2) it states the amount of the controlled substance to be compounded or dispensed, with directions for its use; (3) if a written prescription, it contains the handwritten signature, address, and federal registry number of the prescriber and a designation of the branch of the healing art pursued by the prescriber; and if an oral prescription, the name and address of the prescriber and a designation of the prescriber's branch of the healing art; and (4) it shows the date when signed by the prescriber, or the date of acceptance in the pharmacy if an oral prescription.

(b) An electronic prescription for a controlled substance in Schedule II, III, IV, or V is void unless it complies with the standards established pursuant to section 62J.497 and with those portions of Code of Federal Regulations, title 21, parts 1300, 1304, 1306, and 1311, that pertain to electronic prescriptions.

(c) A prescription for a controlled substance in Schedule II, III, IV, or V that is transmitted by facsimile, either computer to facsimile machine or facsimile machine to facsimile machine, is void unless it complies with the applicable requirements of Code of Federal Regulations, title 21, part 1306.

(d) Every licensed pharmacy that dispenses a controlled substance prescription shall retain the original prescription in a file for a period of not less than two years, open to inspection by any officer of the state, county, or municipal government whose duty it is to aid and assist with the enforcement of this chapter. An original electronic or facsimile prescription may be stored in an electronic database, provided that the database provides a means by which original prescriptions can be retrieved, as transmitted to the pharmacy, for a period of not less than two years.

(e) Every licensed pharmacy shall distinctly label the container in which a controlled substance is dispensed with the directions contained in the prescription for the use of that controlled substance.

(f) No prescription for an opiate or narcotic pain reliever listed in Schedules II through IV of section 152.02 shall be dispensed more than 30 days after the date on which the

prescription was issued. After 30 days from the date of issuance of the prescription, no additional authorizations may be accepted for that prescription. If continued therapy is necessary, a new prescription must be issued by the prescriber.

Sec. 2. Minnesota Statutes 2016, section 152.11, subdivision 2, is amended to read:

Subd. 2. **Prescription requirements for Schedule III or IV controlled substances.** No person may dispense a controlled substance included in Schedule III or IV of section 152.02 without a prescription issued, as permitted under subdivision 1, by a doctor of medicine, a doctor of osteopathic medicine licensed to practice medicine, a doctor of dental surgery, a doctor of dental medicine, a doctor of podiatry, a doctor of optometry limited to Schedule IV, or a doctor of veterinary medicine, lawfully licensed to prescribe in this state or from a practitioner licensed to prescribe controlled substances by the state in which the prescription is issued, and having a current federal drug enforcement administration registration number. Such prescription may not be dispensed or refilled except with the documented consent of the prescriber, ~~and in no event more than six months after the date on which such prescription was issued~~ and no such prescription may be refilled more than five times.

Sec. 3. Minnesota Statutes 2016, 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.

(h) For purposes of this section, when the dispenser is a veterinarian or a veterinary hospital, the term "patient" includes the animal for which the prescription is intended for and the animal's owner or caretaker who arranged for the animal's veterinary care.

Sec. 4. Minnesota Statutes 2016, 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 individuals includes persons in the definition of an individual under section 13.02;

(5) personnel or designees of a health-related licensing board 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);

(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.; and

~~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 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.

(c) By July 1, 2017, 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) Notwithstanding paragraph (b), a prescriber or an agent or employee of the prescriber to whom the prescriber has delegated the task of accessing the data, must access the data submitted under subdivision 4 to the extent the information relates specifically to the patient before the prescriber issues a prescription order for a controlled substance to the patient. This paragraph does not apply if:

(1) the patient is receiving hospice care;

(2) the prescription order is for a number of doses that is intended to last the patient three days or less and is not subject to a refill;

(3) the controlled substance is lawfully administered by injection, ingestion, or any other means to the patient by the prescriber, a pharmacist, or by the patient at the direction of a prescriber and in the presence of the prescriber or pharmacist;

(4) due to an emergency, it is not possible for the prescriber to review the data before the prescriber issues the prescription order for the patient; or

(5) the prescriber is unable to access the data due to operational or other technological failure of the program so long as the prescriber reports the failure to the board.

(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) 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.

Sec. 5. Laws 2017, First Special Session chapter 6, article 12, section 2, subdivision 4, is amended to read:

Subd. 4. **Limit on quantity of opiates prescribed ~~for acute dental and ophthalmic pain.~~** (a) When used for the treatment of acute pain, prescriptions for opiates or narcotic pain relievers listed in Schedules II through IV in section 152.02 shall not exceed a seven-day supply for an adult and shall not exceed a five-day supply for a minor under 18 years of age.

~~(a)~~ (b) Notwithstanding paragraph (a), when used for the treatment of acute dental pain or acute pain associated with refractive surgery, prescriptions for opiate or narcotic pain relievers listed in Schedules II through IV of section 152.02 shall not exceed a four-day supply. ~~The quantity prescribed shall be consistent with the dosage listed in the professional labeling for the drug that has been approved by the United States Food and Drug Administration.~~

~~(b)~~ (c) For the purposes of this subdivision, "acute pain" means pain resulting from disease, accidental or intentional trauma, surgery, or another cause, that the practitioner reasonably expects to last only a short period of time. Acute pain does not include chronic pain or pain being treated as part of cancer care, palliative care, or hospice or other end-of-life care.

~~(c) Notwithstanding paragraph (a), if in the professional clinical judgment of a practitioner more than a four-day supply of a prescription listed in Schedules II through IV of section 152.02 is required to treat a patient's acute pain, the practitioner may issue a prescription for the quantity needed to treat such acute pain.~~

APPENDIX
Article locations in SF0730-3