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State of Minnesota

Printed Page No. 45

HOUSE OF REPRESENTATIVES

NINETY-FIRST SESSION H. F. No. 400

01/28/2019	Authored by Olson, Baker, Winkler, Koegel, Halverson and others
	The bill was read for the first time and referred to the Committee on Health and Human Services Policy
1/31/2019	Adoption of Report: Amended and re-referred to the Committee on Commerce
2/07/2019	Adoption of Report: Amended and re-referred to the Committee on Government Operations
2/14/2019	Adoption of Report: Amended and re-referred to the Committee on Ways and Means
3/07/2019	Adoption of Report: Placed on the General Register as Amended
	Read for the Second Time
3/18/2019	Calendar for the Day, Amended
	Read Third Time as Amended
	Passed by the House as Amended and transmitted to the Senate to include Floor Amendments
04/01/2019	Returned to the House as Amended by the Senate
	Refused to concur and a Conference Committee was appointed

05/21/2019 Conference Committee Report Adopted
Read Third Time as Amended by Conference and repassed by the House
Read Third Time as Amended by Conference and repassed by the Senate

A bill for an act 1.1 relating to health; establishing the opiate product registration fee and the Opiate 1.2 Epidemic Response Advisory Council; modifying certain licensure and registration 1.3 fees; modifying sections relating to prescription drugs and controlled substances; 1.4 requiring reports; appropriating money; amending Minnesota Statutes 2018, sections 1.5 16A.151, subdivision 2; 145C.05, subdivision 2; 151.01, subdivision 27; 151.065, 1.6 subdivisions 1, 3, by adding a subdivision; 151.252, subdivision 1; 151.37, 1.7 subdivision 12; 152.105, subdivision 2; 152.11, subdivisions 1, 2d, 4; 152.126, 1.8 subdivision 6; 214.12, by adding a subdivision; proposing coding for new law in 19

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

1.12 ARTICLE 1
1.13 OPIATE EPIDEMIC RESPONSE

Minnesota Statutes, chapters 145C; 151; 256.

Section 1. Minnesota Statutes 2018, section 16A.151, subdivision 2, is amended to read:

Subd. 2. **Exceptions.** (a) If a state official litigates or settles a matter on behalf of specific injured persons or entities, this section does not prohibit distribution of money to the specific injured persons or entities on whose behalf the litigation or settlement efforts were initiated. If money recovered on behalf of injured persons or entities cannot reasonably be distributed to those persons or entities because they cannot readily be located or identified or because the cost of distributing the money would outweigh the benefit to the persons or entities, the money must be paid into the general fund.

(b) Money recovered on behalf of a fund in the state treasury other than the general fund may be deposited in that fund.

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- (c) This section does not prohibit a state official from distributing money to a person or entity other than the state in litigation or potential litigation in which the state is a defendant or potential defendant.
- (d) State agencies may accept funds as directed by a federal court for any restitution or monetary penalty under United States Code, title 18, section 3663(a)(3) or United States Code, title 18, section 3663A(a)(3). Funds received must be deposited in a special revenue account and are appropriated to the commissioner of the agency for the purpose as directed by the federal court.
- (e) Tobacco settlement revenues as defined in section 16A.98, subdivision 1, paragraph (t), may be deposited as provided in section 16A.98, subdivision 12.
 - (f) Any money received by the state resulting from a settlement agreement or an assurance of discontinuance entered into by the attorney general of the state, or a court order in litigation brought by the attorney general of the state, on behalf of the state or a state agency, against one or more opioid manufacturers or opioid wholesale drug distributors related to alleged violations of consumer fraud laws in the marketing, sale, or distribution of opioids in this state or other alleged illegal actions that contributed to the excessive use of opioids, must be deposited in a separate account in the state treasury and the commissioner shall 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. This paragraph does not apply to attorney fees and costs awarded to the state or the Attorney General's Office, to contract attorneys hired by the state or Attorney General's Office, or to other state agency attorneys. If the licensing fees under section 151.065, subdivision 1, clause (16), and section 151.065, subdivision 3, clause (14), are reduced and the registration fee under section 151.066, subdivision 3, is repealed in accordance with section 256.043, subdivision 4, then the commissioner shall transfer from the separate account created in this paragraph to the opiate epidemic response account under section 256.043 an amount that ensures that \$20,940,000 each fiscal year is available for distribution in accordance with section 256.043, subdivisions 2 and 3.
- Sec. 2. Minnesota Statutes 2018, section 151.065, subdivision 1, is amended to read:
- 2.30 Subdivision 1. **Application fees.** Application fees for licensure and registration are as follows:
- 2.32 (1) pharmacist licensed by examination, \$145;
- 2.33 (2) pharmacist licensed by reciprocity, \$240;

- 3.1 (3) pharmacy intern, \$37.50;
- 3.2 (4) pharmacy technician, \$37.50;
- 3.3 (5) pharmacy, \$225;
- 3.4 (6) drug wholesaler, legend drugs only, \$235 \$5,000;
- 3.5 (7) drug wholesaler, legend and nonlegend drugs, \$235 \$5,000;
- 3.6 (8) drug wholesaler, nonlegend drugs, veterinary legend drugs, or both, \$210 \$5,000;
- 3.7 (9) drug wholesaler, medical gases, \$175 \\$5,000;
- 3.8 (10) drug wholesaler, also licensed as a pharmacy in Minnesota, \$150 \$5,000;
- 3.9 (11) drug manufacturer, nonopiate legend drugs only, \$235 \$5,000;
- 3.10 (12) drug manufacturer, nonopiate legend and nonlegend drugs, \$235 \$5,000;
- 3.11 (13) drug manufacturer, nonlegend or veterinary legend drugs, \$\frac{\$210}{5,000}\$;
- 3.12 (14) drug manufacturer, medical gases, \$\frac{\$185}{5,000};
- 3.13 (15) drug manufacturer, also licensed as a pharmacy in Minnesota, \$\frac{\$150}{5,000};
- 3.14 (16) drug manufacturer of opiate-containing controlled substances listed in section
- 3.15 152.02, subdivisions 3 to 5, \$55,000;
- 3.16 $\frac{(16)}{(17)}$ medical gas distributor, \$\frac{\$110}{\$}\$\$ \$5,000;
- 3.17 (18) controlled substance researcher, \$75; and
- 3.18 (18) (19) pharmacy professional corporation, \$125.
- 3.19 **EFFECTIVE DATE.** This section is effective July 1, 2019, and applies to any license
- issued on or after that date.
- Sec. 3. Minnesota Statutes 2018, section 151.065, subdivision 3, is amended to read:
- 3.22 Subd. 3. **Annual renewal fees.** Annual licensure and registration renewal fees are as
- 3.23 follows:
- 3.24 (1) pharmacist, \$145;
- 3.25 (2) pharmacy technician, \$37.50;
- 3.26 (3) pharmacy, \$225;
- 3.27 (4) drug wholesaler, legend drugs only, \$235 \$5,000;
- 3.28 (5) drug wholesaler, legend and nonlegend drugs, \$235 \$5,000;

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4.1	(6) drug wholesaler, nonlegend drugs, veterinary legend drugs, or both, \$210 \$5,000;
4.2	(7) drug wholesaler, medical gases, \$185 \(\frac{\$5,000}{} \);
4.3	(8) drug wholesaler, also licensed as a pharmacy in Minnesota, \$150 \$5,000;
4.4	(9) drug manufacturer, <u>nonopiate</u> legend drugs only, \$235_\$5,000;
4.5	(10) drug manufacturer, <u>nonopiate</u> legend and nonlegend drugs, \$235_\$5,000;
4.6	(11) drug manufacturer, nonlegend, veterinary legend drugs, or both, \$210 \\$5,000;
4.7	(12) drug manufacturer, medical gases, \$185 \(\frac{\$5,000}{} \);
4.8	(13) drug manufacturer, also licensed as a pharmacy in Minnesota, \$150 \$5,000;
4.9	(14) drug manufacturer of opiate-containing controlled substances listed in section
4.10	152.02, subdivisions 3 to 5, \$55,000;
4.11	(14) (15) medical gas distributor, \$110 \$5,000;
4.12	(15) (16) controlled substance researcher, \$75; and
4.13	(16) (17) pharmacy professional corporation, \$75.
4.14	EFFECTIVE DATE. This section is effective July 1, 2019, and applies to any license
4.15	renewed on or after that date.
4.16 4.17	Sec. 4. Minnesota Statutes 2018, section 151.065, is amended by adding a subdivision to read:
4.18	Subd. 7. Deposit of fees. (a) The license fees collected under this section, with the
4.19	exception of the fees identified in paragraphs (b) and (c), shall be deposited in the state
4.20	government special revenue fund.
4.21	(b) \$5,000 of each fee collected under subdivision 1, clauses (6) to (15) and (17), and
4.22	subdivision 3, clauses (4) to (13) and (15), and the fees collected under subdivision 1, clause
4.23	(16), and subdivision 3, clause (14), shall be deposited in the opiate epidemic response
4.24	account established in section 256.043.
4.25	(c) If the fees collected under subdivision 1, clause (16), or subdivision 3, clause (14),

account in section 256.043.

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are reduced, \$5,000 of the reduced fee shall be deposited in the opiate epidemic response

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Sec. 5. [151.066] OPIATE PRODUCT REGISTRATION FEE.

Subdivision 1. **Definition.** (a) For purposes of this section, the following terms have the meanings given to them in this subdivision.

- (b) "Manufacturer" means a manufacturer licensed under section 151.252 that is engaged in the manufacturing of an opiate.
- (c) "Opiate" means any opiate-containing controlled substance listed in section 152.02, subdivisions 3 to 5, that is distributed, delivered, sold, or dispensed into or within this state.
- (d) "Wholesaler" means a wholesale drug distributor licensed under section 151.47 that is engaged in the wholesale drug distribution of an opiate.
 - Subd. 2. Reporting requirements. (a) By March 1 of each year, beginning March 1, 2020, each manufacturer and each wholesaler must report to the board every sale, delivery, or other distribution within or into this state of any opiate 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 that occurred during the previous calendar year. Reporting must be in the automation of reports and consolidated orders system format unless otherwise specified by the board. 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 \$500 per day. This penalty shall not be considered a form of disciplinary action.
 - (b) By March 1 of each year, beginning March 1, 2020, each owner of a pharmacy with at least one location within this state must report to the board any intracompany delivery or distribution into this state, of any opiate, 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 pharmacy. Reporting must be in the manner and format specified by the board for deliveries and distributions that occurred during the previous calendar year. The report must include the name of the manufacturer or wholesaler from which the owner of the pharmacy ultimately purchased the opiate, and the amount and date that the purchase occurred.
 - Subd. 3. Determination of an opiate product registration fee. (a) The board shall annually assess an opiate product registration fee on any manufacturer of an opiate that annually sells, delivers, or distributes an opiate within or into the state 2,000,000 or more units as reported to the board under subdivision 2.

6.1	(b) The annual registration fee for each manufacturer meeting the requirement under
6.2	paragraph (a) is \$250,000.
6.3	(c) In conjunction with the data reported under this section, and notwithstanding section
6.4	152.126, subdivision 6, the board may use the data reported under section 152.126,
6.5	subdivision 4, to determine which manufacturers meet the requirement under paragraph (a)
6.6	and are required to pay the registration fees under this subdivision.
6.7	(d) By April 1 of each year, beginning April 1, 2020, the board shall notify a manufacturer
6.8	that the manufacturer meets the requirement in paragraph (a) and is required to pay the
6.9	annual registration fee in accordance with section 151.252, subdivision 1, paragraph (b).
6.10	(e) A manufacturer may dispute the board's determination that the manufacturer must
6.11	pay the registration fee no later than 30 days after the date of notification. However, the
6.12	manufacturer must still remit the fee as required by section 151.252, subdivision 1, paragraph
6.13	(b). The dispute must be filed with the board in the manner and using the forms specified
6.14	by the board. A manufacturer must submit, with the required forms, data satisfactory to the
6.15	board that demonstrates that the assessment of the registration fee was incorrect. The board
6.16	must make a decision concerning a dispute no later than 60 days after receiving the required
6.17	dispute forms. If the board determines that the manufacturer has satisfactorily demonstrated
6.18	that the fee was incorrectly assessed, the board must refund the amount paid in error.
6.19	(f) For purposes of this subdivision, a unit means the individual dosage form of the
6.20	particular drug product that is prescribed to the patient. One unit equals one tablet, capsule,
6.21	patch, syringe, milliliter, or gram.
6.22	Subd. 4. Report. (a) The Board of Pharmacy shall evaluate the registration fee on drug
6.23	manufacturers established under this section, and whether the registration fee and the
6.24	increased licensure fees have impacted the prescribing practices of opiates by reducing the
6.25	number of opiate prescriptions issued during calendar years 2021, 2022, and 2023, or creating
6.26	any unintended consequences in the availability of opiates for the treatment of chronic or
6.27	intractable pain to the extent the board has the ability to effectively identify a correlation.
6.28	Notwithstanding section 152.126, subdivision 6, the board may access the data reported
6.29	under section 152.126, subdivision 4, to conduct this evaluation.
6.30	(b) The board shall submit the results of its evaluation to the chairs and ranking minority
6.31	members of the legislative committees with jurisdiction over health and human services
6.32	policy and finance by March 1, 2024.
6.33	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),

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7.1	the reports from the commissioner of management and budget on the Results First evaluation
7.2	activities under section 256.042, subdivision 5, paragraph (b), the report from the Board of
7.3	Pharmacy under subdivision 4, and any other relevant report or information related to the
7.4	opioid crisis in Minnesota, to make a determination about whether the opiate product
7.5	registration fee assessed under this section should continue beyond July 1, 2024.
7.6	Sec. 6. Minnesota Statutes 2018, section 151.252, subdivision 1, is amended to read:

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

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which drugs that are shipped into the state are manufactured, except a manufacturer of opiate-containing controlled substances shall not be required to pay the fee under section 151.065, subdivision 1, clause (16), or 151.065, subdivision 3, clause (14), for more than one facility.

(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. 7. [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:

(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, the role of adult protective services in prevention and response, and providing financial support to local law enforcement agencies for opiate antagonist programs;

- (2) training on the treatment of opioid addiction, including the use of all Food and Drug Administration approved opioid addiction medications, detoxification, relapse prevention, patient assessment, individual treatment planning, counseling, recovery supports, diversion control, and other best practices;
- (3) the expansion and enhancement of a continuum of care for opioid-related substance use disorders, including primary prevention, early intervention, treatment, recovery, and aftercare services; and
- (4) the development of measures to assess and protect the ability of cancer patients and survivors, persons battling life threatening illnesses, persons suffering from severe chronic

9.1	pain, and persons at the end stages of life, who legitimately need prescription pain
9.2	medications, to maintain their quality of life by accessing these pain medications without
9.3	facing unnecessary barriers. The measures must also address the needs of individuals
9.4	described in this clause who are elderly or who reside in underserved or rural areas of the
9.5	state.
9.6	(b) The council shall:
9.7	(1) review local, state, and federal initiatives and activities related to education,
9.8	prevention, treatment, and services for individuals and families experiencing and affected
9.9	by opioid use disorder;
9.10 9.11	(2) establish priorities to address the state's opioid epidemic, for the purpose of recommending initiatives to fund;
9.12	(3) recommend to the commissioner of human services specific projects and initiatives
9.13	to be funded;
0.14	(4) ensure that available funding is allocated to align with other state and federal funding,
9.149.15	to achieve the greatest impact and ensure a coordinated state effort;
9.13	to achieve the greatest impact and clisure a coordinated state effort,
9.16	(5) consult with the commissioners of human services, health, and management and
9.17	budget to develop measurable outcomes to determine the effectiveness of funds allocated;
9.18	<u>and</u>
9.19	(6) develop recommendations for an administrative and organizational framework for
9.20	the allocation, on a sustainable and ongoing basis, of any money deposited into the separate
9.21	account under section 16A.151, subdivision 2, paragraph (f), in order to address the opioid
9.22	abuse and overdose epidemic in Minnesota and the areas of focus specified in paragraph
9.23	<u>(a).</u>
9.24	(c) The council, in consultation with the commissioner of management and budget, and
9.25	within available appropriations, shall select from the awarded grants projects that include
9.26	promising practices or theory-based activities for which the commissioner of management
9.27	and budget shall conduct evaluations using experimental or quasi-experimental design.
9.28	Grants awarded to proposals that include promising practices or theory-based activities and
9.29	that are selected for an evaluation shall be administered to support the experimental or
9.30	quasi-experimental evaluation and require grantees to collect and report information that is
9.31	needed to complete the evaluation. The commissioner of management and budget, under
9.32	section 15.08, may obtain additional relevant data to support the experimental or
9.33	quasi-experimental evaluation studies.

10.1	(d) The council, in consultation with the commissioners of human services, health, public
10.2	safety, and management and budget, shall establish goals related to addressing the opioid
10.3	epidemic and determine a baseline against which progress shall be monitored and set
10.4	measurable outcomes, including benchmarks. The goals established must include goals for
10.5	prevention and public health, access to treatment, and multigenerational impacts. The council
10.6	shall use existing measures and data collection systems to determine baseline data against
10.7	which progress shall be measured. The council shall include the proposed goals, the
10.8	measurable outcomes, and proposed benchmarks to meet these goals in its initial report to
10.9	the legislature under subdivision 5, paragraph (a), due January 31, 2021.
10.10	Subd. 2. Membership. (a) The council shall consist of the following 19 voting members,
10.11	appointed by the commissioner of human services except as otherwise specified, and three
10.12	nonvoting members:
10.13	(1) two members of the house of representatives, appointed in the following sequence:
10.14	the first from the majority party appointed by the speaker of the house and the second from
10.15	the minority party appointed by the minority leader. Of these two members, one member
10.16	must represent a district outside of the seven-county metropolitan area, and one member
10.17	must represent a district that includes the seven-county metropolitan area. The appointment
10.18	by the minority leader must ensure that this requirement for geographic diversity in
10.19	appointments is met;
10.20	(2) two members of the senate, appointed in the following sequence: the first from the
10.21	majority party appointed by the senate majority leader and the second from the minority
10.22	party appointed by the senate minority leader. Of these two members, one member must
10.23	represent a district outside of the seven-county metropolitan area and one member must
10.24	represent a district that includes the seven-county metropolitan area. The appointment by
10.25	the minority leader must ensure that this requirement for geographic diversity in appointments
10.26	is met;
10.27	(3) one member appointed by the Board of Pharmacy;
10.28	(4) one member who is a physician appointed by the Minnesota Medical Association;
10.29	(5) one member representing opioid treatment programs, sober living programs, or
10.30	substance use disorder programs licensed under chapter 245G;
10.31	(6) one member appointed by the Minnesota Society of Addiction Medicine who is an
10.32	addiction psychiatrist;

11.1	(7) one member representing professionals providing alternative pain management
11.2	therapies, including, but not limited to, acupuncture, chiropractic, or massage therapy;
11.3	(8) one member representing nonprofit organizations conducting initiatives to address
11.4	the opioid epidemic, with the commissioner's initial appointment being a member
11.5	representing the Steve Rummler Hope Network, and subsequent appointments representing
11.6	this or other organizations;
11.7	(9) one member appointed by the Minnesota Ambulance Association, who is serving
11.8	with an ambulance service as an emergency medical technician, advanced emergency
11.9	medical technician, or paramedic;
11.10	(10) one member representing the Minnesota courts who is a judge or law enforcement
11.11	officer;
11.12	(11) one public member who is a Minnesota resident and who is in opioid addiction
11.13	recovery;
11.14	(12) two members representing Indian tribes, one representing the Ojibwe tribes and
11.15	one representing the Dakota tribes;
11.16	(13) one public member who is a Minnesota resident and who is suffering from chronic
11.17	pain, intractable pain, or a rare disease or condition;
11.18	(14) one mental health advocate representing persons with mental illness;
11.19	(15) one member representing the Minnesota Hospital Association;
11.20	(16) one member representing a local health department; and
11.21	(17) the commissioners of human services, health, and corrections, or their designees,
11.22	who shall be ex officio nonvoting members of the council.
11.23	(b) The commissioner of human services shall coordinate the commissioner's
11.24	appointments to provide geographic, racial, and gender diversity, and shall ensure that at
11.25	least one-half of council members appointed by the commissioner reside outside of the
11.26	seven-county metropolitan area. Of the members appointed by the commissioner, to the
11.27	extent practicable, at least one member must represent a community of color
11.28	disproportionately affected by the opioid epidemic.
11.29	(c) The council is governed by section 15.059, except that members of the council shall
11.30	receive no compensation other than reimbursement for expenses. Notwithstanding section
11.31	15.059, subdivision 6, the council shall not expire.

12.1	(d) The chair shall convene the council at least quarterly, and may convene other meetings
12.2	as necessary. The chair shall convene meetings at different locations in the state to provide
12.3	geographic access, and shall ensure that at least one-half of the meetings are held at locations
12.4	outside of the seven-county metropolitan area.
12.5	(e) The commissioner of human services shall provide staff and administrative services
12.6	for the advisory council.
12.7	(f) The council is subject to chapter 13D.
12.8	Subd. 3. Conflict of interest. Advisory council members must disclose to the council,
12.9	refrain from participating in discussions, and recuse themselves from voting on any matter
12.10	before the council if the member has a conflict of interest. A conflict of interest means a
12.11	financial association that has the potential to bias or have the appearance of biasing a council
12.12	member's decision related to the opiate epidemic response grant decision process or other
12.13	council activities under this section.
12.14	Subd. 4. Grants. (a) The commissioner of human services shall submit a report of the
12.15	grants proposed by the advisory council to be awarded for the upcoming fiscal year to the
12.16	chairs and ranking minority members of the legislative committees with jurisdiction over
12.17	health and human services policy and finance, by March 1 of each year, beginning March
12.18	<u>1, 2020.</u>
12.19	(b) The commissioner of human services shall award grants from the opiate epidemic
12.20	response account under section 256.043. The grants shall be awarded to proposals selected
12.21	by the advisory council that address the priorities in subdivision 1, paragraph (a), clauses
12.22	(1) to (4), unless otherwise appropriated by the legislature. No more than three percent of
12.23	the grant amount may be used by a grantee for administration.
12.24	Subd. 5. Reports. (a) The advisory council shall report annually to the chairs and ranking
12.25	minority members of the legislative committees with jurisdiction over health and human
12.26	services policy and finance by January 31 of each year, beginning January 31, 2021. The
12.27	report shall include information about the individual projects that receive grants and the
12.28	overall role of the project in addressing the opioid addiction and overdose epidemic in
12.29	Minnesota. The report must describe the grantees and the activities implemented, along
12.30	with measurable outcomes as determined by the council in consultation with the
12.31	commissioner of human services and the commissioner of management and budget. At a
12.32	minimum, the report must include information about the number of individuals who received
12.33	information or treatment, the outcomes the individuals achieved, and demographic
12.34	information about the individuals participating in the project; an assessment of the progress

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toward achieving statewide access to qualified providers and comprehensive treatment and recovery services; and an update on the evaluations implemented by the commissioner of management and budget for the promising practices and theory-based projects that receive funding.

REVISOR

(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 (c), 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.

(c) The advisory council, in its annual report to the legislature under paragraph (a) due by January 31, 2024, shall include recommendations on whether the appropriations to the specified entities under this act should be continued, adjusted, or discontinued; whether funding should be appropriated for other purposes related to opioid abuse prevention, education, and treatment; and on the appropriate level of funding for existing and new uses.

Sec. 8. [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, paragraphs (b) and (c), shall be deposited into the account. Beginning in fiscal year 2021, the funds in the account are appropriated each fiscal year to the commissioner of human services, unless otherwise specified in law.

Subd. 2. Transfers from account to state agencies. (a) Beginning in fiscal year 2021, the commissioner of human services shall transfer the following amounts each fiscal year from the account to the agencies specified in this subdivision.

13.32 (b) \$126,000 to the Board of Pharmacy for the collection of the registration fees under
13.33 section 151.066.

(c) \$672,000 to the commissioner of public safety for the Bureau of Criminal

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Apprehension. Of this amount, \$384,000 is for drug scientists and lab supplies and \$288,000 14.2 14.3 is for special agent positions focused on drug interdiction and drug trafficking. Subd. 3. **Appropriations from account.** (a) After the transfers described in subdivision 14.4 14.5 2, and the appropriations in article 3, section 1, paragraphs (e), (f), (g), and (h) are made, 14.6 \$249,000 shall be allocated by the commissioner for the provision of administrative services to the Opiate Epidemic Response Advisory Council and for the administration of the grants 14.7 awarded under paragraph (c). 14.8 14.9 (b) After the transfers in subdivision 2 and the allocation of funds in paragraph (a) are 14.10 made, 50 percent of the remaining amount shall be distributed by the commissioner to county social service and tribal social service agencies to provide child protection services 14.11 to children and families who are affected by addiction. The commissioner shall distribute 14.12 this money proportionally to counties and tribal social service agencies based on out-of-home 14.13 placement episodes where parental drug abuse is the primary reason for the out-of-home 14.14 placement using data from the previous calendar year. County and tribal social service 14.15 agencies receiving funds from the opiate epidemic response account must annually report 14.16 to the commissioner on how the funds were used to provide child protection services, 14.17 including measurable outcomes, as determined by the commissioner. County social service 14.18 agencies and tribal social service agencies must not use funds received under this paragraph 14.19 to supplant current state or local funding received for child protection services for children 14.20 and families who are affected by addiction. 14.21 (c) After making the transfers in subdivision 2 and the allocation of funds in paragraphs 14.22 (a) and (b), the commissioner shall award grants as specified by the Opiate Epidemic 14.23 Response Advisory Council in accordance with section 256.042, unless otherwise 14.24 appropriated by the legislature. 14.25 14.26 Subd. 4. **Settlement**; sunset. (a) If the state receives a total sum of \$250,000,000 either as a result of a settlement agreement or an assurance of discontinuance entered into by the 14.27 14.28 attorney general of the state, or resulting from a court order in litigation brought by the attorney general of the state on behalf of the state or a state agency, against one or more 14.29 opioid manufacturers or opioid wholesale drug distributors related to alleged violations of 14.30 consumer fraud laws in the marketing, sale, or distribution of opioids in this state, or other 14.31 alleged illegal actions that contributed to the excessive use of opioids, or from the fees 14.32 collected under section 151.065, subdivisions 1 and 3, and section 151.066, that are deposited 14.33 into the opiate epidemic response account established in section 256.043, or from a 14.34 combination of both, the fees specified in section 151.065, subdivision 1, clause (16), and 14.35

15.1	section 151.065, subdivision 3, clause (14), shall be reduced to \$5,260, and the opiate
15.2	registration fee in section 151.066, subdivision 3, shall be repealed.
15.3	(b) The commissioner of management and budget shall inform the board of pharmacy,
15.4	the governor, and the legislature when the amount specified in paragraph (a) has been
15.5	reached. The board shall apply the reduced license fee for the next licensure period.
15.6	(c) Notwithstanding paragraph (a), the reduction of the license fee in section 151.065,
15.7	subdivisions 1 and 3, and the repeal of the registration fee in section 151.066 shall not occur
15.8	before July 1, 2024.
15.9	Sec. 9. OPIATE EPIDEMIC RESPONSE ADVISORY COUNCIL FIRST MEETING.
15.10	The commissioner of human services shall convene the first meeting of the Opiate
15.11	Epidemic Response Advisory Council established under Minnesota Statutes, section 256.042,
15.12	no later than October 1, 2019. The members shall elect a chair at the first meeting.
15.13	Sec. 10. REVISOR INSTRUCTION.
15.14	The fee increases in Minnesota Statutes, section 151.065, subdivisions 1 and 3 in this
15.15	act are in addition to any other fee increases in Minnesota Statutes, section 151.065,
15.16	subdivisions 1 and 3, enacted in 2019 regular or special sessions. If multiple fees are enacted,
15.17	the revisor of statutes shall add the fees together for publication in the 2020 Minnesota
15.18	Statutes Supplement to effectuate the intent of the legislature.
15.19	ARTICLE 2
15.20	OTHER PROVISIONS
15.21	Section 1. Minnesota Statutes 2018, section 145C.05, subdivision 2, is amended to read:
15.22	Subd. 2. Provisions that may be included. (a) A health care directive may include
15.23	provisions consistent with this chapter, including, but not limited to:
15.24	(1) the designation of one or more alternate health care agents to act if the named health
15.25	care agent is not reasonably available to serve;
15.26	(2) directions to joint health care agents regarding the process or standards by which the
15.27	health care agents are to reach a health care decision for the principal, and a statement
15.28	whether joint health care agents may act independently of one another;
15.29	(3) limitations, if any, on the right of the health care agent or any alternate health care
15.30	agents to receive, review, obtain copies of, and consent to the disclosure of the principal's

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16.1	medical records or to visit the principal when the principal is a patient in a health care
16.2	facility;

- (4) limitations, if any, on the nomination of the health care agent as guardian for purposes of sections 524.5-202, 524.5-211, 524.5-302, and 524.5-303;
- 16.5 (5) a document of gift for the purpose of making an anatomical gift, as set forth in chapter 16.6 525A, or an amendment to, revocation of, or refusal to make an anatomical gift;
- 16.7 (6) a declaration regarding intrusive mental health treatment under section 253B.03, 16.8 subdivision 6d, or a statement that the health care agent is authorized to give consent for 16.9 the principal under section 253B.04, subdivision 1a;
 - (7) a funeral directive as provided in section 149A.80, subdivision 2;
 - (8) limitations, if any, to the effect of dissolution or annulment of marriage or termination of domestic partnership on the appointment of a health care agent under section 145C.09, subdivision 2;
 - (9) specific reasons why a principal wants a health care provider or an employee of a health care provider attending the principal to be eligible to act as the principal's health care agent;
 - (10) health care instructions by a woman of child bearing age regarding how she would like her pregnancy, if any, to affect health care decisions made on her behalf; and
- 16.19 (11) health care instructions regarding artificially administered nutrition or hydration—
 16.20 and
- (12) health care instructions to prohibit administering, dispensing, or prescribing an opioid, except that these instructions must not be construed to limit the administering, dispensing, or prescribing an opioid to treat substance abuse, opioid dependence, or an overdose, unless otherwise prohibited in the health care directive.
 - (b) A health care directive may include a statement of the circumstances under which the directive becomes effective other than upon the judgment of the principal's attending physician in the following situations:
- (1) a principal who in good faith generally selects and depends upon spiritual means or prayer for the treatment or care of disease or remedial care and does not have an attending physician, may include a statement appointing an individual who may determine the principal's decision-making capacity; and

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(2) a principal who in good faith does not generally select a physician or a health care
facility for the principal's health care needs may include a statement appointing an individual
who may determine the principal's decision-making capacity, provided that if the need to
determine the principal's capacity arises when the principal is receiving care under the
direction of an attending physician in a health care facility, the determination must be made
by an attending physician after consultation with the appointed individual.

If a person appointed under clause (1) or (2) is not reasonably available and the principal is receiving care under the direction of an attending physician in a health care facility, an attending physician shall determine the principal's decision-making capacity.

(c) A health care directive may authorize a health care agent to make health care decisions for a principal even though the principal retains decision-making capacity.

Sec. 2. [145C.17] OPIOID INSTRUCTIONS ENTERED INTO HEALTH RECORD.

- At the request of the patient or health care agent, a health care provider shall enter into the patient's health care record any instructions relating to administering, dispensing, or prescribing an opioid.
- 17.16 Sec. 3. 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;
- 17.19 (2) compounding, labeling, and dispensing drugs and devices (except labeling by a
 17.20 manufacturer or packager of nonprescription drugs or commercially packaged legend drugs
 17.21 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;
 - (4) participation in drug and therapeutic device selection; drug administration for first dosage and medical emergencies; <u>intramuscular and subcutaneous administration used for the treatment of alcohol or opioid dependence;</u> drug regimen reviews; and drug or drug-related research;

18.1	(5) drug administration, through intramuscular and subcutaneous administration used
18.2	to treat mental illnesses as permitted under the following conditions:
18.3	(i) upon the order of a prescriber and the prescriber is notified after administration is
18.4	complete; or
18.5	(ii) pursuant to a protocol or collaborative practice agreement as defined by section
18.6	151.01, subdivisions 27b and 27c, and participation in the initiation, management,
18.7	modification, administration, and discontinuation of drug therapy is according to the protocol
18.8	or collaborative practice agreement between the pharmacist and a dentist, optometrist,
18.9	physician, podiatrist, or veterinarian, or an advanced practice registered nurse authorized
18.10	to prescribe, dispense, and administer under section 148.235. Any changes in drug therapy
18.11	or medication administration made pursuant to a protocol or collaborative practice agreement
18.12	must be documented by the pharmacist in the patient's medical record or reported by the
18.13	pharmacist to a practitioner responsible for the patient's care;
18.14	(5) (6) participation in administration of influenza vaccines to all eligible individuals
18.15	six years of age and older and all other vaccines to patients 13 years of age and older by
18.16	written protocol with a physician licensed under chapter 147, a physician assistant authorized
18.17	to prescribe drugs under chapter 147A, or an advanced practice registered nurse authorized
18.18	to prescribe drugs under section 148.235, provided that:
18.19	(i) the protocol includes, at a minimum:
18.20	(A) the name, dose, and route of each vaccine that may be given;
18.21	(B) the patient population for whom the vaccine may be given;
18.22	(C) contraindications and precautions to the vaccine;
18.23	(D) the procedure for handling an adverse reaction;
18.24	(E) the name, signature, and address of the physician, physician assistant, or advanced
18.25	practice registered nurse;
18.26	(F) a telephone number at which the physician, physician assistant, or advanced practice
18.27	registered nurse can be contacted; and
18.28	(G) the date and time period for which the protocol is valid;
18.29	(ii) the pharmacist has successfully completed a program approved by the Accreditation
18.30	Council for Pharmacy Education specifically for the administration of immunizations or a
18.31	program approved by the board;

19.1	(iii) the pharmacist utilizes the Minnesota Immunization Information Connection to
19.2	assess the immunization status of individuals prior to the administration of vaccines, except
19.3	when administering influenza vaccines to individuals age nine and older;
19.4	(iv) the pharmacist reports the administration of the immunization to the Minnesota
19.5	Immunization Information Connection; and
19.6	(v) the pharmacist complies with guidelines for vaccines and immunizations established
19.7	by the federal Advisory Committee on Immunization Practices, except that a pharmacist
19.8	does not need to comply with those portions of the guidelines that establish immunization
19.9	schedules when administering a vaccine pursuant to a valid, patient-specific order issued
19.10	by a physician licensed under chapter 147, a physician assistant authorized to prescribe
19.11	drugs under chapter 147A, or an advanced practice nurse authorized to prescribe drugs
19.12	under section 148.235, provided that the order is consistent with the United States Food
19.13	and Drug Administration approved labeling of the vaccine;
19.14	(6) (7) participation in the initiation, management, modification, and discontinuation of
19.15	drug therapy according to a written protocol or collaborative practice agreement between:
19.16	(i) one or more pharmacists and one or more dentists, optometrists, physicians, podiatrists,
19.17	or veterinarians; or (ii) one or more pharmacists and one or more physician assistants
19.18	authorized to prescribe, dispense, and administer under chapter 147A, or advanced practice
19.19	nurses authorized to prescribe, dispense, and administer under section 148.235. Any changes
19.20	in drug therapy made pursuant to a protocol or collaborative practice agreement must be
19.21	documented by the pharmacist in the patient's medical record or reported by the pharmacist
19.22	to a practitioner responsible for the patient's care;
19.23	(7) (8) participation in the storage of drugs and the maintenance of records;
19.24	(8) (9) patient counseling on therapeutic values, content, hazards, and uses of drugs and
19.25	devices;
19.26	(9) (10) offering or performing those acts, services, operations, or transactions necessary
19.27	in the conduct, operation, management, and control of a pharmacy; and
19.28	(10) (11) participation in the initiation, management, modification, and discontinuation
19.29	of therapy with opiate antagonists, as defined in section 604A.04, subdivision 1, pursuant
19.30	to:
19.31	(i) a written protocol as allowed under clause (6); or
19.32	(ii) a written protocol with a community health board medical consultant or a practitioner

designated by the commissioner of health, as allowed under section 151.37, subdivision 13.

20.1	Sec. 4. Minnesota Statutes 2018, section 151.37, subdivision 12, is amended to read:
20.2	Subd. 12. Administration of opiate antagonists for drug overdose. (a) A licensed
20.3	physician, a licensed advanced practice registered nurse authorized to prescribe drugs
20.4	pursuant to section 148.235, or a licensed physician assistant authorized to prescribe drugs
20.5	pursuant to section 147A.18 may authorize the following individuals to administer opiate
20.6	antagonists, as defined in section 604A.04, subdivision 1:
20.7	(1) an emergency medical responder registered pursuant to section 144E.27;
20.8	(2) a peace officer as defined in section 626.84, subdivision 1, paragraphs (c) and (d);
20.9	and
20.10	(3) correctional employees of a state or local political subdivision;
20.11	(4) staff of community-based health disease prevention or social service programs;
20.12	(5) a volunteer firefighter; and
20.13	(6) a licensed school nurse or certified public health nurse employed by, or under contract
20.14	with, a school board under section 121A.21.
20.15	(b) For the purposes of this subdivision, opiate antagonists may be administered by one
20.16	of these individuals only if:
20.17	(1) the licensed physician, licensed physician assistant, or licensed advanced practice
20.18	registered nurse has issued a standing order to, or entered into a protocol with, the individual;
20.19	and
20.20	(2) the individual has training in the recognition of signs of opiate overdose and the use
20.21	of opiate antagonists as part of the emergency response to opiate overdose.
20.22	(c) Nothing in this section prohibits the possession and administration of naloxone
20.23	pursuant to section 604A.04.
20.24	EFFECTIVE DATE. This section is effective the day following final enactment.
20.25	Sec. 5. Minnesota Statutes 2018, section 152.105, subdivision 2, is amended to read:
20.26	Subd. 2. Sheriff to maintain collection receptacle. (a) The sheriff of each county shall
20.27	maintain or contract for the maintenance of at least one collection receptacle for the disposal
20.28	of noncontrolled substances, pharmaceutical controlled substances, and other legend drugs,
20.29	as permitted by federal law. For purposes of this section, "legend drug" has the meaning
20.30	given in section 151.01, subdivision 17. The collection receptacle must comply with federal
20.31	law. In maintaining and operating the collection receptacle, the sheriff shall follow all

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applicable provisions of Code of Federal Regulations, title 21, parts 1300, 1301, 1304, 1305, 1307, and 1317, as amended through May 1, 2017.

- (b) A sheriff may meet the requirements of paragraph (a) by providing public educational information and making an alternative method available to the public, at no charge, for safely destroying unwanted legend drugs, including an at-home prescription drug deactivation and disposal product, so long as the alternative method meets the requirements of the Minnesota Pollution Control Agency, the United States Drug Enforcement Administration, and the Board of Pharmacy.
- Sec. 6. 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.

(e) Every licensed pharmacy shall distinctly label the container in which a controlled

substance is dispensed with the directions contained in the prescription for controlled substance. (f) No prescription for an opiate or narcotic pain reliever listed in Sched IV of section 152.02 may be initially dispensed more than 30 days after the the prescription was issued. No subsequent refills indicated on a prescription III or IV opiate or narcotic pain reliever may be dispensed more than 30 days after the previous date on which the prescription was initially filled or refilled. After refills for Schedule III or IV opiate or narcotic pain relievers have been use expired, no additional authorizations may be accepted for that prescription. therapy is necessary, a new prescription must be issued by the prescriber. Sec. 7. Minnesota Statutes 2018, section 152.11, subdivision 2d, is amendative and the control of th	
(f) No prescription for an opiate or narcotic pain reliever listed in Sched IV of section 152.02 may be initially dispensed more than 30 days after the the prescription was issued. No subsequent refills indicated on a prescription III or IV opiate or narcotic pain reliever may be dispensed more than 30 days after the previous date on which the prescription was initially filled or refilled. After refills for Schedule III or IV opiate or narcotic pain relievers have been use expired, no additional authorizations may be accepted for that prescription. therapy is necessary, a new prescription must be issued by the prescriber. Sec. 7. Minnesota Statutes 2018, section 152.11, subdivision 2d, is amendated.	the use of that
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Sec. 7. Minnesota Statutes 2018, section 152.11, subdivision 2d, is amend	If continued
	ded to read:
Subd. 2d. Identification requirement for Schedule II or III controlle	d substance
prescriptions. (a) No person may dispense a controlled substance included	l in Schedule II
or III Schedules II through V without requiring the person purchasing the c	ontrolled
substance, who need not be the <u>person patient</u> for whom the controlled substar	nce prescription
is written, to present valid photographic identification, unless the person pu	irchasing the
controlled substance , or if applicable the person for whom the controlled su	ıbstance
prescription is written, is known to the dispenser. A doctor of veterinary me	edicine 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.
Sec. 8. Minnesota Statutes 2018, section 152.11, subdivision 4, is amende	ed to read:
Subd. 4. Limit on quantity of opiates prescribed for acute dental and	d ophthalmic
pain. (a) When used for the treatment of acute pain, prescriptions for opiate	es or narcotic
pain relievers listed in Schedules II through IV in section 152.02 shall not exce	eed a seven-day
supply for an adult and shall not exceed a five-day supply for a minor unde	r 18 years of
22.28 <u>age.</u>	
(a) (b) Notwithstanding paragraph (a), when used for the treatment of ac	ute 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 liste	
II through IV of section 152.02 shall not exceed a four-day supply. The quar	ed in Schedules

shall be consistent with the dosage listed in the professional labeling for the drug that has 23.1 been approved by the United States Food and Drug Administration. 23.2 (b) (c) For the purposes of this subdivision, "acute pain" means pain resulting from 23.3 disease, accidental or intentional trauma, surgery, or another cause, that the practitioner 23.4 reasonably expects to last only a short period of time. Acute pain does not include chronic 23.5 pain or pain being treated as part of cancer care, palliative care, or hospice or other end-of-life 23.6 care. 23.7 (c) Notwithstanding paragraph (a), if in the professional clinical judgment of a practitioner 23.8 more than a four-day supply of a prescription listed in Schedules II through IV of section 23.9 152.02 is required to treat a patient's acute pain, the practitioner may issue a prescription 23.10 for the quantity needed to treat such acute pain. 23.11 (d) Notwithstanding paragraph (a) or (b), if, in the professional clinical judgment of a 23.12 practitioner, more than the limit specified in paragraph (a) or (b) is required to treat a patient's 23.13 acute pain, the practitioner may issue a prescription for the quantity needed to treat the 23.14 patient's acute pain. 23.15 23.16 Sec. 9. Minnesota Statutes 2018, section 152.126, subdivision 6, is amended to read: Subd. 6. Access to reporting system data. (a) Except as indicated in this subdivision, 23.17 the data submitted to the board under subdivision 4 is private data on individuals as defined 23.18 in section 13.02, subdivision 12, and not subject to public disclosure. 23.19 (b) Except as specified in subdivision 5, the following persons shall be considered 23.20 permissible users and may access the data submitted under subdivision 4 in the same or 23.21 similar manner, and for the same or similar purposes, as those persons who are authorized 23.22 to access similar private data on individuals under federal and state law: 23.23 (1) a prescriber or an agent or employee of the prescriber to whom the prescriber has 23.24 delegated the task of accessing the data, to the extent the information relates specifically to 23.25 a current patient, to whom the prescriber is: 23.26 (i) prescribing or considering prescribing any controlled substance; 23.27 (ii) providing emergency medical treatment for which access to the data may be necessary; 23.28 (iii) providing care, and the prescriber has reason to believe, based on clinically valid 23.29 indications, that the patient is potentially abusing a controlled substance; or 23.30

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for a clinically valid purpose and the patient has consented to access to the submitted data,

(iv) providing other medical treatment for which access to the data may be necessary

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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;

25.1	(9) personnel of the Minnesota health care programs assigned to use the data collected
25.2	under this section to identify and manage recipients whose usage of controlled substances
25.3	may warrant restriction to a single primary care provider, a single outpatient pharmacy, and
25.4	a single hospital;
25.5	(10) personnel of the Department of Human Services assigned to access the data pursuant
25.6	to paragraph (i);
25.7	(11) personnel of the health professionals services program established under section
25.8	214.31, to the extent that the information relates specifically to an individual who is currently
25.9	enrolled in and being monitored by the program, and the individual consents to access to
25.10	that information. The health professionals services program personnel shall not provide this
25.11	data to a health-related licensing board or the Emergency Medical Services Regulatory
25.12	Board, except as permitted under section 214.33, subdivision 3-; and
25.13	For purposes of clause (4), access by an individual includes persons in the definition of
25.14	an individual under section 13.02; and
25.15	(12) personnel or designees of a health-related licensing board listed in section 214.01,
25.16	subdivision 2, assigned to conduct a bona fide investigation of a complaint received by that
25.17	board that alleges that a specific licensee is inappropriately prescribing controlled substances
25.18	as defined in this section.
25.19	(c) By July 1, 2017, every prescriber licensed by a health-related licensing board listed
25.20	in section 214.01, subdivision 2, practicing within this state who is authorized to prescribe
25.21	controlled substances for humans and who holds a current registration issued by the federal
25.22	Drug Enforcement Administration, and every pharmacist licensed by the board and practicing
25.23	within the state, shall register and maintain a user account with the prescription monitoring
25.24	program. Data submitted by a prescriber, pharmacist, or their delegate during the registration
25.25	application process, other than their name, license number, and license type, is classified
25.26	as private pursuant to section 13.02, subdivision 12.
25.27	(d) Notwithstanding paragraph (b), beginning January 1, 2021, a prescriber or an agent
25.28	or employee of the prescriber to whom the prescriber has delegated the task of accessing
25.29	the data, must access the data submitted under subdivision 4 to the extent the information
25.30	relates specifically to the patient:
25.31	(1) before the prescriber issues an initial prescription order for a Schedules II through

IV opiate controlled substance to the patient; and

26.1	(2) at least once every three months for patients receiving an opiate for treatment of
26.2	chronic pain or participating in medically assisted treatment for an opioid addiction.
26.3	(e) Paragraph (d) does not apply if:
26.4	(1) the patient is receiving palliative care, or hospice or other end-of-life care;
26.5	(2) the patient is being treated for pain due to cancer or the treatment of cancer;
26.6	(3) the prescription order is for a number of doses that is intended to last the patient five
26.7	days or less and is not subject to a refill;
26.8	(4) the prescriber and patient have a current or ongoing provider/patient relationship of
26.9	a duration longer than one year;
26.10	(5) the prescription order is issued within 14 days following surgery or three days
26.11	following oral surgery or follows the prescribing protocols established under the opioid
26.12	prescribing improvement program under section 256B.0638;
26.13	(6) the controlled substance is prescribed or administered to a patient who is admitted
26.14	to an inpatient hospital;
26.15	(7) the controlled substance is lawfully administered by injection, ingestion, or any other
26.16	means to the patient by the prescriber, a pharmacist, or by the patient at the direction of a
26.17	prescriber and in the presence of the prescriber or pharmacist;
26.18	(8) due to a medical emergency, it is not possible for the prescriber to review the data
26.19	before the prescriber issues the prescription order for the patient; or
26.20	(9) the prescriber is unable to access the data due to operational or other technological
26.21	failure of the program so long as the prescriber reports the failure to the board.
26.22	(f) Only permissible users identified in paragraph (b), clauses (1), (2), (3), (6), (7), (9),
26.23	and (10), may directly access the data electronically. No other permissible users may directly
26.24	access the data electronically. If the data is directly accessed electronically, the permissible
26.25	user shall implement and maintain a comprehensive information security program that
26.26	contains administrative, technical, and physical safeguards that are appropriate to the user's
26.27	size and complexity, and the sensitivity of the personal information obtained. The permissible
26.28	user shall identify reasonably foreseeable internal and external risks to the security,
26.29	confidentiality, and integrity of personal information that could result in the unauthorized
26.30	disclosure, misuse, or other compromise of the information and assess the sufficiency of
26.31	any safeguards in place to control the risks.

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(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
- 27.24 (2) direct the medical director of the opioid treatment program to access the data directly, 27.25 review the effect of the multiple prescribers or multiple prescriptions, and document the 27.26 review.
- 27.27 If determined necessary, the commissioner of human services shall seek a federal waiver 27.28 of, or exception to, any applicable provision of Code of Federal Regulations, title 42, section 27.29 2.34, paragraph (c), prior to implementing this paragraph.
 - (j) (l) 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. 10. Minnesota Statutes 2018, section 214.12, is amended by adding a subdivision to

Subd. 6. Opioid and controlled substances prescribing. (a) The Board of Medical
Practice, the Board of Nursing, the Board of Dentistry, the Board of Optometry, and the
Board of Podiatric Medicine shall require that licensees with the authority to prescribe
controlled substances obtain at least two hours of continuing education credit on best practices
in prescribing opioids and controlled substances, including nonpharmacological and
implantable device alternatives for treatment of pain and ongoing pain management, as part
of the continuing education requirements for licensure renewal. Licensees shall not be
required to complete more than two credit hours of continuing education on best practices
in prescribing opioids and controlled substances before this subdivision expires. Continuing
education credit on best practices in prescribing opioids and controlled substances must
meet board requirements.
(b) Paragraph (a) does not apply to any licensee who is participating in the opioid
prescribing improvement program under section 256B.0638, unless the licensee has been
terminated as a medical assistance provider under section 256B.0638, subdivision 5,
paragraph (d).
(c) This subdivision expires January 1, 2023.
EFFECTIVE DATE. This section is effective January 1, 2020.
ARTICLE 3
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APPROPRIATIONS Section 1. APPROPRIATIONS. (a) Board of Pharmacy; administration. \$244,000 in fiscal year 2020 is appropriated from the general fund to the Board of Pharmacy for onetime information technology and operating costs for administration of licensing activities under Minnesota Statutes, section 151.066. This is a onetime appropriation. (b) Commissioner of human services; administration. \$309,000 in fiscal year 2020 is appropriated from the general fund and \$60,000 in fiscal year 2021 is appropriated from the opiate epidemic response account to the commissioner of human services for the provision of administrative services to the Opiate Epidemic Response Advisory Council and for the

29.1	(c) Board of Pharmacy; administration. \$126,000 in fiscal year 2020 is appropriated
29.2	from the general fund to the Board of Pharmacy for the collection of the registration fees
29.3	under section 151.066.
29.4	(d) Commissioner of public safety; enforcement activities. \$672,000 in fiscal year
29.5	2020 is appropriated from the general fund to the commissioner of public safety for the
29.6	Bureau of Criminal Apprehension. Of this amount, \$384,000 is for drug scientists and lab
29.7	supplies and \$288,000 is for special agent positions focused on drug interdiction and drug
29.8	trafficking.
29.9	(e) Commissioner of management and budget; evaluation activities. \$300,000 in
29.10	fiscal year 2020 is appropriated from the general fund and \$300,000 in fiscal year 2021 is
29.11	appropriated from the opiate epidemic response account to the commissioner of management
29.12	and budget for evaluation activities under Minnesota Statutes, section 256.042, subdivision
29.13	1, paragraph (c). The opiate epidemic response account base for this appropriation is \$300,000
29.14	in fiscal year 2022, \$300,000 in fiscal year 2023, \$300,000 in fiscal year 2024, and \$0 in
29.15	fiscal year 2025.
29.16	(f) Commissioner of human services; grants for Project ECHO. \$400,000 in fiscal
29.17	year 2020 is appropriated from the general fund and \$400,000 in fiscal year 2021 is
29.18	appropriated from the opiate epidemic response account to the commissioner of human
29.19	services for grants of \$200,000 to CHI St. Gabriel's Health Family Medical Center for the
29.20	opioid-focused Project ECHO program and \$200,000 to Hennepin Health Care for the
29.21	opioid-focused Project ECHO program. The opiate epidemic response account base for this
29.22	appropriation is \$400,000 in fiscal year 2022, \$400,000 in fiscal year 2023, \$400,000 in
29.23	fiscal year 2024, and \$0 in fiscal year 2025.
29.24	(g) Commissioner of human services; opioid overdose prevention grant. \$100,000
29.25	in fiscal year 2020 is appropriated from the general fund and \$100,000 in fiscal year 2021
29.26	is appropriated from the opiate epidemic response account to the commissioner of human
29.27	services for a grant to a nonprofit organization that has provided overdose prevention
29.28	programs to the public in at least 60 counties within the state, for at least three years, has
29.29	received federal funding before January 1, 2019, and is dedicated to addressing the opioid
29.30	epidemic. The grant must be used for opioid overdose prevention, community asset mapping,
29.31	education, and overdose antagonist distribution. The opiate epidemic response account base
29.32	for this appropriation is \$100,000 in fiscal year 2022, \$100,000 in fiscal year 2023, \$100,000
29.33	in fiscal year 2024, and \$0 in fiscal year 2025.

30.1	(h) Commissioner of human services; traditional healing. \$2,000,000 in fiscal year
30.2	2020 is appropriated from the general fund and \$2,000,000 in fiscal year 2021 is appropriated
30.3	from the opiate epidemic response account to the commissioner of human services to award
30.4	grants to tribal nations and five urban Indian communities for traditional healing practices
30.5	to American Indians and to increase the capacity of culturally specific providers in the
30.6	behavioral health workforce. The opiate epidemic response account base for this appropriation
30.7	is \$2,000,000 in fiscal year 2022, \$2,000,000 in fiscal year 2023, \$2,000,000 in fiscal year
30.8	2024, and \$0 in fiscal year 2025.
30.9	(i) Board of Dentistry; continuing education. \$11,000 in fiscal year 2020 is
30.10	appropriated from the state government special revenue fund to the Board of Dentistry to
30.11	implement the continuing education requirements under Minnesota Statutes, section 214.12,
30.12	subdivision 6.
30.13	(j) Board of Medical Practice; continuing education. \$17,000 in fiscal year 2020 is
30.14	appropriated from the state government special revenue fund to the Board of Medical Practice
30.15	to implement the continuing education requirements under Minnesota Statutes, section
30.16	214.12, subdivision 6.
30.17	(k) Board of Nursing; continuing education. \$17,000 in fiscal year 2020 is appropriated
30.18	from the state government special revenue fund to the Board of Nursing to implement the
30.19	continuing education requirements under Minnesota Statutes, section 214.12, subdivision
30.20	<u>6.</u>
30.21	(1) Board of Optometry; continuing education. \$5,000 in fiscal year 2020 is
30.22	appropriated from the state government special revenue fund to the Board of Optometry to
30.23	implement the continuing education requirements under Minnesota Statutes, section 214.12,
30.24	subdivision 6.
30.25	(m) Board of Podiatric Medicine; continuing education. \$5,000 in fiscal year 2020
30.26	is appropriated from the state government special revenue fund to the Board of Podiatric
30.27	Medicine to implement the continuing education requirements under Minnesota Statutes,
30.28	section 214.12, subdivision 6.
30.29	(n) Commissioner of health; nonnarcotic pain management and wellness. \$1,250,000
30.30	is appropriated in fiscal year 2020 from the general fund to the commissioner of health, to
30.31	provide funding for:
30.32	(1) statewide mapping and assessment of community-based nonnarcotic pain management
30.33	and wellness resources; and

31.1	(2) up to five demonstration projects in different geographic areas of the state to provide
31.2	community-based nonnarcotic pain management and wellness resources to patients and
31.3	consumers.
31.4	The demonstration projects must include an evaluation component and scalability analysis.
31.5	The commissioner shall award the grant for the statewide mapping and assessment, and the
31.6	demonstration project grants, through a competitive request for proposal process. Grants
31.7	for statewide mapping and assessment and demonstration projects may be awarded
31.8	simultaneously. In awarding demonstration project grants, the commissioner shall give
31.9	preference to proposals that incorporate innovative community partnerships, are informed
31.10	and led by people in the community where the project is taking place, and are culturally
31.11	relevant and delivered by culturally competent providers. This is a onetime appropriation.
31.12	(o) Commissioner of health; administration. \$38,000 in fiscal year 2020 is appropriated
31.13	from the general fund to the commissioner of health for the administration of the grants
31.14	awarded in paragraph (n).
31.15	Sec. 2. TRANSFER.
31.16	By June 30, 2021, the commissioner of human services shall transfer \$5,439,000 from
31.17	the opiate epidemic response account to the general fund. This is a onetime transfer.
31.18	Sec. 3. EXPIRATION OF UNCODIFIED LANGUAGE.

The uncodified language in this article shall not expire on June 30, 2021.