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State of Minnesota
HOUSE OF REPRESENTATIVES
NINETIETH SESSION

H. F. No. 4516

05/16/2018 Authored by Sundin, Olson and Clark
The bill was read for the first time and referred to the Committee on Health and Human Services Reform

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, subdivision
1.4 3; 151.252, subdivision 1; proposing coding for new law in Minnesota Statutes,
1.5 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, subdivision 3, is amended to read:

1.8 Subd. 3. **Annual renewal fees.** Annual licensure and registration renewal fees are as
1.9 follows:

- 1.10 (1) pharmacist, \$145;
- 1.11 (2) pharmacy technician, \$37.50;
- 1.12 (3) pharmacy, \$225;
- 1.13 (4) drug wholesaler, legend drugs only, \$235;
- 1.14 (5) drug wholesaler, legend and nonlegend drugs, \$235;
- 1.15 (6) drug wholesaler, nonlegend drugs, veterinary legend drugs, or both, \$210;
- 1.16 (7) drug wholesaler, medical gases, \$185;
- 1.17 (8) drug wholesaler, also licensed as a pharmacy in Minnesota, \$150;
- 1.18 (9) drug manufacturer, legend drugs only, \$235;
- 1.19 (10) drug manufacturer, legend and nonlegend drugs, \$235;
- 1.20 (11) drug manufacturer, nonlegend, veterinary legend drugs, or both, \$210;

- 2.1 (12) drug manufacturer, medical gases, \$185;
- 2.2 (13) drug manufacturer, also licensed as a pharmacy in Minnesota, \$150;
- 2.3 (14) drug manufacturer, stewardship fee, one cent per morphine equivalent milligram
- 2.4 of opiates sold in the state, calculated as specified in section 151.252, subdivision 1,
- 2.5 paragraph (h);
- 2.6 ~~(14)~~ (15) medical gas distributor, \$110;
- 2.7 ~~(15)~~ (16) controlled substance researcher, \$75; and
- 2.8 ~~(16)~~ (17) pharmacy professional corporation, \$75.

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

2.10 Subdivision 1. **Requirements.** (a) No person shall act as a drug manufacturer without

2.11 first obtaining a license from the board and paying any applicable fee specified in section

2.12 151.065.

2.13 (b) Application for a drug manufacturer license under this section shall be made in a

2.14 manner specified by the board.

2.15 (c) No license shall be issued or renewed for a drug manufacturer unless the applicant

2.16 agrees to operate in a manner prescribed by federal and state law and according to Minnesota

2.17 Rules.

2.18 (d) No license shall be issued or renewed for a drug manufacturer that is required to be

2.19 registered pursuant to United States Code, title 21, section 360, unless the applicant supplies

2.20 the board with proof of registration. The board may establish by rule the standards for

2.21 licensure of drug manufacturers that are not required to be registered under United States

2.22 Code, title 21, section 360.

2.23 (e) No license shall be issued or renewed for a drug manufacturer that is required to be

2.24 licensed or registered by the state in which it is physically located unless the applicant

2.25 supplies the board with proof of licensure or registration. The board may establish, by rule,

2.26 standards for the licensure of a drug manufacturer that is not required to be licensed or

2.27 registered by the state in which it is physically located.

2.28 (f) The board shall require a separate license for each facility located within the state at

2.29 which drug manufacturing occurs and for each facility located outside of the state at which

2.30 drugs that are shipped into the state are manufactured.

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

3.11 (h) The board shall not issue a renewed license for a drug manufacturer unless the
 3.12 manufacturer annually pays the stewardship fee required by section 151.065, subdivision
 3.13 3, and calculated as specified in this paragraph. Annually by March 1, a manufacturer must
 3.14 report the quantity of each opiate listed in section 152.02, subdivision 3, paragraphs (b) and
 3.15 (c), that the manufacturer sold into the state in the previous calendar year. The board shall
 3.16 use the information in the report to calculate the stewardship fee for each manufacturer.
 3.17 The stewardship fee shall be equal to one cent per morphine milligram equivalent of opiates
 3.18 listed in section 152.02, subdivision 3, paragraphs (b) and (c). The board shall use a morphine
 3.19 equivalent chart published by the Centers for Disease Control and Prevention or another
 3.20 reputable source to calculate morphine equivalents. If there is no commonly accepted
 3.21 morphine equivalent for an opiate in a manufacturer's report, the board shall determine an
 3.22 appropriate conversion based on its knowledge and expertise and shall notify the
 3.23 manufacturer of the conversion value and method.

3.24 **Sec. 3. [151.2521] OPIATE PRODUCT STEWARDSHIP.**

3.25 Subdivision 1. **Product stewardship.** A manufacturer licensed under section 151.252
 3.26 that sells opiates as defined in section 152.02, subdivision 3, paragraphs (b) and (c), shall
 3.27 pay to the Board of Pharmacy an annual stewardship fee as specified in section 151.065.

3.28 Subd. 2. **Appropriation.** Charges collected by the Board of Pharmacy under section
 3.29 151.065, subdivision 3, clause (14), must be deposited in the state treasury and credited to
 3.30 a dedicated account in the special revenue fund. Money in the account is annually
 3.31 appropriated to the commissioner of human services for the purposes in subdivision 3. This
 3.32 appropriation is available until expended.

3.33 Subd. 3. **Purposes.** The commissioner of human services, in consultation with the
 3.34 commissioner of health and the Opiate Product Stewardship Advisory Council established

4.1 in subdivision 4, must use the money appropriated under subdivision 2 to add or expand
 4.2 care services for individuals who are addicted to opiates, subject to the following conditions:
 4.3 (1) at least 50 percent of the money appropriated under subdivision 2 must be for competitive
 4.4 grants to one or more nonprofit organizations engaged in expanding prescriber education,
 4.5 public awareness, and overdose prevention program development and sustainability, to
 4.6 include the public and emergency medical services providers regulated under chapter 144E;
 4.7 and (2) at least 2.5 percent of the money appropriated under subdivision 2 must be for a
 4.8 grant to the Board of Pharmacy to be used for the Minnesota prescription monitoring program
 4.9 and for administration of the charge under section 151.252, subdivision 1, paragraph (h).
 4.10 The commissioner of human services may use up to 5 percent of the money appropriated
 4.11 under subdivision 3 for administration of this section. The commissioner of human services
 4.12 must develop a grant process to provide funding to successful applicants the first quarter
 4.13 after revenue is collected under section 151.252, subdivision 1, paragraph (h).

4.14 Subd. 4. **Opiate Product Stewardship Advisory Council.** (a) An Opiate Product
 4.15 Stewardship Advisory Council is created. The council must consist, at a minimum, of the
 4.16 following voting members, appointed by the commissioners of human services and health
 4.17 except where otherwise specified:

4.18 (1) one representative of the Board of Pharmacy;

4.19 (2) one representative of the Minnesota chapter of the Academy of Emergency Physicians
 4.20 who is a medical doctor;

4.21 (3) one representative of treatment facilities or sober living facilities;

4.22 (4) one representative of the Minnesota Hospital Association who is a medical doctor;

4.23 (5) one member of the Minnesota Society of Addiction Medicine who is a medical
 4.24 doctor;

4.25 (6) one pain psychologist;

4.26 (7) one representative of the Steve Rummler Hope Network;

4.27 (8) one representative of the Minnesota Ambulance Association;

4.28 (9) one representative of Minnesota courts who is a judge or law enforcement officer;

4.29 (10) one Minnesota resident who has been impacted by opiates; and

4.30 (11) one representative from an Indian tribe.

4.31 (b) The council shall also include, at a minimum, the following nonvoting members:

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

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

5.6 (c) The council shall be organized and administered under section 15.059.

5.7 (d) The commissioners of health and human services must convene the first meeting of
5.8 the council no later than October 1, 2017. The members shall elect a chair at the first meeting.

5.9 (e) The advisory council shall meet when convened by the chair, and must meet at least
5.10 quarterly.

5.11 (f) By February 1, 2018, and annually thereafter, the council shall submit a report to the
5.12 committees in the house of representatives and the senate with jurisdiction over health and
5.13 human services policy. The report shall include information on funds spent pursuant to
5.14 subdivision 3 in the previous year and outcomes resulting from the expenditures.