MN HOUSE RESEARCH

Chapter 63

2019 Regular Session

Subject Opiate Omnibus

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Article 1: Opiate Epidemic Response

This article establishes the Opiate Epidemic Response Advisory Council and the opiate epidemic response account. The article also increases license fees, establishes a new license fee for opiate drug manufacturers, and requires drug manufacturers 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 a separate account in the state treasury, and specifies annual transfers and appropriations from the opiate epidemic response account.

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1	**Exceptions.** Amends § 16A.151, subd. 2. Requires any money received by the state from a settlement agreement, assurance of discontinuance, or court order from opioid litigation brought by the Attorney General of the state to be deposited into a separate account in the state treasury. States that this does not apply to attorney fees and costs awarded to the Attorney General, contract attorneys, or other state agency attorneys. If opioid manufacturer licensing fees are reduced, and the opiate product registration fee is repealed, requires the commissioner to transfer from this separate account to the opiate epidemic response account an amount that ensures that $20.940 million is available for distribution from the opiate epidemic response account.
2	**Application fees.** Amends § 151.065, subd. 1. Establishes a new license application fee of $55,000 for opiate drug manufacturers. Increases existing license application fees (which range from $110 to $235) for various categories of drug wholesalers, nonopiate drug manufacturers, and medical gas distributors to $5,000. Provides a July 1, 2019 effective date.
3	**Annual renewal fees.** Amends § 151.065, subd. 3. Establishes a new license renewal fee of $55,000 for opiate drug manufacturers. Increases existing license renewal fees (which range from $110 to $235) for various categories of drug wholesalers, nonopiate drug manufacturers, and medical gas distributors to $5,000. Provides a July 1, 2019 effective date.
4	**Deposit of fees.** Amends § 151.065, by adding subd. 7. Requires money collected from the new license application and renewal fees for opiate manufacturers, and from the increased fees for drug wholesalers, nonopiate drug manufacturers, and medical gas distributors (under sections 2 and 3) to be deposited into the opiate epidemic response account. Provides that if the fees for opiate manufacturers are reduced, $5,000 of the reduced fee is to be deposited into the opiate epidemic response account.

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5	**Opiate product registration fee.** Adds § 151.066. **Subd. 1. Definition.** Defines the following terms: manufacturer, opiate, and wholesaler. **Subd. 2. Reporting requirements.** (a) By March 1 of each year, beginning March 1, 2020, requires opiate manufacturers and opiate wholesalers 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. (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. **Subd. 3. Determination of an opiate product registration fee.** (a) Requires the board to annually assess an opiate product registration fee on any opiate manufacturer that annually sells, delivers, or distributes 2,000,000 or more units. (b) Sets the annual registration fee for each manufacturer meeting the requirement under paragraph (a) at $250,000. (c) Allows the board to use data reported by dispensers through the prescription monitoring program, in conjunction with the data reported under this section, to determine which manufacturers meet the requirement under paragraph (a). (d) Requires the board to notify each manufacturer meeting the requirement under paragraph (a), by April 1 of each year beginning April 1, 2020, that they are required to pay the fee specified in paragraph (b). (e) 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. (f) Defines “unit.” **Subd. 4. Report.** (a) Requires the Board of Pharmacy to evaluate the opiate product registration fee on drug manufacturers, and whether the registration fee and increased licensure fees have impacted prescribing practices by reducing the number of opiate prescriptions issued during calendar years 2021, 2022, and 2023, or created any unintended consequences in the availability of opiates for treatment of chronic or intractable pain. Allows the board to use data reported

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by dispensers through the prescription monitoring program to conduct this evaluation.

(b) Requires the board to submit evaluation results to the legislature by March 1, 2024.

Subd. 5. Legislative review. Requires the legislature to review the reports from the Opiate Epidemic Response Advisory Council, reports on Results First evaluation activities, the Board of Pharmacy under subdivision 4, and other relevant information, to determine whether the opiate product registration fee should continue beyond July 1, 2024.

6 **Requirements.**

Amends § 151.252, subd. 1. Requires a manufacturers subject to the opioid product registration fee to pay the fee by June 1 of each year, beginning June 1, 2020. Requires the fee to be deposited into the opiate epidemic response account. States the manufacturers are not required to pay the fee for more than one facility.

7 **Opiate Epidemic Response Advisory Council.**

Adds § 256.042.

Subd. 1. Establishment of advisory council. (a) Establishes the Opiate Epidemic Response Advisory Council to develop and implement a comprehensive and effective statewide effort to address the opioid addiction and overdose epidemic in Minnesota. Requires the council to 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 use disorder;

(2) establish priorities for the purposes of recommending initiatives to fund;

(3) recommend to the commissioner of human services specific projects and initiatives to be funded;

(4) ensure available funding is aligned with existing funding;

(4) consult with the commissioners of human services, health, and management and budget to develop measurable outcomes to determine the effectiveness of funds allocated; and

(6) develop recommendations for an administrative and organizational framework for the sustained and ongoing allocation of money deposited into the separate settlement account.

(c) Requires the council, in consultation with the commissioner of management and budget and within available appropriations, to select projects awarded

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grants for evaluations using experimental or quasi-experimental design, and specifies related criteria.

(d) Requires the council, in consultation with the commissioners of human services, health, public safety, and management and budget, to establish goals for addressing the opioid epidemic, determine a baseline to monitor progress, and set measurable outcomes. Requires the council to include proposed goals, measurable outcomes, and proposed benchmarks in its initial report to the legislature due January 31, 2021.

Subd. 2. Membership. (a) States that the council shall consist of 19 voting and 3 non-voting members, and specifies membership.

(b) Requires the commissioner of human services to coordinate the commissioner's appointments to provide geographic, racial, and gender diversity and ensure that at least one-half of members appointed by the commissioner reside outside of the seven-county metropolitan area. To the extent practicable, at least one member must represent a community of color disproportionately affected by the opioid epidemic.

(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 of human services to provide staff and administrative services for the council.

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

Subd. 3. Conflict of interest. Specifies disclosure and other conflict of interest requirements for council members.

Subd. 4. Grants. (a) Requires the commissioner of human services to submit a report of the grant awards proposed by the advisory council for the upcoming fiscal year to the legislature, by March 1 of each year, beginning March 1, 2020.

(b) Requires the commissioner to award grants from the opiate epidemic response account to the proposals selected by the advisory council, unless otherwise appropriated by the legislature. Limits grantee administrative costs to no more than three percent of the grant amount.

Subd. 5. Reports. (a) Requires the advisory council to report annually to the legislature by January 31 of each year, beginning January 31, 2021, on the projects that received grants. Specifies report criteria.

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	(b) Requires the commissioner of management and budget, in consultation with the advisory council, to report to the legislature when a grant evaluation under subdivision 1, paragraph (c) is complete, including information on outcomes, results, and whether the grant program can be scaled to achieve statewide results. (c) Requires the advisory council, in its annual report due January 31, 2024, to include recommendations on whether the appropriations in this act should be continued, adjusted, or discontinued, whether funding should be appropriated for other purposes, and the appropriate level of funding for existing and new uses.
8	**Opiate epidemic response account.** Adds § 256.043. **Subd. 1. Establishment.** Establishes the opiate epidemic response account as a special revenue fund in the state treasury. Requires the opiate product registration fees and the increased license fees to be deposited into the account. Annually appropriates money in the account to the commissioner of human services, beginning in FY 2021, unless otherwise specified in law. **Subd. 2. Transfers from account to state agencies.** Requires the commissioner to make the following transfers from the account on an annual basis, beginning in FY 2021: -- $126,000 to the Board of Pharmacy for the collection of opiate product registration fees -- $672,000 to the commissioner of public safety for the Bureau of Criminal Apprehension, to be used for drug scientists and lab supplies, and for special agent positions focused on drug interdiction and drug trafficking. **Subd. 3. Appropriations from account.** (a) After the transfers in subdivision 2, and the appropriations in Article 3 for Results First, Project ECHO, the Steve Rummler Foundation, and traditional healing, allocates $249,000 for the provision of administrative services to the advisory council and the administration of grants awarded as specified by the advisory council under paragraph (c). (b) After the transfers in subdivision 2 and the allocation for administrative services in paragraph (a), requires 50 percent of the remaining amount to be distributed by the commissioner to county and tribal social services agencies to provide child protection services to children and families affected by addiction. Requires the money to be distributed proportionately based on out-of-home placement episodes where parental drug use is the primary reason for the placement. Requires county and tribal social service agencies to report on how funds were used, and prohibits these agencies from supplanting existing funding.

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	(c) After the transfers in subdivision 2, and the allocation of funds in paragraphs (a) and (b), requires the commissioner to award grants as specified by the advisory council, unless otherwise appropriated by the legislature. **Subd. 4. Settlement; sunset.** (a) If the state receives a total of $250 million, either as a result of an opioid-related settlement agreement, assurance of discontinuance, or court order, or from the license and opioid product fees collected, or both, requires the license fees for opioid manufacturers to be reduced to $5,260 and the opioid product fee to be repealed. (b) Requires the commissioner of management and budget to inform the board of pharmacy, the governor, and the legislature when the $250 million amount has been reached, and requires the board to reduce the license fee for the next licensure period. (c) Notwithstanding paragraph (a), provides that the license fee reduction and the opioid product fee repeal shall not occur before July 1, 2024.
9	**Opiate epidemic response advisory council first meeting.** Requires the commissioner of human services to convene the first meeting of the Opiate Epidemic Response Advisory Council, no later than October 1, 2019. Directs the members to elect a chair at the first meeting.
10	**Revisor instruction.** States that the license fee increases in sections 2 and 3 are in addition to any other fee increases enacted during the 2019 regular or special sessions, and that if multiple fees are enacted, the revisor shall add the fees together.

Article 2: Other Provisions

This article contains a variety of provisions related to opioids. Sections in the article allow persons to include in health care directives instructions to prohibit the use of opioids, allows pharmacists to administer certain drugs used for treatment of alcohol or opioid dependence or mental illness, expand the list of persons who may administer opiate antagonists, provide alternative methods of drug disposal for county sheriffs, place time limits on filling opioid prescriptions, expand photo identification requirements for the purchase of controlled substances, establish opioid quantity limits for treating acute pain associated with a major trauma or surgical procedure, require prescribers to access the prescription monitoring program database, and require continuing education on prescribing opioids and other controlled substances, including nonpharmacological alternatives for pain treatment and management.

Section	Description
1	**Provisions that may be included.** 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.
2	**Opioid instructions entered into health record.** 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.
3	**Practice of pharmacy.** Amends § 151.01, subd. 27. Includes in the definition of "practice of pharmacy" the intramuscular and subcutaneous administration of drugs used for the treatment of alcohol or opioid dependence, or the treatment of mental illness if specified conditions are met.
4	**Administration of opiate antagonists for drug overdose.** Amends § 151.37, subd. 12. Adds correctional employees, 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 and other requirements are met. Provides an immediate effective date.
5	**Sheriff to maintain collection receptacle.** 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 providing public educational information and making an alternative method for disposal available to the public at no charge, for safely destroying unwanted drugs, including an at-home drug deactivation and disposal product. Requires the alternative method to meet the requirements of the Minnesota Pollution Control Agency, the Drug Enforcement Administration, and the Board of Pharmacy.
6	**General prescription requirements for controlled substances.** Amends § 152.11, subd. 1. Prohibits the initial dispensing of an opiate or narcotic pain reliever listed in schedules II through IV more than 30 days after the date the prescription was issued, and prohibits refills from being dispensed more than 30 days after the previous date on which the prescription was filled or refilled. Requires a new prescription if authorized refills have been used up or are expired.
7	**Identification requirement for controlled substance prescriptions.** 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

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	the requirement to purchases not covered by a health plan company or other third-party payor.
8	**Limit on quantity of opiates prescribed.** Amends § 152.11, subd. 4. A new paragraph (a) Limits prescriptions for opiate or narcotic pain relievers listed in Schedules II through IV for the treatment of acute pain to a seven-day supply for an adult, and a five-day supply for minors. The amendment to paragraph (b) limits prescriptions to a four-day supply to treat acute pain associated with wisdom teeth extraction surgery. This is added to a provision in current law specifying a four-day supply for treatment of acute dental pain and acute pain associated with refractive surgery. Makes various conforming changes, including changes that extend a provision allowing a practitioner to override the quantity limit based on professional clinical judgment to the new paragraph (a).
9	**Access to reporting system data.** Amends § 152.125, subd. 6. Beginning January 1, 2021, requires a prescriber, or agent or employee of the prescriber, to access the prescription monitoring program database, to the extent the information relates specifically to the patient: (1) before issuing an initial prescription for a schedule II to IV opiate controlled substance; and (2) at least once every three months for patients receiving opiates for chronic pain or participating in medically assisted treatment for an opioid addiction. Provides various exemptions from this requirement.
10	**Opioid and controlled substances prescribing.** Amends § 214.12 by adding subd. 6. (a) 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 and implantable device alternatives for treatment of pain and ongoing pain management, by the expiration date of the section, January 1, 2023. (b) States that paragraph (a) does not apply to any licensee participating in the opioid prescribing improvement program, unless the licensee has been terminated as an MA provider due to their prescribing practice falling within the standard for disenrollment. (c) States that the section expires January 1, 2023. Provides a January 1, 2020 effective date.

Article 3: Appropriations

This article appropriates money to the commissioners of human services, health, public safety, and management and budget, and to health-related licensing boards, for specified opioid-related initiatives. This article also directs the commissioner of human services to make a onetime transfer from the opiate epidemic response account to the general fund.

Section	Description
1	**Appropriations.** Appropriates money to various boards and agencies, as follows: (a) $244,000 in FY 2020 from the general fund to the board of pharmacy for information and technology costs related to the opioid product registration fee. (b) $309,000 in FY 2020 from the general fund and $60,000 in FY 2021 from opiate epidemic response account to the commissioner of human services to provide administrative services to the advisory council and to administer grants for Project ECHO, the Steve Rummler HOPE Foundation, and traditional healing. Sets base funding as $60,000 each year for FY's 2022 through FY 2024, and $0 in FY 2025. (c) $126,000 in FY 2020 from the general fund to the board of pharmacy for the collection of the opioid product registration fee. (d) $672,000 in FY 2020 from the general fund to the commissioner of public safety for the Bureau of Criminal Apprehension, for drug scientists and lab supplies and special agent positions. (e) $300,000 in FY 2020 from the general fund and $300,000 in FY 2021 from the opiate epidemic response account to the commissioner of management and budget for Results First evaluation activities. Sets base funding as $300,000 each year for FY's 2022 through 2024, and $0 in FY 2025. (f) $400,000 in FY 2020 from the general fund and $400,000 in FY 2021 from the opiate epidemic response account to the commissioner of human services for grants to CHI St. Gabriel's Health Family Medical Center and Hennepin Health Care, for the opioid-focused Project ECHO program. Sets base funding as $400,000 each year for FY's 2022 throgh 2024, and $0 in FY 2025. (g) $100,000 in FY 2020 from the general fund and $100,000 in FY 2021 from the opiate epidemic response account to the commissioner of human services for a grant to the Steve Rummler Hope Foundation for opioid overdose prevention and other activities. Sets base funding as $100,000 each fiscal year for FY's 2022 through 2024, and $0 in Fy 2025. (h) $2 million in FY 2020 from the general fund and $2 million in FY 2021 from the opiate epidemic response account to the commissioner of human services from grants to tribal nations and five urban Indian communities for traditional healing practices and to increase the capacity of culturally specific providers in the behavioral health workforce.

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	Sets base funding at $2 million each fiscal year for fiscal years 2022 through 2025, and $0 in fiscal year 2025. (i) through (m) provide funding from the state government special revenue fund for FY 2020 (ranging between $5,000 to $17,000) to the boards of dentistry, medical practice, nursing, optometry, and podiatric medicine to implement the continuing education requirements of Minnesota Statutes, section 214.12, subdivision 6. (n) $1.25 million in FY 2020 from the general fund to the commissioner of health, to provide funding for: (1) statewide mapping and assessment of community-based nonnarcotic pain management and wellness resources; and (2) up to five demonstration projects to provide community-based nonnarcotic pain management and wellness resources to patients and consumers. States that this appropriation is onetime. (o) $38,000 in FY 2020 from the general fund to the commissioner of health for the administration of grants awarded under paragraph (n).
2	**Transfer.** Requires the commissioner of human services, by June 30, 2021, to transfer $5.439 million from the opiate epidemic response account to the general fund. States that this is a onetime transfer.
3	**Expiration of codified language.** States that the uncodified language in this article does not expire on June 30, 2021.