

Subject Opioid Omnibus

Authors Olson

Analyst Randall Chun

Date February 7, 2019

## Overview

This bill contains articles related to: opioid product stewardship; health plan company requirements; prevention and education initiatives to address opioid addiction; intervention, treatment, and recovery initiatives to address opioid addiction; and appropriations for opioid initiatives.

## Article 1: Opioid Product Stewardship

This article establishes the Opioid Stewardship Advisory Council and the opioid stewardship account. The article also requires drug manufacturers and wholesale drug distributors that sell or distribute opioids in Minnesota to pay an opiate product registration fee. The article also requires any revenues from opioid settlement to be deposited into the opioid stewardship account.

Section	Description
1	<p><b>Exceptions.</b></p> <p>Amends § 16A.151, subd. 2. Requires revenues received by the state from the settlement of legal proceedings against opioid manufacturers to be deposited into the opioid stewardship account.</p>
2	<p><b>Requirements.</b></p> <p>Amends § 151.252, subd. 1. Requires a manufacturer of a Schedule II through IV opiate controlled substance to pay the opiate product registration fee, by June 1 of each year, beginning June 1, 2020. Allows the board to assess a ten percent late fee for each month or portion of a month of noncompliance.</p>
3	<p><b>Opioid Stewardship Advisory Council.</b></p> <p>Adds § 151.255.</p> <p><b>Subd. 1. Establishment of advisory council.</b> (a) Establishes the Opioid Stewardship Advisory Council to confront the opioid addiction and overdose epidemic in the state and focus on specified policy areas and services.</p> <p>(b) Requires the council to:</p>

Section	Description
	<p>(1) review local, state, and federal initiatives and activities related to education, prevention, and services related to opioid addiction;</p> <p>(2) establish priorities and actions allocating funds;</p> <p>(3) ensure available funding is aligned with existing funding;</p> <p>(4) develop criteria and procedures to be used in awarding grants and allocating funds from the opioid stewardship account; and</p> <p>(5) develop measurable outcomes to determine the effectiveness of funds allocated.</p> <p>(c) Requires the council to make recommendations on grant and funding options for funds annually appropriated to the commissioner from the opioid stewardship account. Lists options for funding. Requires the council to submit recommendations for funding options to the commissioner and the legislative committees with jurisdiction over health and human services policy and finance, by March 1 of each year, beginning March 1, 2020.</p> <p><b>Subd. 2. Membership.</b> (a) States that the council shall consist of 20 members, and specifies membership.</p> <p>(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.</p> <p>(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.</p> <p>(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.</p> <p>(e) Requires the commissioner to provide staff and administrative services for the council.</p> <p>(f) States that the council is subject to chapter 13D (open meeting law).</p>
4	<p><b>Opioid stewardship account.</b> Adds § 151.256.</p> <p><b>Subd. 1. Establishment.</b> Establishes the opioid stewardship account as a special revenue fund in the state treasury. Requires all opiate product registration fees and all state appropriations to the account to be deposited into the account.</p>

Section	Description
	<p><b>Subd. 2. Use of account funds.</b> (a) For fiscal year 2020, appropriates money from the fund as specified in article 5.</p> <p>(b) For fiscal year 2021 and subsequent years, appropriates money in the account to the commissioner, to distributed in consultation with the advisory council, as grants or other funding, or agency transfers, to address the opioid epidemic. Allows the commissioner to retain up to five percent of the appropriation for administrative costs and to support the advisory council. Requires each recipient of grants or funds to report to the commissioner and the advisory council on how the funds were spent and outcomes achieved.</p> <p><b>Subd. 3. Annual report.</b> Beginning January 15, 2020, and each January 15 thereafter, requires the commissioner, in consultation with the advisory council, to report to the legislative committees with jurisdiction over health and human services policy and finance, on the grants and funds awarded under this section and article 5, and the outcomes achieved. Requires each report to identify those instances for which the commissioner did not follow the recommendations of the advisory council, and the commissioner's rationale.</p>
5	<p><b>Controlled substance wholesale drug distributor requirements.</b></p> <p>Amends § 151.47, by adding subd. 1a. Requires a wholesale drug distributor distributing a Schedule II through IV opiate controlled substance to pay the opiate product registration fee, by June 1 of each year, beginning June 1, 2020. Allows the board to assess a ten percent late fee for each month or portion of a month of noncompliance.</p>
6	<p><b>Opiate product registration fee.</b></p> <p>Adds § 151.77.</p> <p><b>Subd. 1. Definition.</b> Defines the following terms: manufacturer, opiate, and wholesaler.</p> <p><b>Subd. 2. Reporting requirements.</b> (a) By March 1 of each year, beginning March 1, 2020, requires manufacturers and wholesale drug distributors to report to the board every sale, delivery, or other distribution within or into the state of any opiate that occurred during the previous calendar year, using the automation of reports and consolidated orders system (ARCOS) format, unless otherwise specified by the board. Allows the board to assess an administrative penalty of \$500 per day for noncompliance.</p> <p>(b) By March 1 of each year, beginning March 1, 2020, requires owners of pharmacies with at least one location in the state to report to the board the intracompany delivery or distribution into the state of any opiate, if this is not reported by a licensed wholesale drug distributor. Requires reporting to be done as specified by the board, for deliveries and distributions for the previous calendar year.</p>

Section	Description
	<p><b>Subd. 3. Determination of each manufacturer's registration fee.</b> (a) Requires the board to annually assess manufacturer registration fees in the aggregate amount of \$12 million, and to determine each manufacturer's annual registration on a pro-rated basis based on the manufacturer's percentage of the total number of units reported.</p> <p>(b) Requires the board to notify each manufacturer, by April 1 of each year beginning April 1, 2020, of the annual fee amount that must be paid by June 1.</p> <p>(c) Allows the board to use data reported by dispensers through the prescription monitoring program to determine registration fees, in conjunction with the data reported under this section.</p> <p>(d) Allows a manufacturer to dispute the registration fee within 30 days after notification, and specifies the procedures to be used. Requires a manufacturer disputing the fee to still remit the fee.</p>
	<p><b>Subd. 4. Determination of each wholesaler's registration fee.</b> (a) Requires the board to annually assess wholesaler registration fees in the aggregate amount of \$8 million, and to determine each wholesaler's annual registration on a pro-rated basis based on the wholesaler's percentage of the total number of units reported.</p> <p>(b) Requires the board to notify each wholesaler, by April 1 of each year beginning April 1, 2020, of the annual fee amount that must be paid by June 1.</p> <p>(c) Allows a wholesaler to dispute the registration fee within 30 days after notification, and specifies the procedures to be used. Requires a wholesaler disputing the fee to still remit the fee.</p>
	<p><b>Subd. 5. Report.</b> (a) Requires the Board of Pharmacy to evaluate the registration fee on drug manufacturers and wholesalers, and whether the fee has impacted prescribing practices by reducing the number of opiate prescriptions issued during calendar years 2020, 2021, and 2022. Allows the board to use data reported by dispensers through the prescription monitoring program to conduct this evaluation.</p> <p>(b) Requires the board to submit evaluation results to the legislative committees with jurisdiction over health and human services policy and finance by March 1, 2023.</p>
	<p><b>Subd. 6. Legislative review.</b> Requires the legislature to review the reports from the Opioid Stewardship Advisory Council, the Board of Pharmacy under subdivision 5, and other relevant information, to determine whether the opiate product registration fee should continue beyond July 1, 2023.</p>

Section	Description
7	<p><b>Advisory council first meeting.</b></p> <p>Requires the commissioner of human services to convene the first meeting of the Opioid Stewardship Advisory Council, no later than October 1, 2019. Directs the members to elect a chair at the first meeting.</p>

## Article 2: Health Plan Company Requirements

This article requires health plans to cover acupuncture services for the treatment of pain and ongoing pain management. The article also prohibits health plan companies and pharmacy benefit managers from requiring consumers to pay amounts for prescription drugs that are higher than a defined allowable cost.

Section	Description
1	<p><b>Coverage for plan management services.</b></p> <p>Adds § 62Q.528. Requires all health plans to cover acupuncture services for the treatment of pain and ongoing pain management, when provided by an acupuncture practitioner or chiropractor. Provides a January 1, 2020, effective date.</p>
2	<p><b>Lowest cost to consumers.</b></p> <p>Amends § 151.71, by adding subd. 3. (a) Prohibits a health plan company or a pharmacy benefits manager from requiring an individual to pay, for a covered prescription medication at the point of sale, an amount greater than the allowable cost to consumers as defined in paragraph (b).</p> <p>(b) Defines “allowable cost to consumers” as the lowest of: (1) the applicable copayment; or (2) the cost of the medication if purchased without using a health plan benefit.</p>

## Article 3: Prevention and Education

This article allows persons to execute voluntary nonopioid directives, provides alternative methods of drug disposal for county sheriffs, expands photo identification requirements for the purchase of controlled substances, places time limits on filling opioid prescriptions, establishes opioid quantity limits for treating acute pain associated with a major trauma or surgical procedure, and requires continuing education on prescribing opioids and other controlled substances, including nonpharmacological alternatives for pain treatment and management.

Section	Description
1	<p data-bbox="354 275 727 302"><b>Voluntary nonopioid directive.</b></p> <p data-bbox="354 317 548 344">Adds § 144.348.</p> <p data-bbox="453 386 878 413"><b>Subd. 1. Definitions.</b> Defines terms.</p> <p data-bbox="453 455 1425 800"><b>Subd. 2. Execution of directive.</b> Allows the following persons to execute a voluntary nonopioid directive instructing health care providers that an opioid may not be administered or prescribed to the individual or minor: an individual age 18 or older, an emancipated minor, parent or legal guardian of a minor, or an individual's guardian or other person appointed by the individual or court to manage the individual's health care. Requires the directive to be in the format prescribed by the commissioner of health. Provides that the person executing the directive may submit the directive to a health care provider or hospital. Allows the individual executing the directive to revoke the directive at any time, in writing or orally.</p> <p data-bbox="453 842 1354 940"><b>Subd. 3. Duties of the commissioner.</b> Directs the commissioner of health to adopt rules establishing guidelines to govern the use of directives. Specifies requirements for the guidelines.</p> <p data-bbox="453 982 1419 1220"><b>Subd. 4. Exemption from liability.</b> Provides an exemption from liability or disciplinary action for a health care provider, hospital, or employees for failure to administer, prescribe, or dispense an opioid, or for inadvertent administration of an opioid, to an individual or minor with a directive. States that a prescription presented to a pharmacy is presumed to be valid, and provides an exemption from liability or disciplinary action for a pharmacist who dispenses an opioid in contradiction to a directive.</p> <p data-bbox="453 1262 1419 1394"><b>Subd. 5. Construction.</b> Provides that the section shall not be construed to: alter a health directive; limit the prescribing, dispensing, or administering of an opioid overdose drug; or limit the prescribing, dispensing, or administering of an opioid for the treatment of substance abuse or opioid dependence.</p>
2	<p data-bbox="354 1451 850 1478"><b>Sheriff to maintain collection receptacle.</b></p> <p data-bbox="354 1493 1425 1696">Amends § 152.105, subd. 2. Allows county sheriffs to satisfy the requirement to maintain a collection receptacle for the disposal of controlled substances and other drugs, by using an alternate method for disposal that has been approved by the Board of Pharmacy. This may include making available to the public, without charge, at-home prescription drug deactivation and disposal products that render drugs and medications inert and irretrievable.</p>
3	<p data-bbox="354 1755 1154 1782"><b>Identification requirement for controlled substance prescriptions.</b></p> <p data-bbox="354 1797 1425 1929">Amends § 152.11, subd. 2d. Requires a valid photo identification for the purchase of controlled substances in Schedules II through V (current law requires this for controlled substances in Schedules II and III). Requires doctors of veterinary medicine to comply with the requirement for photo identification. Also strikes language limiting the application of</p>

Section	Description
4	<p>the requirement to purchases not covered by a health plan company or other third-party payor.</p> <p><b>Limitations on the dispensing of opioid prescription drug orders.</b> Amends § 152.11 by adding subd. 5.</p> <p>(a) Prohibits a pharmacist or dispenser from filling a prescription drug order for an opioid drug listed in Schedule II more than 30 days after the date on which the prescription drug order was issued.</p> <p>(b) Prohibits a pharmacist or dispenser from filling a prescription drug order for an opioid drug listed in Schedules III through V more than 30 days after the date on which the prescription drug order was issued and prohibits a pharmacist or dispenser from refilling the drug more than 30 days after the previous date on which it was dispensed.</p> <p>(c) Provides a definition of “dispenser.”</p>
5	<p><b>Limit on quantity of opiates prescribed for acute dental and ophthalmic pain.</b> Amends § 152.11, subd. 4. Provides that pharmacists and pharmacies shall not be subject to disciplinary action or civil or criminal liability for dispensing or refusing to dispense opiate prescriptions for acute dental and ophthalmic pain that exceed the quantity limit.</p>
6	<p><b>Limit on quantity of opiates prescribed for acute pain associated with a major trauma or surgical procedure.</b> Amends § 152.11, subd. 6. (a) Limits initial prescriptions for opiate or narcotic pain relievers listed in Schedules II through IV to a seven-day supply, when used for the treatment of acute pain associated with a major trauma or surgical procedure. Requires the quantity prescribed to be consisted with the dosage listed in the professional labeling for the drug that has been approved by the Food and Drug Administration.</p> <p>(b) Defines “acute pain.”</p> <p>(c) Allows an override of the quantity limit based on the professional clinical judgment of the practitioner.</p> <p>(d) Provides that the section does not apply to the treatment of acute dental pain or acute pain associated with refractive surgery, and that the quantity of opiates that may be prescribed for these conditions is governed by subd. 4.</p> <p>(e) Provides that pharmacists and pharmacies shall not be subject to disciplinary action or civil or criminal liability for dispensing or refusing to dispense opiate prescriptions that exceed the quantity limit.</p>
7	<p><b>Opioid and controlled substances prescribing.</b> Amends § 214.12 by adding subd. 6. Requires the Boards of Medical Practice, Nursing, Dentistry, Optometry, and Podiatric Medicine to require that licensees with prescribing</p>

Section	Description
	authority obtain at least two hours of continuing education credit on best practices in prescribing opioids and controlled substances, including nonpharmacological alternatives for treatment of pain and ongoing pain management, by the expiration date of the section, January 1, 2023.
	Makes the section effective January 1, 2020.

## Article 4: Intervention, Treatment, and Recovery

This article directs the Commissioner of Health to provide grants to federally qualified health centers and other qualified entities for opioid addiction and substance use disorder programs. The article also allows probation or supervised release officers, and volunteer firefighters, to administer opioid antagonists.

Section	Description
1	<p><b>Definitions.</b></p> <p>Amends § 145.9269, subd. 1. Applies an existing definition of “federally qualified health center” to § 145.9272.</p>
2	<p><b>Grants for opioid addiction and substance use disorder treatment, recovery, and prevention programs.</b></p> <p>Adds § 145.9272.</p> <p><b>Subd. 1. Grant program established.</b> (a) Directs the commissioner of health to distribute grants to qualified entities operating in Minnesota as of January 1, 2019, for integrated, community-based programs in primary care settings to treat, prevent, and raise awareness of opioid addiction and substance use disorders.</p> <p>(b) Defines “qualified entity” as a federally qualified health center, substance use disorder treatment program, or other providers of opioid prevention, treatment, and recovery services as designated by the commissioner.</p> <p><b>Subd. 2. Grant allocation; allowable uses.</b> (a) Requires grants to be allocated to qualified entities through a competitive process. Grants are to be awarded to establish opioid addiction and substance use disorder programs, or to expand existing programs.</p> <p>(b) Directs the commissioner, in awarding grants, to give preference to proposals that expand access to services for low-income populations, populations at greatest risk of addiction, or populations or areas of the state that are underserved.</p>



Section	Description
	<b>Subd. 3. Report.</b> Requires grant recipients to report to the commissioner information on the use of grant funding and outcomes. Requires the commissioner to report this information to the legislative committees with jurisdiction over health and human services policy and finance.
3	<b>Administration of opiate antagonists for drug overdose.</b> Amends § 151.37, subd. 12. Adds probation or supervised release officers, and volunteer firefighters, to the list of persons who may administer opiate antagonists, if authorized by a physician or other specified health care professional.

## Article 5: Appropriations

This article appropriates money to the Bureau of Criminal Apprehension, Commissioner of Human Services, Commissioner of Health, Department of Commerce, and health-related boards, for specified opioid-related initiatives.

Section	Description
1	<b>Bureau of Criminal Apprehension.</b> Appropriates money in fiscal year 2020 from the opioid stewardship account to the Bureau of Criminal Apprehension for two additional special agent positions focused on drug interdiction and drug trafficking.
2	<b>Commissioner of human services.</b> (a) For fiscal year 2020, appropriates money from the opioid stewardship account to the commissioner. Requires the commissioner, in consultation with the advisory council, to distribute the appropriation according to this section.  (b) At least 30 percent of available funds is for county social services agencies to provide services to children in placement, to be distributed in proportion to the number of open child protection cases in each county.  (c) At least 10 percent of available funds is for grants to county boards for programs and services to prevent and treat opioid addiction.  (d) The commissioner may use up to 5 percent of available funds for administration of this section, and to provide staff and administrative services for the advisory council.  (e) The remaining appropriation is to be used for:

Section	Description
	<p>(1) providing grants to nonprofit organizations to expand prescriber education and public awareness, and to purchase opiate antagonists for distribution to the health care and public safety community; and</p> <p>(2) providing a ... percent MA rate increase for substance use disorder services under section 254B.05, subd. 5, beginning July 1, 2019.</p> <p>(f) Requires each recipient of grants or funding to report to the commissioner and the advisory council on how funds were spent and on outcomes achieved.</p>
3	<p><b>Commissioner of health.</b></p> <p><b>Subd. 1. Grants to qualified entities.</b> Appropriates money in fiscal year 2020 from the opioid stewardship account to the commissioner of health for grants to qualified entities for opioid addiction and substance use disorder programs. Provides that this is a onetime appropriation.</p> <p><b>Subd. 2. Opioid prevention pilot project.</b> Appropriates money in fiscal year 2020 from the opioid stewardship account to the commissioner of health to continue and expand opioid abuse prevention pilot projects. Provides that this is a onetime appropriation.</p> <p><b>Subd. 3. Non-narcotic pain management and wellness.</b> Appropriates money in fiscal year 2020 from the opioid stewardship account to the commissioner of health, to provide funding for a mapping and assessment of community-based non-narcotic pain management and wellness resources, and for five related demonstration projects. Specifies criteria for the projects and states that this is a onetime appropriation.</p> <p><b>Subd. 4. Culturally specific opioid addiction prevention and treatment programs.</b> (a) Appropriates money from the opioid stewardship account to the commissioner of health, to award, beginning July 1, 2019, five-year grants to tribal government and urban American Indian organizations, to design, implement, and evaluate culturally specific opioid addiction prevention and treatment programs, or to expand or modify existing programs. Specifies grant criteria.</p> <p>(b) Requires the commissioner to award grants of a uniform amount to each tribe, and to allocate an additional amount based on the number of tribal members.</p> <p>(c) Requires grants to urban American Indian organizations to be awarded on a competitive basis, and specifies the maximum grant amount.</p>
4	<p><b>Health-related boards.</b></p> <p><b>Subds. 1 to 5.</b> Appropriates money from the opioid stewardship fund to the boards of dentistry, nursing, optometry, podiatric medicine, and medical practice</p>

Section	Description
	<p>for costs associated with continuing education related to prescribing opioids and controlled substances, and to the boards of dentistry, nursing, and medical practice for costs associated with continuing education on nonpharmacologic alternatives to pain management. Provides that these are onetime appropriations.</p>
	<p><b>Subd. 6. Board of Pharmacy.</b> Appropriates money in fiscal year 2020 from the opioid stewardship account to the Board of Pharmacy for collection of the drug manufacturer and wholesaler registration fee.</p>



*Minnesota House Research Department provides nonpartisan legislative, legal, and information services to the Minnesota House of Representatives. This document can be made available in alternative formats.*

[www.house.mn/hrd](http://www.house.mn/hrd) | 651-296-6753 | 600 State Office Building | St. Paul, MN 55155