

Subject Opioid Omnibus

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## 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 Addiction Advisory Council and the opioid stewardship fund. 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 any money received by the state from a settlement or court order from opioid litigation brought by the attorney general of the state to be deposited into the opioid stewardship fund. States that this does not apply to attorney fees and costs awarded to the Attorney General, contract attorneys, or other state agency attorneys.</p>
2	<p><b>Opioid stewardship fund.</b></p> <p>Adds § 16A.7245. Creates an opioid stewardship fund in the state treasury and requires the commissioner of management and budget to credit to the fund the registration fees collected by the Board of Pharmacy under section 151.77 and any other money made available. Credits investment income and investment losses to the fund.</p>
3	<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 10 percent late fee for each month or portion of a month of noncompliance.</p>

Section	Description
4	<p data-bbox="355 275 776 302"><b>Opioid Addiction Advisory Council.</b></p> <p data-bbox="355 317 545 344">Adds § 151.255.</p> <p data-bbox="453 386 1403 485"><b>Subd. 1. Establishment of advisory council.</b> (a) Establishes the Opioid Addiction Advisory Council to confront the opioid addiction and overdose epidemic in the state and focus on specified policy areas and services.</p> <p data-bbox="453 522 776 550">(b) Requires the council to:</p> <ol data-bbox="453 588 1403 995" style="list-style-type: none"><li data-bbox="453 588 1403 657">(1) review local, state, and federal initiatives and activities related to education, prevention, and services related to opioid addiction;</li><li data-bbox="453 688 1057 716">(2) establish priorities and actions allocating funds;</li><li data-bbox="453 753 1166 781">(3) ensure available funding is aligned with existing funding;</li><li data-bbox="453 819 1403 888">(4) develop criteria and procedures to be used in awarding grants and allocating funds from the opioid stewardship fund; and</li><li data-bbox="453 926 1338 995">(5) develop measurable outcomes to determine the effectiveness of funds allocated.</li></ol> <p data-bbox="453 1033 1414 1236">(c) Requires the council to make recommendations on grant and funding options for funds annually appropriated to the commissioner from the opioid stewardship fund. 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 data-bbox="453 1274 1378 1344"><b>Subd. 2. Membership.</b> (a) States that the council shall consist of 20 members, and specifies membership.</p> <ol data-bbox="453 1381 1419 1892" style="list-style-type: none"><li data-bbox="453 1381 1419 1480">(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.</li><li data-bbox="453 1518 1419 1587">(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.</li><li data-bbox="453 1625 1382 1724">(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.</li><li data-bbox="453 1761 1425 1831">(e) Requires the commissioner to provide staff and administrative services for the council.</li><li data-bbox="453 1869 1300 1896">(f) States that the council is subject to chapter 13D (open meeting law).</li></ol>

Section	Description
5	<p data-bbox="355 275 743 302"><b>Use of opioid stewardship fund.</b></p> <p data-bbox="355 317 545 344">Adds § 151.256.</p> <p data-bbox="453 386 1422 449"><b>Subd. 1. Use of funds.</b> (a) For fiscal year 2020, appropriates money from the fund as specified in article 5.</p> <p data-bbox="453 491 1422 730">(b) For fiscal year 2021 and subsequent years, appropriates money in the fund to the commissioner, to be 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 5 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 data-bbox="453 772 1422 1010"><b>Subd. 2. 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>
6	<p data-bbox="355 1066 1117 1094"><b>Controlled substance wholesale drug distributor requirements.</b></p> <p data-bbox="355 1108 1422 1241">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 10 percent late fee for each month or portion of a month of noncompliance.</p>
7	<p data-bbox="355 1297 743 1325"><b>Opiate product registration fee.</b></p> <p data-bbox="355 1339 532 1367">Adds § 151.77.</p> <p data-bbox="453 1409 1349 1472"><b>Subd. 1. Definition.</b> Defines the following terms: manufacturer, opiate, and wholesaler.</p> <p data-bbox="453 1514 1422 1753"><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 data-bbox="453 1795 1422 1925">(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</p>

Section	Description
	<p>as specified by the board, for deliveries and distributions for the previous calendar year.</p> <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 Addiction Advisory Council, the Board of Pharmacy under subdivision</p>

Section	Description
	5, and other relevant information, to determine whether the opiate product registration fee should continue beyond July 1, 2023.
8	<b>Advisory council first meeting.</b> Requires the commissioner of human services to convene the first meeting of the Opioid Addiction Advisory Council, no later than October 1, 2019. Directs the members to elect a chair at the first meeting.

## 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	<b>Coverage for pain management services.</b> Adds § 62Q.528. (a) 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.  (b) Provides that coverage of acupuncture services under MA and MinnesotaCare shall be as provided under § 256B.0625, subd. 8f (this subdivision governs acupuncture coverage under MA).  Provides a January 1, 2020, effective date.
2	<b>Lowest cost to consumers.</b> 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).  (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.

## Article 3: Prevention and Education

This article allows persons to include in health care directives instructions to prohibit the use of opioids, 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><b>Provisions that may be included.</b></p> <p>Amends § 145C.05, subd. 2. Allows a health care directive to include instructions to prohibit the administration, dispensing, or prescribing of an opioid. States that these instructions should not be construed to limit opioid use for the treatment of substance abuse, opioid dependence, or an overdose, unless otherwise prohibited in the directive.</p>
2	<p><b>Opioid instructions entered into health record.</b></p> <p>Adds § 145C.17. Requires a health care provider, at the request of the patient or health care agent, to enter into the patient's health record any instructions relating to the use of opioids.</p>
3	<p><b>Sheriff to maintain collection receptacle.</b></p> <p>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>
4	<p><b>Identification requirement for controlled substance prescriptions.</b></p> <p>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 the requirement to purchases not covered by a health plan company or other third-party payor.</p>
5	<p><b>Limitations on the dispensing of opioid prescription drug orders.</b></p> <p>Amends § 152.11 by adding subd. 5. (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</p>

Section	Description
	<p>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>
6	<p><b>Limit on quantity of opiates prescribed for acute pain associated with a major trauma or surgical procedure.</b></p> <p>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 consistent 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>
7	<p><b>Opioid and controlled substances prescribing.</b></p> <p>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 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.</p> <p>Makes the section effective January 1, 2020.</p>

## **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, volunteer firefighters, and school nurses 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> <p><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.</p>
3	<p><b>Administration of opiate antagonists for drug overdose.</b></p> <p>Amends § 151.37, subd. 12. Adds probation or supervised release officers, volunteer firefighters, and licensed school nurses or certified public health nurses employed by or under contract with a school board, to the list of persons who may administer opiate antagonists, if authorized by a physician or other specified health care professional.</p>

## 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	<p><b>Bureau of Criminal Apprehension.</b></p> <p>Appropriates \$288,000 in FY 2020 and \$288,000 in FY 2021 from the opioid stewardship fund to the Bureau of Criminal Apprehension for two additional special agent positions focused on drug interdiction and drug trafficking. States that this is an ongoing appropriation.</p>
2	<p><b>Commissioner of human services.</b></p> <p>(a) For fiscal year 2020, appropriates \$8,802,000 from the opioid stewardship fund to the commissioner. Requires the commissioner, in consultation with the advisory council, to distribute the appropriation according to this section.</p> <p>(b) At least 30 percent of available funds is for county social services agencies and tribal social service agency initiative projects to provide services to children in placement, to be distributed in proportion to the number of open child protection cases.</p> <p>(c) At least 10 percent of available funds is for grants to county boards for programs and services to prevent and treat opioid addiction.</p> <p>(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.</p> <p>(e) The remaining appropriation is to be used for 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.</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 \$2,000,000 in FY 2020 from the opioid stewardship fund 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 \$2,400,000 in FY 2020 from the opioid stewardship fund 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 \$1,250,000 in FY 2020 from the opioid stewardship fund 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>

Section	Description
4	<p><b>Subd. 4. Culturally specific opioid addiction prevention and treatment programs.</b> (a) Appropriates \$4,520,000 in FY 2020 and \$4,520,000 in FY 2021 from the opioid stewardship fund 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. Also sets base funding levels.</p> <p>(b) Of the appropriation in paragraph (a), allocates \$3,300,000 each fiscal year to 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) Of the appropriation in paragraph (a), allocates \$1,250,000 each fiscal year for the commissioner to award grants to urban American Indian organizations on a competitive basis, and sets the maximum grant amount at \$250,000.</p> <p><b>Subd. 5. Administration.</b> Appropriates \$890,000 in FY 2020 and \$702,000 in FY 2021 from the opioid stewardship fund to the commissioner of health to administer the programs in this section. Also sets base funding for fiscal years 2022 and 2023.</p> <p><b>Health-related boards.</b></p> <p><b>Subds. 1 to 5.</b> Appropriates specified amounts from the opioid stewardship fund to the boards of dentistry, nursing, optometry, podiatric medicine, and medical practice 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 \$284,000 in FY 2020 and \$126,000 in FY 2021 from the opioid stewardship fund to the Board of Pharmacy for collection of the drug manufacturer and wholesaler registration fee. Provides that this is an ongoing appropriation.</p>



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