

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; licensure of pharmacy benefit managers; 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.

Section	Description
1	Requirements. 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.
2	Opioid Stewardship Advisory Council. Adds § 151.255. Subd. 1. Establishment of advisory council. (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. (b) Requires the council to: (1) review local, state, and federal initiatives and activities related to education, prevention, and services related to opioid addiction; (2) establish priorities and actions allocating funds; (3) ensure available funding is aligned with existing funding; (4) develop criteria and procedures to be used in awarding grants and allocating funds from the opioid stewardship account; and

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	<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>Subd. 2. Membership. (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 semiannually. 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>
3	<p>Opioid stewardship account. Adds § 151.256.</p> <p>Subd. 1. Establishment. Establishes the opioid stewardship account as a special revenue fund in the state treasury. Requires all opiate product registration fees to be deposited into the account. Requires all state appropriations to the account, and any federal funds or grant dollars received for the prevention and treatment of opioid addiction, to be deposited into the account.</p> <p>Subd. 2. Use of account funds. (a) For fiscal year 2020, appropriates money from the fund as specified in article 6.</p> <p>(b) For fiscal year 2021 and subsequent years, appropriates money in the account to the commissioner, to be awarded in consultation with the advisory council, as grants or other funding to address the opioid epidemic. 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>

Section	Description
	<p>Subd. 3. Annual report. 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 6, 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>
4	<p>Controlled substance wholesale drug distributor requirements. 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.</p>
5	<p>Opiate product registration fee. Adds § 151.77.</p> <p>Subd. 1. Definition. Defines the following terms: manufacturer, opiate, and wholesaler.</p> <p>Subd. 2. Reporting requirements. (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 \$100 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> <p>Subd. 3. Determination of each manufacturer's registration fee. (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>

Section	Description
	<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>Subd. 4. Determination of each wholesaler's registration fee. (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 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 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>Subd. 5. Report. (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>Subd. 6. Legislative review. Requires the legislature to review the reports from the Opiate 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>
6	<p>Advisory council first meeting.</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>Coverage for plan management services.</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>Lowest cost to consumers.</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 requires school districts to include substance misuse prevention instruction in the health curriculum for certain grades, and encourages districts to integrate substance misuse prevention instruction into existing curriculum and programs. This article also 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, and requires continuing education on prescribing opioids and other controlled substances, and on nonpharmacological alternatives for pain treatment and management.

Section	Description
1	<p>Required academic standards.</p> <p>Amends § 120B.021, subd 1. Requires school districts to include substance misuse prevention instruction in a health curriculum in grades 5, 6, 8, 10, and 12.</p>
2	<p>Substance misuse prevention.</p> <p>Adds § 120B.215. Encourages school districts to integrate substance misuse prevention instruction into existing programs, curriculum, or school environment.</p>

Section	Description
3	<p data-bbox="355 275 727 302">Voluntary nonopioid directive.</p> <p data-bbox="355 317 532 344">Adds § 151.72.</p> <p data-bbox="453 386 878 413">Subd. 1. Definitions. Defines terms.</p> <p data-bbox="453 455 1422 800">Subd. 2. Execution of directive. 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 Board of Pharmacy. 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 1338 940">Subd. 3. Duties of the board. Directs the board to adopt rules establishing guidelines to govern the use of directives. Specifies requirements for the guidelines.</p> <p data-bbox="453 982 1422 1220">Subd. 4. Exemption from liability. 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 1422 1394">Subd. 5. Construction. 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>
4	<p data-bbox="355 1451 850 1478">Sheriff to maintain collection receptacle.</p> <p data-bbox="453 1493 1422 1703">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>
5	<p data-bbox="355 1755 1154 1782">Identification requirement for controlled substance prescriptions.</p> <p data-bbox="355 1797 1422 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
6	<p>the requirement to purchases not covered by a health plan company or other third-party payor.</p> <p>Limitations on the dispensing of opioid prescription drug orders. 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>
7	<p>Opioid and controlled substances prescribing. 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 by the expiration date of the section, January 1, 2024.</p> <p>Makes the section effective January 1, 2020.</p>
8	<p>Opioid alternatives. Amends § 214.12 by adding subd. 7. Requires the Boards of Medical Practice, Nursing, and Dentistry to require licensees with the authority to prescribe opioids to receive two hours of continuing education on nonpharmacological alternatives for the treatment of pain and pain management. Provides a January 1, 2020 effective date.</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, and volunteer firefighters, to administer opioid antagonists.

Section	Description
1	<p>Definitions.</p> <p>Amends § 145.9269, subd. 1. Applies an existing definition of “federally qualified health center” to § 145.9272.</p>
2	<p>Grants for opioid addiction and substance use disorder treatment, recovery, and prevention programs.</p> <p>Adds § 145.9272.</p> <p>Subd. 1. Grant program established. (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>Subd. 2. Grant allocation; allowable uses. (a) For each grant cycle, 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>Subd. 3. Report. 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>Administration of opiate antagonists for drug overdose. 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.</p>

Article 5: Pharmacy Benefit Manager Licensure

This article requires pharmacy benefit managers to be licensed by the Commissioner of Commerce, in order to conduct business in Minnesota.

Section	Description
1	<p>Definitions.</p> <p>Adds § 62W.01. Defines the following terms: commissioner, health plan, health plan company, and pharmacy benefit manager. “Pharmacy benefit manager” is defined to be “a person or entity doing business in this state which contracts to administer prescription drug benefits on behalf of a health plan company or employer.”</p>
2	<p>Licensure of pharmacy benefit managers.</p> <p>Adds § 62W.03.</p> <p>Subd. 1. Requirement to obtain a license. (a) Effective January 1, 2020, requires a pharmacy benefit manager (PBM) to obtain a license from the commissioner of commerce to conduct business in Minnesota. To obtain or renew a license, requires a PBM to submit to the commissioner: (1) a licensure or licensure renewal fee; (2) a copy of the corporate charter, articles of incorporation, or other similar document; and (3) a completed licensure form containing specified information.</p> <p>(b) Requires the licensee to report changes in required information within 60 days of the change occurring.</p> <p>Subd. 2. Issuance of certificate of licensure. Requires the commissioner to issue a certificate of licensure upon receipt of the licensure fee and required documents. Specifies related criteria and provides that the certificate of licensure is valid for two years.</p> <p>Subd. 3. Disciplinary action. When the commissioner finds that a licensee has violated a requirement of this chapter, allows the commissioner to: deny issuance of a license, refuse to renew a license, revoke or suspend the license, and impose a civil penalty of up to \$10,000 for each separate violation.</p>

Article 6: Appropriations

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

Section	Description
1	<p>Bureau of Criminal Apprehension.</p> <p>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.</p>
2	<p>Commissioner of human services.</p> <p>(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.</p> <p>(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.</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:</p> <p>(1) providing grants to nonprofit organizations, including 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;</p> <p>(2) providing a ... percent MA rate increase for substance use disorder services under section 254B.05, subd. 5, beginning July 1, 2019; and</p> <p>(3) providing a ... percent MA rate increase for mental health services, 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>Commissioner of health.</p> <p>Subd. 1. Grants to qualified entities. Appropriates money in fiscal year 2020 from the opioid stewardship account to the commissioner of health for grants to</p>

Section	Description
	<p>qualified entities for opioid addiction and substance use disorder programs. Provides that this is a onetime appropriation.</p> <p>Subd. 2. Opioid prevention pilot project. Appropriates money in fiscal year 2020 from the opioid stewardship account to the commissioner of health for opioid abuse prevention pilot projects. Allocates money from this appropriation to the opioid abuse prevention pilot project and Project Echo through CHI St. Gabriel's Health Family Medical Center. Provides that this is a onetime appropriation.</p> <p>Subd. 3. Non-narcotic pain management and wellness. 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>
4	<p>Department of Education.</p> <p>Appropriates money in fiscal year 2020 from the opioid stewardship fund to the commissioner of education for a grant to a private sector entity to collaborate with school districts to integrate substance misuse prevention instruction into school district programs and curricula. Specifies criteria for the use of funds and requires a report to the legislature on grant expenditures and outcomes. Allows the department to retain up to 5 percent of the appropriation to administer the grant program and assist school districts with implementation.</p>
5	<p>Health related boards.</p> <p>Subds. 1 to 5 appropriate money 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>Subd. 6. Board of Pharmacy. 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. Provides that this is a onetime appropriation.</p>
6	<p>Department of Commerce.</p> <p>Appropriates money in fiscal year 2020 from the opioid stewardship account to the commissioner of commerce to implement the licensure of pharmacy benefit managers under Minnesota Statutes, chapter 62W.</p>



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