SF751 REVISOR LCB S0751-2 2nd Engrossment

SENATE STATE OF MINNESOTA NINETY-FIRST SESSION

S.F. No. 751

(SENATE AUTHORS: ROSEN, Eaton, Draheim, Abeler and Klein)
OFFICIAL STATUS

D-I G	OFFICIAL STATUS
226	Introduction and first reading
	Referred to Health and Human Services Finance and Policy
360a	Comm report: To pass as amended and re-refer to State Government Finance and Policy and
	Elections
410a	Comm report: To pass as amended and re-refer to Judiciary and Public Safety Finance and Policy
	Comm report: To pass as amended and re-refer to Human Services Reform Finance and Policy
	226 360a

A bill for an act 1.1 relating to health; establishing an opiate epidemic response; establishing an Opiate 1.2 Epidemic Response Advisory Council; establishing an opiate epidemic response 1.3 account; increasing the annual license fee for drug manufacturers and wholesale 1.4 drug distributors; establishing an opiate product registration fee for certain opiate 1.5 manufacturers; requiring a prescriber to access the prescription monitoring program 1.6 before prescribing a controlled substance; limiting the quantity of opiates and 1.7 narcotics that can be prescribed for acute pain at any one time; requiring a report; 1.8 appropriating money; amending Minnesota Statutes 2018, sections 151.01, 1.9 subdivision 27; 151.065, subdivisions 1, 3, by adding a subdivision; 151.252, 1.10 subdivision 1; 152.105, subdivision 2; 152.11, subdivisions 1, 2, 2d, 4; 152.126, 1.11 subdivisions 6, 10; 214.12, by adding a subdivision; proposing coding for new 1.12 law in Minnesota Statutes, chapters 151; 256. 1.13 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA: 1.14 **ARTICLE 1** 1.15 **OPIATE EPIDEMIC RESPONSE** 1.16 Section 1. Minnesota Statutes 2018, section 151.065, subdivision 1, is amended to read: 1.17 Subdivision 1. **Application fees.** Application fees for licensure and registration are as 1.18 follows: 1.19 (1) pharmacist licensed by examination, \$145; 1.20 (2) pharmacist licensed by reciprocity, \$240; 1.21 (3) pharmacy intern, \$37.50; 1.22 (4) pharmacy technician, \$37.50; 1.23 (5) pharmacy, \$225; 1.24

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(6) drug wholesaler, legend drugs only, \$235 \$5,000;

- (7) drug wholesaler, legend and nonlegend drugs, \$235 \$5,000;
- 2.2 (8) drug wholesaler, nonlegend drugs, veterinary legend drugs, or both, \$\frac{\$210}{5,000}\$;
- 2.3 (9) drug wholesaler, medical gases, \$175 \$5,000;
- 2.4 (10) drug wholesaler, also licensed as a pharmacy in Minnesota, \$150 \$5,000;
- 2.5 (11) drug manufacturer, nonopiate legend drugs only, \$235 \$5,000;
- 2.6 (12) drug manufacturer, nonopiate legend and nonlegend drugs, \$235 \$5,000;
- 2.7 (13) drug manufacturer, nonlegend or veterinary legend drugs, \$210 \$5,000;
- 2.8 (14) drug manufacturer, medical gases, \$185 \$5,000;
- 2.9 (15) drug manufacturer, also licensed as a pharmacy in Minnesota, \$150 \$5,000;
- 2.10 (16) drug manufacturer of opiate-containing controlled substances listed in section
- 2.11 152.02, subdivisions 3 to 5, \$55,000;
- 2.12 $\frac{(16)(17)}{(17)}$ medical gas distributor, $\frac{$110}{5,000}$;
- (17) (18) controlled substance researcher, \$75; and
- 2.14 (18) (19) pharmacy professional corporation, \$125.
- 2.15 **EFFECTIVE DATE.** This section is effective July 1, 2019, and applies to any license
- 2.16 issued on or after that date.
- Sec. 2. Minnesota Statutes 2018, section 151.065, subdivision 3, is amended to read:
- Subd. 3. **Annual renewal fees.** Annual licensure and registration renewal fees are as
- 2.19 follows:
- 2.20 (1) pharmacist, \$145;
- 2.21 (2) pharmacy technician, \$37.50;
- 2.22 (3) pharmacy, \$225;
- 2.23 (4) drug wholesaler, legend drugs only, \$235 \(\frac{\$5,000}{} \);
- 2.24 (5) drug wholesaler, legend and nonlegend drugs, \$235 \$5,000;
- 2.25 (6) drug wholesaler, nonlegend drugs, veterinary legend drugs, or both, \$210 \$5,000;
- 2.26 (7) drug wholesaler, medical gases, \$185 \\$5,000;
- 2.27 (8) drug wholesaler, also licensed as a pharmacy in Minnesota, \$150 \$5,000;
- 2.28 (9) drug manufacturer, nonopiate legend drugs only, \$235 \$5,000;

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is engaged in the wholesale drug distribution of an opiate.

(c) "Opiate" means any opiate-containing controlled substance listed in section 152.02,

(d) "Wholesaler" means a wholesale drug distributor licensed under section 151.47 that

subdivisions 3 to 5, that is distributed, delivered, sold, or dispensed into or within this state.

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Subd. 2. Re	eporting requirements. (a) By March 1 of each year, beginning March 1,
2020, each mar	nufacturer and each wholesaler must report to the board every sale, delivery
or other distrib	ution within or into this state of any opiate that is made to any practitioner,
pharmacy, hosp	pital, veterinary hospital, or other person who is permitted by section 151.37
to possess cont	crolled substances for administration or dispensing to patients that occurred
during the prev	vious calendar year. Reporting must be in the automation of reports and
consolidated or	ders system format unless otherwise specified by the board. If a manufacture
or wholesaler f	ails to provide information required under this paragraph on a timely basis
the board may	assess an administrative penalty of \$100 per day. This penalty shall not be
considered a fo	orm of disciplinary action.
(b) By Mare	ch 1 of each year, beginning March 1, 2020, each owner of a pharmacy with
at least one loc	ation within this state must report to the board any intracompany delivery
	into this state, of any opiate, to the extent that those deliveries and distributions
	d to the board by a licensed wholesaler owned by, under contract to, or
otherwise oper	ating on behalf of the owner of the pharmacy. Reporting must be in the
manner and for	rmat specified by the board for deliveries and distributions that occurred
during the prev	vious calendar year.
Subd 2 Da	etermination of an opiate product registration fee. (a) The board shall
	s an opiate product registration fee on any manufacturer of an opiate that
	delivers, or distributes an opiate within or into the state 2,000,000 or more
units as reporte	ed to the board under subdivision 2.
(b) The ann	nual registration fee for each manufacturer meeting the requirement under
paragraph (a) i	s \$250,000.
(c) In conju	nction with the data reported under this section, and notwithstanding section
	vision 6, the board may use the data reported under section 152.126,
	to determine which manufacturers meet the requirement under paragraph (a
and are require	ed to pay the registration fees under this subdivision.
	1 1 of each year, beginning April 1, 2020, the board shall notify a manufacture
	acturer meets the requirement in paragraph (a) and is required to pay the
annuai registra	tion fee in accordance with section 151.252, subdivision 1, paragraph (b).
(e) A manu	facturer may dispute the board's determination that the manufacturer must
pay the registra	ation fee no later than 30 days after the date of notification. However, the
manufacturer m	nust still remit the fee as required by section 151.252, subdivision 1, paragraph
(b). The disput	e must be filed with the board in the manner and using the forms specified

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by the board. A manufacturer must submit, with the required forms, data satisfactory to the board that demonstrates that the assessment of the registration fee 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 fee was incorrectly assessed, the board must refund the amount paid in error.

- Subd. 4. Report. (a) The Board of Pharmacy shall evaluate the registration fee on drug manufacturers established under this section, and whether the registration fee and the increased licensure fees have impacted the prescribing practices of opiates by reducing the number of opiate prescriptions issued during calendar years 2020, 2021, and 2022, or creating any unintended consequences in the availability of opiates for the treatment of chronic or intractable pain to the extent the board has the ability to effectively identify a correlation. Notwithstanding section 152.126, subdivision 6, the board may access the data reported under section 152.126, subdivision 4, to conduct this evaluation.
- (b) The board shall submit the results of its evaluation to the chairs and ranking minority members of the legislative committees with jurisdiction over health and human services policy and finance by March 1, 2023.
- Subd. 5. **Legislative review.** The legislature shall review the reports from the Opiate Epidemic Response Advisory Council under section 256.042, subdivision 5, paragraph (a), the reports from the commissioner of management and budget on the Results First evaluation activities under section 256.042, subdivision 5, paragraph (b), the report from the Board of Pharmacy under subdivision 4, and any other relevant report or information related to the opioid crisis in Minnesota, to make a determination about whether the opiate product registration fee assessed under this section should continue beyond July 1, 2023.
- Sec. 5. Minnesota Statutes 2018, section 151.252, subdivision 1, is amended to read:
- 5.25 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 5.26 151.065. 5.27
 - (b) In addition to the license required under paragraph (a), each manufacturer required to pay the registration fee under section 151.066 must pay the fee by June 1 of each year, beginning June 1, 2020. In the event of a change of ownership of the manufacturer, the new owner must pay the registration fee specified under section 151.066, subdivision 3, that the original owner would have been assessed had the original owner retained ownership. The registration fee collected under this paragraph shall be deposited in the opiate epidemic response account established under section 256.043.

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

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- (e) (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. 6. [256.042] OPIATE EPIDEMIC RESPONSE ADVISORY COUNCIL.

Subdivision 1. Establishment of the advisory council. (a) The Opiate Epidemic

Response 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:

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(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, including alternatives to the use of opiates or narcotic pain relievers for the treatment of chronic pain;
- (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 epidemic response 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

8.1	(5) in consultation with the commissioner of management and budget, and within
8.2	available appropriations, select from the awarded grants projects that include promising
8.3	practices or theory-based activities for which the commissioner of management and budget
8.4	shall conduct evaluations using experimental or quasi-experimental design. Grants awarded
8.5	to proposals that include promising practices or theory-based activities and that are selected
8.6	for an evaluation shall be administered to support the experimental or quasi-experimental
8.7	evaluation and require grantees to collect and report information that is needed to complete
8.8	the evaluation. The commissioner of management and budget, under section 15.08, may
8.9	obtain additional relevant data to support the experimental or quasi-experimental evaluation
8.10	studies.
8.11	Subd. 2. Membership. (a) The council shall consist of 18 voting members appointed
8.12	by the commissioner of human services, except as otherwise specified:
8.13	(1) two members of the house of representatives, one from the majority party appointed
8.14	by the speaker of the house and one from the minority party appointed by the minority
8.15	<u>leader;</u>
8.16	(2) two members of the senate, one from the majority party appointed by the senate
8.17	majority leader and one from the minority party appointed by the senate minority leader;
8.18	(3) one member appointed by the Board of Pharmacy;
8.19	(4) one member who is a physician appointed by the Minnesota chapter of the American
8.20	College of Emergency Physicians;
8.21	(5) one member representing opioid treatment programs or sober living programs;
8.22	(6) one member who is a physician appointed by the Minnesota Hospital Association;
8.23	(7) one member who is a physician appointed by the Minnesota Society of Addiction
8.24	Medicine;
8.25	(8) one member who is a pain psychologist;
8.26	(9) one member appointed by the Steve Rummler Hope Network;
8.27	(10) one member appointed by the Minnesota Ambulance Association;
8.28	(11) one member representing the Minnesota courts who is a judge or law enforcement
8.29	officer;
8.30	(12) one public member who is a Minnesota resident and who has been impacted by the
8.31	opioid epidemic;

9.1	(13) one member representing a manufacturer of opiates;
9.2	(14) one member representing an Indian tribe; and
9.3	(15) two public members who are Minnesota residents and are suffering from chronic
9.4	pain, intractable pain, or a rare disease or condition.
9.5	(b) The commissioners of human services and health or their designees shall be ex officio
9.6	nonvoting members of the council.
9.7	(c) The commissioner of human services shall coordinate appointments to provide
9.8	geographic diversity and shall ensure that at least one-half of council members reside outside
9.9	of the seven-county metropolitan area.
9.10	(d) The council is governed by section 15.059, except that members of the council shall
9.11	receive no compensation other than reimbursement for expenses. Notwithstanding section
9.12	15.059, subdivision 6, the council shall not expire.
9.13	(e) The chair shall convene the council at least quarterly, and may convene other meetings
9.14	as necessary. The chair shall convene meetings at different locations in the state to provide
9.15	geographic access, and shall ensure that at least one-half of the meetings are held at locations
9.16	outside of the seven-county metropolitan area.
9.17	(f) The commissioner of human services shall provide staff and administrative services
9.18	for the advisory council.
9.19	(g) The council is subject to chapter 13D.
9.20	Subd. 3. Conflict of interest. Advisory council members must disclose to the council
9.21	and recuse themselves from voting on any matter before the council if the member has a
9.22	conflict of interest. A conflict of interest means a financial association that has the potential
9.23	to bias or have the appearance of biasing a council member's decision related to the opiate
9.24	epidemic response grant decision process or other council activities under this section.
9.25	Subd. 4. Grants. (a) The commissioner of human services shall submit a report of the
9.26	grants proposed by the advisory council to be awarded for the upcoming fiscal year to the
9.27	chairs and ranking minority members of the legislative committees with jurisdiction over
9.28	health and human services policy and finance, by March 1 of each year, beginning March
9.29	<u>1, 2020.</u>
9.30	(b) The commissioner of human services shall award grants from the opiate epidemic
9.31	response account under section 256.043. The grants shall be awarded to proposals selected
9.32	by the advisory council that address the priorities in subdivision 1, paragraph (a), clauses

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(1) to (3), unless otherwise appropriated by the legislature. No more than three percent of the grant amount may be used by a grantee for administration.

Subd. 5. Reports. (a) The advisory council shall report annually to the chairs and ranking minority members of the legislative committees with jurisdiction over health and human services policy and finance by January 1 of each year beginning January 1, 2022, information about the individual projects that receive grants and the overall role of the project in addressing the opioid addiction and overdose epidemic in Minnesota. The report must describe the grantees and the activities implemented, along with measurable outcomes as determined by the council in consultation with the commissioner of human services and the commissioner of management and budget. At a minimum, the report must include information about the number of individuals who received information or treatment, the outcomes the individuals achieved, and demographic information about the individuals participating in the project; an assessment of the progress toward achieving statewide access to qualified providers and comprehensive treatment and recovery services; and an update on the evaluation implemented by the commissioner of management and budget for the promising practices and theory-based projects that receive funding.

(b) The commissioner of management and budget, in consultation with the Opiate
Epidemic Response Advisory Council, shall report to the chairs and ranking minority
members of the legislative committees with jurisdiction over health and human services
policy and finance when an evaluation study described in subdivision 1, paragraph (b),
clause (5), is complete on the promising practices or theory-based projects that are selected
for evaluation activities. The report shall include demographic information; outcome
information for the individuals in the program; the results for the program in promoting
recovery, employment, family reunification, and reducing involvement with the criminal
justice system; and other relevant outcomes determined by the commissioner of management
and budget that are specific to the projects that are evaluated. The report shall include
information about the ability of grant programs to be scaled to achieve the statewide results
that the grant project demonstrated.

Sec. 7. [256.043] OPIATE EPIDEMIC RESPONSE ACCOUNT.

Subdivision 1. **Establishment.** The opiate epidemic response account is established in the special revenue fund in the state treasury. The registration fees assessed by the Board of Pharmacy under section 151.066 and the license fees identified in section 151.065, subdivision 7, paragraph (b), shall be deposited into the account.

11.1	Subd. 2. Use of account funds. (a) Beginning in fiscal year 2020, money in the account
11.2	shall be appropriated each fiscal year as specified in this subdivision.
11.3	(b) \$300,000 is appropriated to the commissioner of management and budget for
11.4	evaluation activities under section 256.042.
11.5	(c) \$249,000 is appropriated to the commissioner of human services for the provision
11.6	of administrative services to the Opiate Epidemic Response Advisory Council and for the
11.7	administration of the grants awarded under paragraph (g).
11.8	(d) \$33,000 is appropriated to the Board of Pharmacy for the collection of the registration
11.9	fees under section 151.066.
11.10	(e) \$384,000 is appropriated to the commissioner of public safety for Bureau of Criminal
11.11	Apprehension drug scientists and lab supplies.
11.12	(f) \$800,000 is appropriated to the commissioner of human services for opioid-focused
11.13	Project Echo programs that have received federal funding prior to January 1, 2019, dedicated
11.14	to addressing the opioid epidemic.
11.15	(g) Money remaining in the opiate epidemic response account after making the
11.16	appropriations required in paragraphs (b) to (f) is appropriated to the commissioner of human
11.17	services. The commissioner shall distribute the appropriations as follows:
11.18	(1) at least 50 percent shall be distributed to county social service agencies to provide
11.19	child protection services to children and families who are affected by addiction. The
11.20	commissioner shall distribute this money proportionally to counties based on the number
11.21	of open child protection case management cases in the county using data from the previous
11.22	calendar year; and
11.23	(2) the remaining money shall be awarded as specified by the Opiate Epidemic Response
11.24	Advisory Council as grants in accordance with section 256.042, unless otherwise appropriated
11.25	by the legislature.
11.26	Sec. 8. OPIATE EPIDEMIC RESPONSE ADVISORY COUNCIL FIRST MEETING.
11.27	The commissioner of human services shall convene the first meeting of the Opiate
11.28	Epidemic Response Advisory Council established under Minnesota Statutes, section 256.042,
11.29	no later than October 1, 2019. The members shall elect a chair at the first meeting.

Sec. 9.	SETTI	LEMENT;	SUNSET
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- (a) Notwithstanding Minnesota Statutes, sections 151.065 and 151.066, if the state receives a settlement, payout, or judgment from any lawsuit brought by the state or group of states, in which Minnesota is a named party against an opiate drug manufacturer or manufacturers, in an amount of \$20,000,000 or greater, the application fee and the annual license fee for opiate manufacturers under Minnesota Statutes, section 151.065, subdivisions 1 and 3, shall be reduced to \$5,000 and any registration fee assessed under Minnesota Statutes, section 152.066, subdivision 3, shall be reduced to \$5,000.
- (b) If the fees identified in paragraph (a) are reduced, the reduced fee shall remain in effect until the fee is reviewed and adjusted, restored, or repealed by the legislature.
- (c) If the state receives any money from a settlement, payout, or judgment as described in paragraph (a), regardless of the amount, the funds received by the state shall be deposited in the state treasury according to paragraph (d).
- (d) If payment subject to paragraph (a) is received, the commissioner of management and budget shall deposit the funds received in a separate account in the state treasury and notify the chairs and ranking minority members of the finance committee in the senate and the ways and means committee in the house of representatives that an account has been created and the amount of funds deposited.

12.19 **ARTICLE 2**12.20 **OTHER OPIATE PROVISIONS**

Section 1. Minnesota Statutes 2018, section 151.01, subdivision 27, is amended to read:

- Subd. 27. **Practice of pharmacy.** "Practice of pharmacy" means:
- (1) interpretation and evaluation of prescription drug orders;
- 12.24 (2) compounding, labeling, and dispensing drugs and devices (except labeling by a
 12.25 manufacturer or packager of nonprescription drugs or commercially packaged legend drugs
 12.26 and devices);
 - (3) participation in clinical interpretations and monitoring of drug therapy for assurance of safe and effective use of drugs, including the performance of laboratory tests that are waived under the federal Clinical Laboratory Improvement Act of 1988, United States Code, title 42, section 263a et seq., provided that a pharmacist may interpret the results of laboratory tests but may modify drug therapy only pursuant to a protocol or collaborative practice agreement;

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(4) participation in drug and therapeutic device selection; drug administration for first
dosage and medical emergencies; intramuscular and subcutaneous administration of drugs
used for the treatment of alcohol or opioid dependence and the treatment of mental health
conditions; drug regimen reviews; and drug or drug-related research;

- (5) participation in administration of influenza vaccines to all eligible individuals six years of age and older and all other vaccines to patients 13 years of age and older by written protocol with a physician licensed under chapter 147, a physician assistant authorized to prescribe drugs under chapter 147A, or an advanced practice registered nurse authorized to prescribe drugs under section 148.235, provided that:
- (i) the protocol includes, at a minimum:
 - (A) the name, dose, and route of each vaccine that may be given;
- (B) the patient population for whom the vaccine may be given; 13.12
- (C) contraindications and precautions to the vaccine; 13.13
- 13.14 (D) the procedure for handling an adverse reaction;
- (E) the name, signature, and address of the physician, physician assistant, or advanced 13.15 practice registered nurse; 13.16
- 13.17 (F) a telephone number at which the physician, physician assistant, or advanced practice registered nurse can be contacted; and 13.18
 - (G) the date and time period for which the protocol is valid;
- (ii) the pharmacist has successfully completed a program approved by the Accreditation 13.20 Council for Pharmacy Education specifically for the administration of immunizations or a 13.21 program approved by the board; 13.22
 - (iii) the pharmacist utilizes the Minnesota Immunization Information Connection to assess the immunization status of individuals prior to the administration of vaccines, except when administering influenza vaccines to individuals age nine and older;
 - (iv) the pharmacist reports the administration of the immunization to the Minnesota Immunization Information Connection; and
 - (v) the pharmacist complies with guidelines for vaccines and immunizations established by the federal Advisory Committee on Immunization Practices, except that a pharmacist does not need to comply with those portions of the guidelines that establish immunization schedules when administering a vaccine pursuant to a valid, patient-specific order issued by a physician licensed under chapter 147, a physician assistant authorized to prescribe

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drugs under chapter 147A, or an advanced practice nurse authorized to prescribe drugs under section 148.235, provided that the order is consistent with the United States Food and Drug Administration approved labeling of the vaccine;

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- (6) participation in the initiation, management, modification, and discontinuation of drug therapy according to a written protocol or collaborative practice agreement between: (i) one or more pharmacists and one or more dentists, optometrists, physicians, podiatrists, or veterinarians; or (ii) one or more pharmacists and one or more physician assistants authorized to prescribe, dispense, and administer under chapter 147A, or advanced practice nurses authorized to prescribe, dispense, and administer under section 148.235. Any changes in drug therapy made pursuant to a protocol or collaborative practice agreement must be documented by the pharmacist in the patient's medical record or reported by the pharmacist to a practitioner responsible for the patient's care;
- (7) participation in the storage of drugs and the maintenance of records;
- 14.14 (8) patient counseling on therapeutic values, content, hazards, and uses of drugs and devices;
- 14.16 (9) offering or performing those acts, services, operations, or transactions necessary in 14.17 the conduct, operation, management, and control of a pharmacy; and
 - (10) participation in the initiation, management, modification, and discontinuation of therapy with opiate antagonists, as defined in section 604A.04, subdivision 1, pursuant to:
 - (i) a written protocol as allowed under clause (6); or
- 14.21 (ii) a written protocol with a community health board medical consultant or a practitioner 14.22 designated by the commissioner of health, as allowed under section 151.37, subdivision 13.
- Sec. 2. Minnesota Statutes 2018, section 152.105, subdivision 2, is amended to read:
 - Subd. 2. Sheriff to maintain collection receptacle or medicine disposal program. (a) The sheriff of each county shall maintain or contract for the maintenance of at least one collection receptacle or implement a medicine disposal program for the disposal of noncontrolled substances, pharmaceutical controlled substances, and other legend drugs, as permitted by federal law. For purposes of this section, "legend drug" has the meaning given in section 151.01, subdivision 17. The collection receptacle and medicine disposal program must comply with federal law. In maintaining and operating the collection receptacle or medicine disposal program, the sheriff shall follow all applicable provisions of Code of Federal Regulations, title 21, parts 1300, 1301, 1304, 1305, 1307, and 1317, as amended through May 1, 2017.

(b) For purposes of this subdivision:

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(1) a medicine disposal program means providing to the public educational information, and making materials available for safely destroying unwanted legend drugs, including but not limited to drug destruction bags or drops; and

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- (2) a collection receptacle means the operation and maintenance of at least one drop-off receptacle.
- Sec. 3. Minnesota Statutes 2018, 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 is 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.

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- (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. 4. Minnesota Statutes 2018, 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. 5. Minnesota Statutes 2018, section 152.11, subdivision 2d, is amended to read:
- Subd. 2d. **Identification requirement for Schedule II or III controlled substance prescriptions.** (a) No person may dispense a controlled substance included in Schedule II or III Schedules II through V without requiring the person purchasing the controlled substance, who need not be the person patient for whom the controlled substance prescription is written, to present valid photographic identification, unless the person purchasing the controlled substance, or if applicable the person for whom the controlled substance prescription is written, is known to the dispenser. A doctor of veterinary medicine who dispenses a controlled substance must comply with this subdivision.
- (b) This subdivision applies only to purchases of controlled substances that are not covered, in whole or in part, by a health plan company or other third-party payor.

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Sec. 6. Minnesota Statutes 2018, section 152.11, subdivision 4, is amended to read:

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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, including acute pain associated with wisdom teeth extraction surgery 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.
- (d) Notwithstanding paragraph (a) or (b), if, in the professional clinical judgment of a practitioner, more than the limit specified in paragraph (a) or (b) is required to treat a patient's acute pain, the practitioner may issue a prescription for the quantity needed to treat the patient's acute pain.
- Sec. 7. Minnesota Statutes 2018, section 152.126, subdivision 6, is amended to read: 17.26
- 17.27 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 17.28 in section 13.02, subdivision 12, and not subject to public disclosure. 17.29
 - (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:

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- (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);

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(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;

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- (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;
- 19.16 (10) personnel of the Department of Human Services assigned to access the data pursuant 19.17 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

20.1	within the state, shall register and maintain a user account with the prescription monitoring
20.2	program. Data submitted by a prescriber, pharmacist, or their delegate during the registration
20.3	application process, other than their name, license number, and license type, is classified
20.4	as private pursuant to section 13.02, subdivision 12.
20.5	(d) Notwithstanding paragraph (b), beginning January 1, 2021, a prescriber or an agent
20.6	or employee of the prescriber to whom the prescriber has delegated the task of accessing
20.7	the data, must access the data submitted under subdivision 4 to the extent the information
20.8	relates specifically to the patient:
20.9	(1) before the prescriber issues an initial prescription order for a Schedules II through
20.10	IV opiate controlled substance to the patient; and
20.11	(2) at least once every three months for patients receiving an opiate for treatment of
20.12	chronic pain or participating in medically assisted treatment for an opioid addiction.
20.13	(e) Paragraph (d) does not apply if:
20.14	(1) the patient is receiving palliative care, or hospice or other end-of-life care;
20.15	(2) the patient is being treated for pain due to cancer or the treatment of cancer;
20.16	(3) the prescription order is for a number of doses that is intended to last the patient five
20.17	days or less and is not subject to a refill;
20.18	(4) the prescriber and patient have a current or ongoing provider/patient relationship of
20.19	a duration longer than one year;
20.20	(5) the prescription order is issued within 14 days following surgery or three days
20.21	following oral surgery or follows the prescribing protocols established under the opioid
20.22	prescribing improvement program under section 256B.0638;
20.23	(6) the controlled substance is prescribed or administered to a patient who is admitted
20.24	to an inpatient hospital;
20.25	(7) the controlled substance is lawfully administered by injection, ingestion, or any other
20.26	means to the patient by the prescriber, a pharmacist, or by the patient at the direction of a
20.27	prescriber and in the presence of the prescriber or pharmacist;
20.28	(8) due to a medical emergency, it is not possible for the prescriber to review the data
20.29	before the prescriber issues the prescription order for the patient; or
20.30	(9) the prescriber is unable to access the data due to operational or other technological

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failure of the program so long as the prescriber reports the failure to the board.

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(f) 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) (g) 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) (h) 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) (i) 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) (j) 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) (k) 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

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(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.

- (i) (1) 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. 8. Minnesota Statutes 2018, 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, 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 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.
- (c) The board has 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, 2019, the board has the authority to collect an annual fee from each

23.1	prescriber or pharmacist who accesses prescription monitoring program data through the
23.2	service offered by the vendor. The annual fee collected must not exceed \$50 per user. The
23.3	fees collected by the board under this paragraph shall be deposited in the state government
23.4	special revenue fund and are appropriated to the board for the purposes of this paragraph.
23.5	Sec. 9. Minnesota Statutes 2018, section 214.12, is amended by adding a subdivision to
23.6	read:
23.7	Subd. 6. Opioid and controlled substances prescribing. (a) The Board of Medical
23.8	Practice, the Board of Nursing, the Board of Dentistry, the Board of Optometry, and the
23.9	Board of Podiatric Medicine shall require that licensees with the authority to prescribe
23.10	controlled substances obtain at least two hours of continuing education credit on best practices
23.11	in prescribing opioids and controlled substances, as part of the continuing education
23.12	requirements for licensure renewal. Licensees shall not be required to complete more than
23.13	two credit hours of continuing education on best practices in prescribing opioids and
23.14	controlled substances before this subdivision expires. Continuing education credit on best
23.15	practices in prescribing opioids and controlled substances must meet board requirements.
23.16	(b) Paragraph (a) does not apply to any licensee who is participating in the opioid
23.17	prescribing improvement program under section 256B.0638, unless the licensee has been
23.18	terminated as a medical assistance provider under section 256B.0638, subdivision 5,
23.19	paragraph (d).
23.20	(c) This subdivision expires January 1, 2024.
23.21	EFFECTIVE DATE. This section is effective January 1, 2020.
23.22	Sec. 10. OPIOID OVERDOSE REDUCTION PILOT PROGRAM.
23.23	Subdivision 1. Establishment. The commissioner of health shall provide grants to
23.24	ambulance services to fund activities by community paramedic teams to reduce opioid
23.25	overdoses in the state. Under this pilot program, ambulance services shall develop and
23.26	implement projects in which community paramedics connect with patients who are discharged
23.27	from a hospital or emergency department following an opioid overdose episode, develop
23.28	personalized care plans for those patients in consultation with the ambulance service medical
23.29	director, and provide follow-up services to those patients.
23.30	Subd. 2. Priority areas; services. (a) In a project developed under this section, an
23.31	ambulance service must target community paramedic team services to portions of the service

24.1	area with high levels of opioid use, high death rates from opioid overdoses, and urgent needs
24.2	<u>for interventions.</u>
24.3	(b) In a project developed under this section, a community paramedic team shall:
24.4	(1) provide services to patients released from a hospital or emergency department
24.5	following an opioid overdose episode and place priority on serving patients who were
24.6	administered the opiate antagonist naloxone hydrochloride by emergency medical services
24.7	personnel in response to a 911 call during the opioid overdose episode;
24.8	(2) provide the following evaluations during an initial home visit: (i) a home safety
24.9	assessment including whether there is a need to dispose of prescription drugs that are expired
24.10	or no longer needed; (ii) medication compliance; (iii) an HIV risk assessment; (iv) instruction
24.11	on the use of naloxone hydrochloride; and (v) a basic needs assessment;
24.12	(3) provide patients with health assessments, chronic disease monitoring and education,
24.13	and assistance in following hospital discharge orders; and
24.14	(4) work with a multidisciplinary team to address the overall physical and mental health
24.15	needs of patients and health needs related to substance use disorder treatment.
24.16	(c) An ambulance service receiving a grant under this section may use grant funds to
24.17	cover the cost of evidence-based training in opioid addiction and recovery treatment.
24.18	Subd. 3. Evaluation. An ambulance service that receives a grant under this section shall
24.19	evaluate the extent to which the project was successful in reducing the number of opioid
24.20	overdoses and opioid overdose deaths among patients who received services and in reducing
24.21	the inappropriate use of opioids by patients who received services. The commissioner of
24.22	health shall develop specific evaluation measures and reporting timelines for ambulance
24.23	services receiving grants. Ambulance services shall submit the information required by the
24.24	commissioner to the commissioner and the commissioner shall submit a summary of the
24.25	information reported by the ambulance services to the chairs and ranking minority members
24.26	of the legislative committees with jurisdiction over health and human services by December
24.27	<u>1, 2020.</u>
24.28	Sec. 11. APPROPRIATION.
24.29	(a) \$1,000,000 in fiscal year 2020 is appropriated from the general fund to the
24.30	commissioner of health for the opioid overdose reduction pilot program. This appropriation
24.31	is available until June 30, 2021. Of this appropriation, the commissioner may use up to

\$50,000 to administer the program. This is a onetime appropriation.

25.1	(b) \$150,000 is appropriated in fiscal year 2020 from the general fund to the commissioner
25.2	of health to award through a competitive request for proposal process a grant to an
25.3	organization to conduct a statewide inventory of nonnarcotic pain management, prevention,
25.4	and resiliency resources available through community organizations, health clinics, and
25.5	health care systems. By January 15, 2021, the commissioner shall submit the completed
25.6	inventory to the chairs and ranking minority members of the house of representatives and
25.7	senate committees with jurisdiction over health and human services policy and finance.
25.8	This is a onetime appropriation.
25.9	(c) \$2,000,000 in fiscal year 2020 and \$2,000,000 in fiscal year 2021 are appropriated
25.10	from the general fund to the commissioner of public safety for violent crime enforcement
25.11	team grants under Minnesota Statutes, section 299A.642, subdivision 9. In awarding these
25.12	grants, the commissioner must place a priority on funding nonmetro teams. The commissioner
25.13	of public safety shall provide outreach, technical assistance, and program development
25.14	support to increase the capacity of small communities to access grants under Minnesota
25.15	Statutes, section 299A.642, subdivision 9, particularly in areas where violent crime
25.16	enforcement teams have not been established, especially in greater Minnesota.
25.17	(d) Notwithstanding Minnesota Statutes, section 256.043, subdivision 2, paragraph (a),
25.18	if no fees are deposited into the opiate epidemic response account by June 30, 2020, for any
25.19	reason, \$ is appropriated from the general fund for the appropriations in fiscal year
25.20	2020 described in Minnesota Statutes, section 256.043, subdivision 2, paragraphs (c), (d),
25.21	(e), and (f).
25.22	(e) If appropriations are made under paragraph (d) and if money equal to the amount
25.23	appropriated in paragraph (d) is subsequently deposited into the opiate epidemic response
25.24	account, the amount appropriated under paragraph (d) must be transferred from the opiate
25.25	epidemic response account to the general fund.