..... moves to amend H.F. No. 1440 as follows:

Delete everything after the enacting clause and insert:

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

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

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

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

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

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

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

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

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

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

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

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

Subd. 2. **Reporting requirements.** (a) Effective December 1, 2018, a manufacturer licensed under section 151.252 shall provide the board with data about each of its prescription products that contain controlled substances listed in section 152.02, subdivisions 3 through 6 that are sold within this state. The data shall include, for each product, the trade and generic names, strength, package size, and National Drug Code. A manufacturer required to report this data shall also report a billing address to which the board can send invoices and inquiries related to the product stewardship fee. A manufacturer shall notify the board of any change to this data no later than 30 days after the change is made. The board may require a manufacturer to confirm the accuracy of the data on a quarterly basis. If a manufacturer fails to provide information required under this paragraph on a timely basis, the board may

assess an administrative penalty of $100 per day. This penalty shall not be considered a form of disciplinary action.

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

(c) Effective February 1, 2019, any pharmacy licensed under section 151.19 and located outside of this state, including, but not limited to, community, long-term care, mail order, and compounding and central service pharmacies, must report the dispensing of controlled substances to patients located within this state. Reporting shall be in the manner and format specified by the board, and shall occur by the 15th day of each month, for dispensing that occurred during the previous calendar month, except that the first report submitted to the board shall include data retroactive to July 1, 2018. If a pharmacy fails to provide information required under this paragraph on a timely basis, the board may assess an administrative penalty of $100 per day. This penalty shall not be considered a form of disciplinary action.

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

Subd. 3. **Invoicing and payment.** (a) The board, beginning January 1, 2019, and at least quarterly, shall use the data submitted under subdivision 2 to prepare invoices for each manufacturer that is required to pay the opiate stewardship fee required by this section. The

invoices for each quarter shall be prepared and sent to manufacturers no later than 30 days after the end of each quarter, except that the first invoice prepared by the board shall be for the first three quarters of fiscal year 2019. Manufacturers shall remit payment to the board by no later than 30 days after the date of the invoice. If a manufacturer fails to remit payment by that date, the board shall charge interest at the rate that manufacturers are charged interest for making late Medicaid rebate payments.

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

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

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

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

(1) oxycodone: 15;

(2) oxymorphone: 15;

(3) hydromorphone: 15;

(4) methadone: 20; and

(5) fentanyl: 20.

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

(1) liquid: 0.2; and

(2) patch: 20.

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

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

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

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

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

(b) The council shall:

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

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

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

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

(5) develop measurable outcomes to determine the effectiveness of the funds allocated.

(c) The council shall make recommendations on grant and funding options for the funds annually appropriated to the commissioner of human services from the opiate stewardship account. The options for funding may include, but are not limited to: prescriber education; the development and sustainability of prevention programs; the creation of a continuum of care for opioid-related substance abuse disorders from detox to sober houses; and additional funding for child protection case management services for children and families affected

by opioid addiction. The council shall submit recommendations for funding options to the commissioner of human services, and to the chairs and ranking minority members of the legislative committees with jurisdiction over health and human services policy and finance, by March 1 of each year, beginning March 1, 2019.

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

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

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

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

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

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

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

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

(8) one member representing a pain psychologist;

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

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

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

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

(13) one member representing a manufacturer of opiates;

(14) one member representing an Indian tribe;

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

(16) the commissioner of health or designee.

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

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

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

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

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

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

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

Subd. 2. **Use of account funds.** (a) For fiscal year 2019, money in the account is appropriated as specified in section 5.

(b) For fiscal year 2020 and subsequent fiscal years, $740,000 each fiscal year is appropriated from the opiate stewardship account to the Board of Pharmacy, for administrative costs related to collection of the stewardship fee established under section 151.2521.

(c) For fiscal year 2020 and subsequent fiscal years, money remaining in the opiate stewardship account after making the appropriation required by paragraph (b) is appropriated to the commissioner of human services, to be awarded, in consultation with the opiate stewardship advisory council, as grants or as other funding as determined appropriate to address the opioid epidemic in the state.

Sec. 5. **USE OF OPIATE STEWARDSHIP ACCOUNT FUNDING FOR FISCAL YEAR 2019.**

Subdivision 1. **Commissioner of human services.** (a) For fiscal year 2019, all money in the account after making the appropriation required by subdivision 2 is appropriated to the commissioner of human services. The commissioner, in consultation with the Opiate Stewardship Advisory Council, shall distribute the appropriation according to this subdivision.

(b) At least 30 percent of the available funds shall be used for county social services agencies to provide services to children in placement who are affected by opioid addiction. The commissioner shall distribute the money allocated under this subdivision proportionally to counties based on the number of open child protection case management cases in the county using data from the previous calendar year.

(c) At least ten percent of the available funds shall be used to provide grants to county boards to fund programs and services to prevent and treat opioid abuse and addiction.

(d) The commissioner may use up to five percent of the available funds for administration of this section and to provide staff and administrative services for the Opiate Stewardship Advisory Council.

(e) The remaining appropriation must be used for the following purposes:

(1) providing grants to nonprofit organizations, including grants to regional emergency medical services programs regulated under Minnesota Statutes, section 144E.50, for the purpose of expanding prescriber education and public awareness, and the purchase of opiate antagonists for distribution to the healthcare and public safety communities; and

(2) providing a five percent increase in medical assistance payment rates for opioid treatment programs operating under Minnesota Statutes, chapter 245G.

(f) The commissioner shall award grants under this subdivision to successful applicants beginning the first quarter after revenue is collected under Minnesota Statutes, section 151.2521. Each grant recipient shall report to the commissioner and the Opiate Stewardship Advisory Council on how the funds were spent and the outcomes achieved, in the form and manner specified by the commissioner.

Subd. 2. **Board of Pharmacy.** (a) $1,200,000 in fiscal year 2019 is appropriated from the opiate stewardship account to the Board of Pharmacy for administrative costs related to collection of the stewardship fee established under Minnesota Statutes, section 151.2521.

(b) For fiscal year 2019, $3,500,000 is appropriated from the opiate stewardship account to the Board of Pharmacy, to integrate the prescription monitoring program database with electronic health records on a statewide basis. The board may use this funding to contract with a vendor for technical assistance, provide grants to health care providers, and to make any necessary technological modifications to the prescription monitoring program database. This funding does not cancel and is available until expended.

Sec. 6. **OPIATE STEWARDSHIP ADVISORY COUNCIL FIRST MEETING.**

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

Renumber the sections in sequence and correct the internal references

Amend the title accordingly