

SENATE
STATE OF MINNESOTA
NINETIETH SESSION

S.F. No. 730

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

1.1 A bill for an act

1.2 relating to health; establishing an opiate stewardship program; appropriating money;

1.3 requiring a report; amending Minnesota Statutes 2016, sections 151.065, by adding

1.4 a subdivision; 151.252, subdivision 1; proposing coding for new law in Minnesota

1.5 Statutes, chapter 151.

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

1.7 Section 1. Minnesota Statutes 2016, section 151.065, is amended by adding a subdivision

1.8 to read:

1.9 Subd. 3a. **Stewardship fee.** (a) In addition to the annual renewal fee specified under

1.10 subdivision 3, any drug manufacturer licensed under section 151.252 that sells opiates listed

1.11 under section 152.02, subdivision 3, paragraph (b) or (c), in this state shall pay an annual

1.12 stewardship fee.

1.13 (b) Annually by March 1, beginning March 1, 2018, a manufacturer must report to the

1.14 board the quantity of each opiate listed in section 152.02, subdivision 3, paragraphs (b) and

1.15 (c), that the manufacturer sold in the state in the previous calendar year. The board shall

1.16 use the information in the report to calculate the stewardship fee for each manufacturer.

1.17 The stewardship fee shall be equal to one cent per morphine milligram equivalent of opiates

1.18 listed in section 152.02, subdivision 3, paragraphs (b) and (c). The board shall use a morphine

1.19 equivalent chart published by the Centers for Disease Control and Prevention or another

1.20 reputable source to calculate morphine equivalents. If there is no commonly accepted

1.21 morphine equivalent for an opiate in a manufacturer's report, the board shall determine an

1.22 appropriate conversion based on its knowledge and expertise and shall notify the

1.23 manufacturer of the conversion value and method.

2.1 (c) The stewardship fees received by the board under this subdivision shall be deposited
2.2 in the state treasury and credited to the opiate stewardship account established under section
2.3 151.255.

2.4 Sec. 2. Minnesota Statutes 2016, section 151.252, subdivision 1, is amended to read:

2.5 Subdivision 1. **Requirements.** (a) No person shall act as a drug manufacturer without
2.6 first obtaining a license from the board and paying any applicable fee specified in section
2.7 151.065.

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

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

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

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

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

2.26 (g) The board shall not issue an initial or renewed license for a drug manufacturing
2.27 facility unless the facility passes an inspection conducted by an authorized representative
2.28 of the board. In the case of a drug manufacturing facility located outside of the state, the
2.29 board may require the applicant to pay the cost of the inspection, in addition to the license
2.30 fee in section 151.065, unless the applicant furnishes the board with a report, issued by the
2.31 appropriate regulatory agency of the state in which the facility is located or by the United
2.32 States Food and Drug Administration, of an inspection that has occurred within the 24
2.33 months immediately preceding receipt of the license application by the board. The board

3.1 may deny licensure unless the applicant submits documentation satisfactory to the board
3.2 that any deficiencies noted in an inspection report have been corrected.

3.3 (h) The board shall not renew the license of any drug manufacturer that is required to
3.4 pay the stewardship fee under section 151.065, subdivision 3a, unless the drug manufacturer
3.5 pays the board the required fee in accordance with section 151.065, subdivision 3a.

3.6 **Sec. 3. [151.255] OPIATE PRODUCT STEWARDSHIP.**

3.7 Subdivision 1. Establishment of the advisory council. (a) The Opiate Product
3.8 Stewardship Advisory Council is established to confront the opioid addiction and overdose
3.9 epidemic in this state and focus on:

3.10 (1) prevention and education, including public education and awareness for adults and
3.11 youth, prescriber education, and the development and sustainability of opioid overdose
3.12 prevention programs;

3.13 (2) a continuum of care for opioid-related substance use disorders that expands and
3.14 enhances all modalities of treatment from detox to sober housing; and

3.15 (3) services to ensure overdose prevention as well as public safety and community
3.16 well-being, including expanding access to naloxone and providing social services to families
3.17 affected by the opioid overdose epidemic.

3.18 (b) The council shall:

3.19 (1) review local, state, and federal initiatives and activities related to education,
3.20 prevention, and services for individuals and families experiencing and affected by opioid
3.21 abuse;

3.22 (2) establish priorities and actions to address the state's opioid epidemic for the purpose
3.23 of allocating funds;

3.24 (3) ensure optimal allocation of available funding and alignment of existing state and
3.25 federal funding to achieve the greatest impact and ensure a coordinated state effort;

3.26 (4) develop criteria and procedures to be used in awarding grants and allocating available
3.27 funds from the opiate stewardship account; and

3.28 (5) develop measurable outcomes to determine the effectiveness of the funds allocated
3.29 under this section.

3.30 (c) The council shall make recommendations on possible grant and funding options for
3.31 the funds annually appropriated to the commissioner of human services from the opiate

4.1 stewardship account. The options for funding may include prescriber education, the
4.2 development and sustainability of prevention programs, the creation of a continuum of care
4.3 for opioid-related substance abuse disorders from detox to sober houses, and additional
4.4 funding for child protection case management services for children and families affected
4.5 by opioid addiction.

4.6 (d) The council shall submit recommendations for possible funding options to the chairs
4.7 and ranking minority members of the legislative committees with jurisdiction over health
4.8 and human services policy and finance by March 1 of each year beginning March 1, 2019.

4.9 Subd. 2. **Membership.** (a) The council shall consist of 17 members appointed by the
4.10 commissioner of human services, except as otherwise specified:

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

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

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

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

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

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

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

4.24 (8) one member representing a pain psychologist;

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

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

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

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

4.31 (13) one member representing an Indian tribe;

5.1 (14) the commissioner of human services or designee; and

5.2 (15) the commissioner of health or designee.

5.3 (b) Except for section 15.059, subdivisions 2 and 3, section 15.059 shall apply to the
5.4 council and all the council member appointments, except those members who are
5.5 commissioners or their designees. The members of the council shall receive no compensation
5.6 other than reimbursement for expenses. Notwithstanding section 15.059, subdivision 6, the
5.7 council shall not expire.

5.8 (c) The chair must convene the council at least quarterly, and may convene other meetings
5.9 as deemed necessary.

5.10 (d) The commissioner of human services shall provide staff for administrative services
5.11 for the advisory council.

5.12 Subd. 3. **Dedicated account.** (a) The opiate stewardship account is created in the special
5.13 revenue fund in the state treasury. The fees collected by the Board of Pharmacy under section
5.14 151.065, subdivision 3a, shall be deposited in the account.

5.15 (b) In fiscal year 2018, money in the account is appropriated to the commissioner of
5.16 human services to be allocated in accordance with section 4.

5.17 (c) Beginning July 1, 2019, and each fiscal year thereafter, money in the account shall
5.18 be appropriated to the commissioner of human services to be awarded as grants as determined
5.19 appropriate to address the opioid epidemic in the state.

5.20 Sec. 4. **OPIOID ABUSE PREVENTION GRANTS FOR FISCAL YEAR 2018.**

5.21 Subdivision 1. **Opioid prescriber education and public awareness grants.** For fiscal
5.22 year 2018, from the funds appropriated to the commissioner of human services from the
5.23 opiate stewardship account established in Minnesota Statutes, section 151.255, subdivision
5.24 3, the commissioner of human services shall award up to \$1,000,000 in grants to nonprofit
5.25 organizations for the purpose of expanding prescriber education, public awareness and
5.26 outreach on the opioid epidemic and overdose prevention programs. The grantees must
5.27 coordinate with health care systems, professional associations, and emergency medical
5.28 services providers. Each grantee receiving funds under this paragraph shall report to the
5.29 commissioner of human services and the Opiate Product Stewardship Advisory Council on
5.30 how the funds were spent and the outcomes achieved.

5.31 Subd. 2. **County social services.** For fiscal year 2018, \$15,000,000 of the funds
5.32 appropriated to the commissioner of human services from the opiate stewardship account

6.1 established in Minnesota Statutes, section 151.255, subdivision 3, shall be used for county
6.2 social services agencies to provide services to children in placement who are affected by
6.3 opioid addiction. The commissioner shall distribute the money allocated under this
6.4 subdivision proportionally to counties based on the number of open child protection case
6.5 management cases in the county using data from the previous calendar year.

6.6 Subd. 3. **Pilot projects.** (a) For fiscal year 2018, from the funds appropriated to the
6.7 commissioner of human services from the opiate stewardship account in Minnesota Statutes,
6.8 section 151.255, subdivision 3, the commissioner of human services shall transfer \$2,500,000
6.9 to the commissioner of health to establish up to 12 opioid abuse prevention pilot projects.

6.10 (b) Each pilot project must:

6.11 (1) be designed to reduce emergency room and other health care provider visits resulting
6.12 from opioid use or abuse, and reduce rates of opioid addiction in the community;

6.13 (2) establish multi-disciplinary controlled substance care teams, that may consist of
6.14 physicians, pharmacists, social workers, nurse care coordinators, and mental health
6.15 professionals;

6.16 (3) deliver health care services and care coordination, through controlled substance care
6.17 teams, to reduce the inappropriate use of opioids by patients and rates of opioid addiction;

6.18 (4) address any unmet social service needs that create barriers to managing pain
6.19 effectively and obtaining optimal health outcomes;

6.20 (5) provide prescriber and dispenser education and assistance to reduce the inappropriate
6.21 prescribing and dispensing of opioids;

6.22 (6) promote the adoption of best practices related to opioid disposal and reducing
6.23 opportunities for illegal access to opioids; and

6.24 (7) engage partners outside of the health care system, including schools, law enforcement,
6.25 and social services, to address root causes of opioid abuse and addiction at the community
6.26 level.

6.27 (c) The commissioner shall contract with an accountable community for health that
6.28 operates an opioid abuse prevention project, and can document success in reducing opioid
6.29 use through the use of controlled substance care teams, to assist the commissioner in
6.30 administering this section, and to provide technical assistance to the commissioner and to
6.31 entities selected to operate a pilot project.

7.1 (d) The contract under paragraph (c) shall require the accountable community for health
7.2 to evaluate the extent to which the pilot projects were successful in reducing the inappropriate
7.3 use of opioids. The evaluation must analyze changes in the number of opioid prescriptions,
7.4 the number of emergency room visits related to opioid use, and other relevant measures.
7.5 The accountable community for health shall report evaluation results to the chairs and
7.6 ranking minority members of the legislative committees with jurisdiction over health and
7.7 human services policy and finance and public safety, by December 15, 2019.

7.8 Subd. 4. **Board of Pharmacy.** For fiscal year 2018, from the funds appropriated to the
7.9 commissioner of human services from the opiate stewardship account in Minnesota Statutes,
7.10 section 151.255, subdivision 3, the commissioner shall transfer \$50,000 to the Board of
7.11 Pharmacy to be used for system changes needed to collect the stewardship fee specified in
7.12 Minnesota Statutes, section 151.065, subdivision 3a.

7.13 Sec. 5. **OPIATE PRODUCT STEWARDSHIP ADVISORY COUNCIL FIRST**
7.14 **MEETING.**

7.15 The commissioner of human services shall convene the first meeting of the Opiate
7.16 Product Stewardship Advisory Council no later than October 1, 2017. The members shall
7.17 elect a chair at the first meeting.