

1.1 ..... moves to amend H.F. No. 1440, the third engrossment, as follows:

1.2 Page 1, after line 6, insert:

1.3 **"ARTICLE 1**

1.4 **OPIOID ADDICTION PREVENTION AND TREATMENT"**

1.5 Page 2, line 22, delete "18" and insert "19"

1.6 Page 3, delete line 8 and insert:

1.7 "(9) one member representing a nonprofit organization that operates programs related  
1.8 to opioid awareness, prescriber education, and overdose prevention;"

1.9 Page 3, line 16, delete "and"

1.10 Page 3, line 17, delete the period and insert "; and"

1.11 Page 3, after line 17, insert:

1.12 "(17) one member representing a local health department."

1.13 Page 6, after line 14, insert:

1.14 **"ARTICLE 2**

1.15 **PRESCRIPTION MONITORING PROGRAM FUNDING**

1.16 Section 1. Minnesota Statutes 2016, section 151.065, is amended by adding a subdivision  
1.17 to read:

1.18 Subd. 3a. **Annual controlled substance registration fees.** (a) By March 1 of each year  
1.19 beginning March 1, 2019, the board shall determine for each opiate drug manufacturer the  
1.20 number of dosage units of that manufacturer's schedule II and III opiates that were reported  
1.21 to the board through the prescription monitoring program established under section 152.126  
1.22 for the previous calendar year and inform the manufacturer of the amount of the fee.

2.1 (b) By March 1 of each year beginning March 1, 2019, the board shall determine for  
2.2 each controlled substance drug manufacturer the number of dosage units of that  
2.3 manufacturer's controlled substances, excluding controlled substances that are schedule II  
2.4 and III opiates, that were reported to the board through the prescription monitoring program  
2.5 established under section 152.126 for the previous calendar year and inform the manufacturer  
2.6 of the amount of the fee.

2.7 (c) Based on the quantity of reported dosage units under paragraph (a), the fee due on  
2.8 June 1, 2019, and each succeeding June 1 shall be for:

2.9 (1) more than 15,000,000, \$150,000;

2.10 (2) 5,000,001 to 15,000,000, \$95,000;

2.11 (3) 1,000,001 to 5,000,000, \$35,000;

2.12 (4) 100,000 to 1,000,000, \$1,500; and

2.13 (5) less than 100,000, \$625.

2.14 (d) Based on the quantity of reported dosage units under paragraph (b), the fee due on  
2.15 June 1, 2019, and each succeeding June 1 shall be for:

2.16 (1) more than 15,000,000, \$.....;

2.17 (2) 5,000,001 to 15,000,000, \$.....;

2.18 (3) 1,000,001 to 5,000,000, \$.....;

2.19 (4) 100,000 to 1,000,000, \$.....; and

2.20 (5) less than 100,000, \$.....

2.21 (e) Fees collected by the board under this subdivision must be deposited in the opioid  
2.22 addiction prevention and treatment account.

2.23 (f) A drug manufacturer that reports controlled substances described in both paragraphs  
2.24 (a) and (b) shall pay a fee under either paragraph (c) or (d), based on the highest quantity  
2.25 of reported dosage units.

2.26 Sec. 2. Minnesota Statutes 2016, section 151.252, subdivision 1, is amended to read:

2.27 Subdivision 1. **Requirements.** (a) No person shall act as a drug manufacturer without  
2.28 first obtaining a license from the board and paying any applicable fee specified in section  
2.29 151.065.

3.1 (b) In addition to the license required under paragraph (a), a manufacturer of controlled  
3.2 substances must pay the registration fee required in accordance with section 151.065,  
3.3 subdivision 3a, by June 1 of each year, beginning June 1, 2019. In the event of the change  
3.4 of ownership of a manufacturer, or of a controlled substance, the new owner must pay the  
3.5 registration fee required under section 151.065, subdivision 3a, that the original owner  
3.6 would have been assessed had it retained ownership. A manufacturer of controlled substances  
3.7 that has multiple facilities licensed under paragraph (g) of this subdivision is required to  
3.8 obtain and pay for only one registration fee.

3.9 ~~(b)~~ (c) Application for a drug manufacturer license under this section shall be made in  
3.10 a manner specified by the board.

3.11 ~~(c)~~ (d) No license shall be issued or renewed for a drug manufacturer unless the applicant  
3.12 agrees to operate in a manner prescribed by federal and state law and according to Minnesota  
3.13 Rules.

3.14 ~~(d)~~ (e) No license shall be issued or renewed for a drug manufacturer that is required to  
3.15 be registered pursuant to United States Code, title 21, section 360, unless the applicant  
3.16 supplies the board with proof of registration. The board may establish by rule the standards  
3.17 for licensure of drug manufacturers that are not required to be registered under United States  
3.18 Code, title 21, section 360.

3.19 ~~(e)~~ (f) No license shall be issued or renewed for a drug manufacturer that is required to  
3.20 be licensed or registered by the state in which it is physically located unless the applicant  
3.21 supplies the board with proof of licensure or registration. The board may establish, by rule,  
3.22 standards for the licensure of a drug manufacturer that is not required to be licensed or  
3.23 registered by the state in which it is physically located.

3.24 ~~(f)~~ (g) The board shall require a separate license for each facility located within the state  
3.25 at which drug manufacturing occurs and for each facility located outside of the state at  
3.26 which drugs that are shipped into the state are manufactured.

3.27 ~~(g)~~ (h) The board shall not issue an initial or renewed license for a drug manufacturing  
3.28 facility unless the facility passes an inspection conducted by an authorized representative  
3.29 of the board. In the case of a drug manufacturing facility located outside of the state, the  
3.30 board may require the applicant to pay the cost of the inspection, in addition to the license  
3.31 fee in section 151.065, unless the applicant furnishes the board with a report, issued by the  
3.32 appropriate regulatory agency of the state in which the facility is located or by the United  
3.33 States Food and Drug Administration, of an inspection that has occurred within the 24  
3.34 months immediately preceding receipt of the license application by the board. The board

4.1 may deny licensure unless the applicant submits documentation satisfactory to the board  
4.2 that any deficiencies noted in an inspection report have been corrected.

4.3 Sec. 3. Minnesota Statutes 2016, section 152.126, subdivision 10, is amended to read:

4.4 Subd. 10. **Funding.** (a) The board may seek grants and private funds from nonprofit  
4.5 charitable foundations, the federal government, and other sources to fund the enhancement  
4.6 and ongoing operations of the prescription monitoring program established under this section.  
4.7 Any funds received shall be appropriated to the board for this purpose. The board may not  
4.8 expend funds to enhance the program in a way that conflicts with this section without seeking  
4.9 approval from the legislature.

4.10 (b) ~~Notwithstanding any other section,~~ In the event that the controlled substance  
4.11 manufacturer registration fees collected pursuant to section 151.065, subdivision 3a,  
4.12 combined with any grants or funds received by the board under paragraph (a) are not  
4.13 sufficient to fund the appropriation to the board for the operation of the prescription  
4.14 monitoring program, the administrative services unit for the health-related licensing boards  
4.15 shall apportion between the Board of Medical Practice, the Board of Nursing, the Board of  
4.16 Dentistry, the Board of Podiatric Medicine, the Board of Optometry, the Board of Veterinary  
4.17 Medicine, and the Board of Pharmacy an amount to be paid through fees by each respective  
4.18 board. The amount apportioned to each board shall equal each board's share of the portion  
4.19 of the annual appropriation to the Board of Pharmacy from the state government special  
4.20 revenue fund for ~~operating the operation of~~ the prescription monitoring program under this  
4.21 section that is not covered by the combination of the controlled substance manufacturer  
4.22 registration fees collected under section 151.065, subdivision 3a, and any grants or funds  
4.23 received by the board under paragraph (a) of this subdivision. Each board's apportioned  
4.24 share shall be based on the number of prescribers or ~~dispensers~~ pharmacists that each board  
4.25 identified in this paragraph licenses as a percentage of the total number of prescribers and  
4.26 ~~dispensers~~ pharmacists licensed collectively by these boards. Each respective board may  
4.27 adjust the fees that the boards are required to collect to compensate for the amount  
4.28 apportioned to each board by the administrative services unit.

4.29 Sec. 4. **APPROPRIATION.**

4.30 \$..... is appropriated from the opioid addiction and prevention account to the Board of  
4.31 Pharmacy in fiscal year 2019 for the prescription monitoring program.

5.1

**ARTICLE 3**

5.2

**SUBSTANCE USE DISORDER TREATMENT PROVIDER REQUIREMENTS**

5.3

Section 1. Minnesota Statutes 2017 Supplement, section 245G.05, subdivision 1, is

5.4

amended to read:

5.5

Subdivision 1. **Comprehensive assessment.** (a) A comprehensive assessment of the

5.6

client's substance use disorder must be administered face-to-face by an alcohol and drug

5.7

counselor within three calendar days after service initiation for a residential program or

5.8

during the initial session for all other programs. A program may permit a staff person who

5.9

is not qualified as an alcohol and drug counselor to interview the client in areas of the

comprehensive assessment that are otherwise within the competencies and scope of practice

of that staff person, and an alcohol and drug counselor does not need to be face-to-face with

the client during this interview. The alcohol and drug counselor must review all of the

information contained in a comprehensive assessment and, by signature, confirm the

information is competent and meets the requirements for the comprehensive assessment. If

the comprehensive assessment is not completed during the initial session, the client-centered

reason for the delay must be documented in the client's file and the planned completion

date. If the client received a comprehensive assessment that authorized the treatment service,

an alcohol and drug counselor must review the assessment to determine compliance with

this subdivision, including applicable timelines. If available, the alcohol and drug counselor

may use current information provided by a referring agency or other source as a supplement.

Information gathered more than 45 days before the date of admission is not considered

current. The comprehensive assessment must include sufficient information to complete

the assessment summary according to subdivision 2 and the individual treatment plan

according to section 245G.06. The comprehensive assessment must include information

about the client's needs that relate to substance use and personal strengths that support

recovery, including:

(1) age, sex, cultural background, sexual orientation, living situation, economic status,

and level of education;

(2) circumstances of service initiation;

(3) previous attempts at treatment for substance misuse or substance use disorder,

compulsive gambling, or mental illness;

(4) substance use history including amounts and types of substances used, frequency

and duration of use, periods of abstinence, and circumstances of relapse, if any. For each

6.1 substance used within the previous 30 days, the information must include the date of the  
6.2 most recent use and previous withdrawal symptoms;

6.3 (5) specific problem behaviors exhibited by the client when under the influence of  
6.4 substances;

6.5 (6) family status, family history, including history or presence of physical or sexual  
6.6 abuse, level of family support, and substance misuse or substance use disorder of a family  
6.7 member or significant other;

6.8 (7) physical concerns or diagnoses, the severity of the concerns, and whether the concerns  
6.9 are being addressed by a health care professional;

6.10 (8) mental health history and psychiatric status, including symptoms, disability, current  
6.11 treatment supports, and psychotropic medication needed to maintain stability; the assessment  
6.12 must utilize screening tools approved by the commissioner pursuant to section 245.4863 to  
6.13 identify whether the client screens positive for co-occurring disorders;

6.14 (9) arrests and legal interventions related to substance use;

6.15 (10) ability to function appropriately in work and educational settings;

6.16 (11) ability to understand written treatment materials, including rules and the client's  
6.17 rights;

6.18 (12) risk-taking behavior, including behavior that puts the client at risk of exposure to  
6.19 blood-borne or sexually transmitted diseases;

6.20 (13) social network in relation to expected support for recovery and leisure time activities  
6.21 that are associated with substance use;

6.22 (14) whether the client is pregnant and, if so, the health of the unborn child and the  
6.23 client's current involvement in prenatal care;

6.24 (15) whether the client recognizes problems related to substance use and is willing to  
6.25 follow treatment recommendations; and

6.26 (16) collateral information. If the assessor gathered sufficient information from the  
6.27 referral source or the client to apply the criteria in Minnesota Rules, parts 9530.6620 and  
6.28 9530.6622, a collateral contact is not required.

6.29 (b) If the client is identified as having opioid use disorder or seeking treatment for opioid  
6.30 use disorder, the program must provide educational information to the client concerning:

6.31 (1) risks for opioid use disorder and dependence;

7.1 (2) treatment options, including the use of a medication for opioid use disorder;

7.2 (3) the risk of and recognizing opioid overdose; and

7.3 (4) the use, availability, and administration of naloxone to respond to opioid overdose.

7.4 (c) The commissioner shall develop educational materials that are supported by research  
7.5 and updated periodically. The license holder must use the educational materials that are  
7.6 approved by the commissioner to comply with this requirement.

7.7 (d) If the comprehensive assessment is completed to authorize treatment service for the  
7.8 client, at the earliest opportunity during the assessment interview the assessor shall determine  
7.9 if:

7.10 (1) the client is in severe withdrawal and likely to be a danger to self or others;

7.11 (2) the client has severe medical problems that require immediate attention; or

7.12 (3) the client has severe emotional or behavioral symptoms that place the client or others  
7.13 at risk of harm.

7.14 If one or more of the conditions in clauses (1) to (3) are present, the assessor must end the  
7.15 assessment interview and follow the procedures in the program's medical services plan  
7.16 under section 245G.08, subdivision 2, to help the client obtain the appropriate services. The  
7.17 assessment interview may resume when the condition is resolved.

7.18 Sec. 2. Minnesota Statutes 2016, section 254B.12, subdivision 1, is amended to read:

7.19 Subdivision 1. **CCDTF rate methodology established.** The commissioner shall establish  
7.20 a new rate methodology for the consolidated chemical dependency treatment fund. The new  
7.21 methodology must replace county-negotiated rates with a uniform statewide methodology  
7.22 that must include a graduated reimbursement scale based on the patients' level of acuity and  
7.23 complexity. ~~At least biennially, the commissioner shall review the financial information~~  
7.24 ~~provided by vendors to determine the need for rate adjustments."~~

7.25 Renumber the sections in sequence and correct the internal references

7.26 Amend the title accordingly