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### Overview

This bill requires drug manufacturers to pay an opiate stewardship fee, appropriates money collected through the fee for opioid abuse treatment and prevention, and establishes an advisory council.

This bill requires drug manufacturers and other entities that sell, deliver, or distribute opioids and narcotics in Minnesota to report information on opiates and other controlled substances to the Board of Pharmacy. The bill requires drug manufacturers to pay to the board an opiate product stewardship fee, for opioids sold, delivered, or distributed in the state on or after July 1, 2018. The fee is calculated using a base rate per unit, with multipliers for active ingredient and dosage form. The board is required to deposit the stewardship fees collected in the opiate stewardship account, a special revenue fund created in the bill.

The bill establishes the Opiate Stewardship Advisory Council, to review state opioid policy and make recommendations to the commissioner of human services on the use of money in the opiate stewardship account. Money from the account is appropriated on an ongoing basis to the Board of Pharmacy for administrative costs related to collecting the stewardship fee, and the bill provides funding in FY 2019 to the board to integrate the prescription monitoring database with electronic health records. The bill appropriates money from the account for FY 2019 to the commissioner of human services, and directs the commissioner to use the appropriation to: fund county child protection services related to opioid addiction, provide grants to counties for opioid-related programs, pay for agency administrative costs and provide staff and administrative services to the advisory

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council, provide grants to nonprofit organizations and regional EMS programs, and increase MA payment rates for opioid treatment programs by five percent. For FY 2020 and future fiscal years, the bill appropriates money to the commissioner to be awarded, in consultation with the advisory council, as grants or other funding to address the opioid epidemic.

- 1       **Requirements.** Amends § 151.252, subd. 1. Prohibits the Board of Pharmacy from issuing a renewed license for a drug manufacturer, unless the manufacturer pays any required opiate product stewardship fee.
- 2       **Opiate product stewardship fee.** Adds § 151.521.

**Subd. 1. Opiate product stewardship fee established.** (a) Requires drug manufacturers that hold a Food and Drug Administration (FDA) approved New Drug Application or Abbreviated New Drug Application, for any products containing the following to pay to the board a stewardship fee: opium or opiates listed in Schedule II of the list of controlled substances, and narcotics (with certain exceptions) listed in Schedule III or IV.

(b) Exempts drugs approved by the FDA for the treatment of opioid dependence from the stewardship fee, when they are used for that purpose.

**Subd. 2. Reporting requirements.** (a) Effective December 1, 2018, requires manufacturers to provide the board with specified information about each of its prescription products that contain controlled substances, and specifies related requirements and procedures. Allows the board to assess manufacturers an administrative penalty of \$100 per day for failure to provide the information on a timely basis, and states that the penalty is not a form of disciplinary action.

(b) Effective February 1, 2019, requires manufacturers and wholesalers to report to the board each month every sale, delivery, or other distribution of a prescription controlled substance within or into the state. Requires reporting to be in the Automation of Reports and Consolidated Orders System, unless otherwise specified by the board. Requires the first report submitted to include data retroactive to July 1, 2018, and specifies other reporting requirements. Allows the board to assess manufacturers an administrative penalty of \$100 per day for failure to provide the information on a timely basis, and states that the penalty is not a form of disciplinary action.

(c) Effective February 1, 2019, requires out of state pharmacies to report each month the dispensing of controlled substances to patients within the state. Requires the first report submitted to include data retroactive to July 1, 2018, and specifies other reporting requirements. Allows the board to assess manufacturers an administrative penalty of \$100 per day for failure to provide the information on a timely basis, and states that the penalty is not a form of disciplinary action.

(d) Effective February 1, 2019, requires the owners of pharmacies located within the state to report the intracompany delivery or distribution into the state of the opiates and narcotics listed in subdivision 1, to the extent these deliveries and distributions are not

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reported to the board by a wholesaler owned by, under contract to, or operating on behalf of the pharmacy owner. Requires the first report to include data retroactive to July 1, 2018.

**Subd. 3. Invoicing and payment.** (a) Requires the board, beginning January 1, 2019, and at least quarterly, to use the data submitted under subdivision 2 to invoice manufacturers required to pay the opiate stewardship fee. Requires invoices to be sent quarterly, except that the first invoice must be for the first three quarters of FY 2019. Requires manufacturers to remit payment within 30 days of the invoice date and allows the board to charge interest for late payments.

(b) Allows manufacturers to dispute the amount invoiced by the board and specifies the procedures to be used by manufacturers and the board in the case of a dispute.

**Subd. 4. Calculation of fees.** (a) Requires the board to calculate the opiate stewardship fee using a base rate for all drugs, with multipliers for certain drugs and dosage forms.

(b) Sets the base rate at one cent per unit distributed or dispensed, and defines unit.

(c) Sets an active ingredient multiplier of ten for Schedule II opium derivatives and opiates, with the following exceptions (multiplier specified): (1) oxycodone 15; (2) oxymorphone 15; (3) hydromorphone 15, (4) methadone 20; and (5) fentanyl 20.

(d) Requires the following dosage form multipliers to be applied, in addition to the active ingredient multiplier: (1) liquid 0.2; and (2) patch 20.

### **3 Opiate Stewardship Advisory Council.** Adds § 151.255.

**Subd. 1. Establishment of advisory council.** (a) Establishes the Opiate Stewardship Advisory Council to confront the opioid addiction and overdose epidemic in the state and focus on specified policy areas and services.

(b) Requires the council to:

(1) review local, state, and federal initiatives and activities related to education, prevention, and services related to opioid abuse;

(2) establish priorities and actions for fund allocation;

(3) ensure optimal allocation of available funding and alignment of existing funding;

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

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

(c) Requires the council to make recommendations on grant and funding options for funds annually appropriated to the commissioner from the opiate stewardship account. Lists possible areas for funding. Requires the council to submit recommendations for funding options to the commissioner and chairs and ranking 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.

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**Subd. 2. Membership.** (a) States that council shall consist of 18 members, and specifies membership.

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

(c) Specifies that the council is governed by section 15.059, except that members are reimbursed only for expenses and the council does not expire.

(d) Requires the chair to convene the council at least quarterly. Requires the council to meet at different locations in the state, with at least one-half of the meetings held at locations outside of the seven-county metropolitan area.

(e) Requires the commissioner to provide staff and administrative services for the council.

(f) States that the council is subject to chapter 13D (open meeting law).

### **4 Opiate stewardship account.** Adds § 151.256.

**Subd. 1. Establishment.** Establishes the opiate stewardship account as a special revenue fund in the state treasury. Requires opiate stewardship fees to be deposited into the account.

**Subd. 2. Use of account funds.** (a) For FY 2019, appropriates money from the fund in accordance with section 5.

(b) For FY 2020 and subsequent years, appropriates \$740,000 each fiscal year from the opiate stewardship account to the Board of Pharmacy, for administrative costs related to collection of the stewardship fee.

(c) For FY 2020 and subsequent years, appropriates the remaining money in the account (after the appropriation in paragraph (b)) to the commissioner, to be awarded in consultation with the Opiate Stewardship Advisory Council as grants or other funding to address the opioid epidemic.

### **5 Use of opiate stewardship account funding for fiscal year 2019.**

**Subd. 1. Commissioner of human services.** (a) For FY 2019, all of the money in the account after the appropriation to the Board of Pharmacy is appropriated to the commissioner. The money is to be distributed according to this subdivision, in consultation with the advisory council.

(b) At least 30 percent of available funds is for county social services agencies to provide services to children in placement affected by opioid addiction, to be distributed in proportion to the number of open child protection cases in each county.

(c) At least ten percent of available funds is for grants to county boards for programs and services to prevent and treat opioid abuse and addiction.

(d) The commissioner may use up to five percent of available funds for administration of this section, and to provide staff and administrative services for the advisory council.

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(e) The remaining appropriation is to be used for:

(1) providing grants to regional EMS programs to expand prescriber education and public awareness, and to purchase opiate antagonists for distribution to the health care and public safety community; and

(2) providing a five percent MA rate increase for opioid treatment programs operating under chapter 245G.

(f) Requires the commissioner to award grants under this section beginning the first quarter after stewardship fee revenue is collected. Requires grant recipients to report to the commissioner and the advisory council on how funds were spent and on outcomes achieved.

**Subd. 2. Board of Pharmacy.** (a) Appropriates \$1.2 million in FY 2019 from the opiate stewardship account to the Board of Pharmacy for administrative costs related to collecting the opiate stewardship fee.

(b) Appropriates \$3.5 million in FY 2019 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. Allows the board to contract with a vendor, provide grants to health care providers, and make technical modifications to the prescription monitoring program database. Provides that this funding does not cancel and is available until expended.

**6 Opiate Stewardship Advisory Council first meeting.** Requires the commissioner of human services to convene the first meeting of the Opiate Stewardship Advisory Council, no later than October 1, 2018. Directs the members to elect a chair at the first meeting.