Minnesota Board of Pharmacy
905th Board of Pharmacy Meeting
Wednesday, June 1, 2022

Statutes, Rules and Guidances

Legislation Update

The Minnesota Legislature adjourned for the year on May 23rd without passing the Health and Human Services Omnibus Budget and Policy bill. Consequently, many of the provisions related to pharmacy were not enacted. As noted below, some policy-only provisions were agreed to and placed into a separate bill (HF 4065) – which passed and was signed into law by the Governor. As of May 25, 2022 – the date this document was prepared – the Governor and legislative leaders had not yet agreed to terms for a Special Session. If one does occur, it is possible that additional pharmacy-related provisions may be enacted.

HF 3980 Prescription Monitoring Program Modifications

Bill Link

This is a bill that the Board authorized staff to pursue at the Legislature – and for which information was provided at the Board’s January business meeting. The Board’s previous Executive Director and the Deputy Director worked diligently with legislators and their staff to get the bill introduced and heard. However, it was not given a hearing.

HF 1158/SF 1825 (Temperature monitoring devices)

Bill Link

This bill requires a mail order or specialty pharmacy to ensure drugs are delivered in compliance with temperature requirements established by the manufacturer. The methods to ensure compliance must include but are not limited to “enclosing in each medication’s packaging a method recognized by the United States Pharmacopeia by which the patient can easily detect improper storage or temperature variations.”

During the 2021 Session, the Legislature did not pass this bill but, instead, directed the Board to study the issue. The Board approved the report developed by Board staff at its January 2022 meeting and it was submitted to the Legislature. One of the findings of that report is:

“Currently there are no studies assessing potential false-positive and false-negative readings with temperature monitoring tags. Also, most tags provide a snap-shot in time indicating that an excursion occurred but they cannot measure temperature over time. However, visual temperature indicators are feasible and could still be used as an added measure of quality assurance but should not be the primary means for ensuring product integrity.”
The bill language was not included in the policy-only HHS bill. Consequently, it appears that the language will not be enacted, unless it is enacted during a Special Session.

**HF 2768/SF 2678 (Pharmacist Drug Administration and Drug Monitoring Device Placement) Bill Link**

This language amends Minnesota Statute 151.01, subdivision 27, which defines the practice of pharmacy. If enacted, this bill modifies the definition of “practice of pharmacy” in two ways:

- It allows a pharmacist to administer all intramuscular and subcutaneous drugs under a prescription drug order. Previously, the ability to administer such drugs was limited to drugs used for the treatment of alcohol or opioid dependence.
- It allows a pharmacist to participate in the placement of drug monitoring devices according to a prescription protocol, or collaborative practice agreement. (For example, certain dermal insulin monitoring devices).

The language in this bill was added to the policy-only bill (HF 4065) and has therefore been enacted:

Minn. Stats. §151.01, subd. 27. Practice of pharmacy. "Practice of pharmacy” means . . . .

(4) participation in drug and therapeutic device selection; drug administration for first dosage and medical emergencies; intramuscular and subcutaneous drug administration used for the treatment of alcohol or opioid dependence under a prescription drug order; drug regimen reviews; and drug or drug-related research;

(13) participation in the placement of drug monitoring devices according to a prescription, protocol, or collaborative practice agreement.

**HF 3924/SF 3953 (Medication Repository Program) Bill Link**

If enacted, this bill would:

- Change references to the “prescription repository program” to the “medication repository program” – because the repository can now accept certain nonprescription drug donations
- Appropriate an unspecified amount of money from the General Fund to the Board of Pharmacy
- Direct the Board to contract with the medication repository program vendor (the Board currently as a memorandum of understanding in place)
- As part of the contract, require the board to transfer to the central repository vendor the money appropriated by the Legislature
• Require the vendor to report certain data to the Board
• Require the Board to annually audit the expenditure by the vendor of any funds appropriated by the Legislature and given to the vendor
• Formally allow the vendor to seek sources of funding other than the appropriation from the Legislature

The language from this bill was not included in the policy-only HHS bill that was enacted. However, it may be enacted during a Special Session. The House of Representatives supported the language, the Senate did not.

**HF 3854/SF 3154 (Pharmacist involvement with HIV testing and drug dispensing)**

**Bill Link**

The first two sections are not under the jurisdiction of the Board of Pharmacy but would: 1). prohibit health plans from using step therapy for HIV/AIDS drugs; and 2). require health plans to pay for HIV/AIDS drugs that would be prescribed by pharmacists, and any related tested performed by pharmacists, if the bill is enacted.

The remainder of the bill would:

• Make pharmacists who prescribe HIV/AIDS drugs practitioners under Minn. Stats. §151.01, subd. 23.
• Amend the definition of “practice of pharmacy” found in Minn. Stats. §151.01, subd. 27 and amend Minn. Stats. §151.37 to allow pharmacists with certain training to prescribe HIV/AIDS drugs for pre- and post-exposure prophylaxis, and to conduct related testing.
• Require the Board of Pharmacy to develop a protocol that pharmacists who prescribe these drugs would have to follow.

The language from this bill was not included in the policy-only HHS bill that was enacted. However, it may be enacted during a Special Session. The House of Representatives supported the language, the Senate did not.

**HF 4009/SF 3940 (Licensed pharmacist authority to initiate, order, and administer vaccines and medical and laboratory tests expanded)**

**Bill Link**

If enacted, this bill would:

• Add language that is meant to clarify the ability of pharmacists to perform CLIA-waived tests. (Pharmacists can already perform CLIA-waived tests and current language would allow them to “collect specimens, interpret results, notify the patient of results, and refer patients to other health care providers for follow-up care” – language added by this bill).
Pharmacists would also be allowed to delegate the authority to “administer” tests to pharmacy technicians and pharmacist interns. (The Board has previously interpreted statutes and rules to allow a pharmacist intern to do anything that a pharmacist can do, while working under the supervision of a pharmacist).

- Allow pharmacists to order and administer all vaccinations, according to Advisory Committee on Immunization Practices schedules, down to the age of three – without needing a protocol with a practitioner.
  - Pharmacists would be allowed to delegate the authority to administer vaccines a pharmacy technician or pharmacy intern who has completed training in vaccine administration. Technicians would have to work under the supervision of a pharmacist, complete two hours of immunization CE per two-year CE cycle, and be certified to perform CPR
  - As currently worded, pharmacy technicians would be allowed to access the Minnesota Immunization Information Connection to assess “the immunization status of individuals prior to the administration of vaccines.” It would therefore be possible for a pharmacist to delegate administration of a vaccine to a technician and allow the technician to review MIIC and decide whether the patient should get a particular vaccine
  - Pharmacists, interns, or technicians would have to informs the patient and any adult caregiver accompanying the patient of the importance of a well-child visit with a pediatrician or other licensed primary care provider

- Require Medical Assistance to cover pharmacist ordered and administered tests and vaccinations at a rate comparable to the rate paid to other providers

The former Executive Director recommended that the Board go on record as opposing the portions of this bill that allow pharmacists to delegate the authority to administer vaccinations to pharmacy technicians – at least as currently drafted. Although this has been allowed under the Federal COVID-19 PREP Act Declaration and its amendments, the Board issued a COVID-19 FAQ document that clarified that:

- In order to be readily and immediately available, the pharmacist and technician needed to be in the same immediate work area – and that remote supervision of a technician through the use of any type of telepharmacy system was not permitted;
- Only pharmacists and interns could check MIIC to determine the immunization status of the patient and decide whether administration of the vaccine was appropriate;
- The supervising pharmacist could decide that a particular technician could not give immunizations – rather than being ordered to allow a technician to immunize when he or she did not think the technician was qualified.

If technicians are going to be allowed to administer vaccines, the language could be improved by:

- Requiring that a pharmacy technician complete the Board required training required by M Rules 6800.3850, plus additional immunization training and CPR certification
- Indicating that a pharmacist can decline to supervise a pharmacy technician if the pharmacist does not believe the technician should administer vaccines
• Clarifying that only a pharmacist or a pharmacist intern can use MIIC to assess the immunization status of a patient

The language from this bill was not included in the policy-only HHS bill that was enacted. However, it may be enacted during a Special Session. The Senate supported the language, the House of Representatives did not.

**HF 3595/SF 3716 (Cannabinoid product regulation provided)**

**BILL LINK**

The Board’s former Executive Director worked with several other state agencies to develop this bill. The language was included in the policy-only HHS bill that was signed into law. The enacted language:

- Addresses an issue that was created when the Minnesota State Court of Appeals issued the *State v. Loveless* decision in September 2021. (Here is a link to that decision: [https://casetext.com/case/state-v-loveless-28](https://casetext.com/case/state-v-loveless-28)). Language in the bill would clarify that products containing non-intoxicating cannabinoids extracted from hemp would not be Schedule I controlled substances simply because they had trace amounts of tetrahydrocannabinols.
- Clarifies that, because the Legislature has only authorized the sale of non-intoxicating cannabinoids, no THC could be present in an amount that exceeds 0.3%.
- Limits the sale of hemp-derived products meant for human consumption to individuals aged 21 and older.
- Allows manufacturers to supply information required to be on the label using bar codes or Q codes. Also, the information could be provided on an outer container, such as a box – rather than on the immediate container that holds the product.
- Clarifies that it is the products sold to consumers that must be tested – not just the hemp from which the cannabinoid is extracted.

Minn. Stats. §151.72 currently allows only non-intoxicating cannabinoids to be extracted from hemp and sold in products – as long as they are not food products. That means that, although they are widely sold, CBD gummies, cookies, chocolate bars, and other CBD-containing foods are not legal in Minnesota. Those food products are under the jurisdiction of the Minnesota Department of Agriculture, which has adopted federal standards into its statutes, by reference. *However, this bill transfers the authority for edible cannabinoid products to the Board of Pharmacy and legalizes them, if they meet the requirements of Minn. Stats. §151.72.*

**HF ####/SF #### (Governor’s Proposal to create a Cannabis Management Office)**

In January, the Governor and Lieutenant Governor released the following proposal:

**Legalize Cannabis for Adult Use**

The Governor and Lieutenant Governor know that Minnesota needs modernized
solutions to harness the benefits of legalizing cannabis, including expanding our economy, creating jobs across the state, allowing law enforcement to focus on violent crime, and regulating the industry in order to keep our kids safe. The Governor and Lieutenant Governor recommend funding for the safe and responsible legalization of cannabis for adult-use in Minnesota. A new Cannabis Management Office would be responsible for the implementation of the regulatory framework for adult-use cannabis, along with the medical cannabis program, and a program to regulate hemp and hemp-derived products. The recommendation also includes funding for grants to assist individuals entering the legal cannabis market, additional resources for substance use disorder treatment and prevention, provides for expungement of non-violent offenses involving cannabis, and implements taxes on adult-use cannabis.”

The Board’s former Executive Director was consulted about this proposal and understands that the Cannabis Management Office (CMO), as alluded to in the announcement, would be a separate state agency that would be given authority over all aspects of cannabis regulation. That would include assuming the Board’s power and duty to regulate cannabis-derived products that meet the legal definition of the word “drug.” Having a single state agency or office regulate everything related to Cannabis sativa is consistent with what many other states has done. It makes sense to have such an agency so that regulatory authority is not spread among several different departments.

As an executive branch agency, the Board is usually expected to support an administration’s policy proposals. In this case, the Board formally went on record as supporting the proposal to create the CMO. However, the Governor’s proposal was not enacted.

The Minnesota Intractable Pain Act (section 152.125) was substantially changed, as follows:

Sec. 2. Minnesota Statutes 2020, section 152.125, is amended to read:

152.125 INTRACTABLE PAIN. Subdivision 1. Definition Definitions.
(a) For purposes of this section, the terms in this subdivision have the meanings given.
(b) "Drug diversion" means the unlawful transfer of prescription drugs from their licit medical purpose to the illicit marketplace.
(c) "Intractable pain" means a pain state in which the cause of the pain cannot be removed or otherwise treated with the consent of the patient and in which, in the generally accepted course of medical practice, no relief or cure of the cause of the pain is possible, or none has been found after reasonable efforts. Conditions associated with intractable pain may include cancer and the recovery period, sickle cell disease, noncancer pain, rare diseases, orphan diseases, severe injuries, and health conditions requiring the provision of palliative care or hospice care. Reasonable efforts for relieving or curing the cause of the pain may be determined on the basis of, but are not limited to, the following:
(1) when treating a nonterminally ill patient for intractable pain, an evaluation conducted by the attending physician, advanced practice registered nurse, or physician assistant and one or more physicians, advanced practice registered nurses, or physician assistants specializing in pain medicine or the treatment of the area, system, or organ of the body confirmed or perceived as the source of the intractable pain; or

(2) when treating a terminally ill patient, an evaluation conducted by the attending physician, advanced practice registered nurse, or physician assistant who does so in accordance with the standard of care and the level of care, skill, and treatment that would be recognized by a reasonably prudent physician, advanced practice registered nurse, or physician assistant under similar conditions and circumstances.

(d) "Palliative care" has the meaning given in section 144A.75, subdivision 12.

(e) "Rare disease" means a disease, disorder, or condition that affects fewer than 200,000 individuals in the United States and is chronic, serious, life altering, or life threatening.

Subd. 1a. Criteria for the evaluation and treatment of intractable pain.

The evaluation and treatment of intractable pain when treating a nonterminally ill patient is governed by the following criteria:

(1) a diagnosis of intractable pain by the treating physician, advanced practice registered nurse, or physician assistant and either by a physician, advanced practice registered nurse, or physician assistant specializing in pain medicine or a physician, advanced practice registered nurse, or physician assistant treating the area, system, or organ of the body that is the source of the pain is sufficient to meet the definition of intractable pain; and

(2) the cause of the diagnosis of intractable pain must not interfere with medically necessary treatment, including but not limited to prescribing or administering a controlled substance in Schedules II to V of section 152.02.

Subd. 2. Prescription and administration of controlled substances for intractable pain.

(a) Notwithstanding any other provision of this chapter, a physician, advanced practice registered nurse, or physician assistant may prescribe or administer a controlled substance in Schedules II to V of section 152.02 to an individual a patient in the course of the physician's, advanced practice registered nurse's, or physician assistant's treatment of the individual patient for a diagnosed condition causing intractable pain. No physician, advanced practice registered nurse, or physician assistant shall be subject to disciplinary action by the Board of Medical Practice or Board of Nursing for appropriately prescribing or administering a controlled substance in Schedules II to V of section 152.02 in the course of treatment of an individual a patient for intractable pain, provided the physician, advanced practice registered nurse, or physician assistant:

(1) keeps accurate records of the purpose, use, prescription, and disposal of controlled substances, writes accurate prescriptions, and prescribes medications in conformance with chapter 147, or 148 or in accordance with the current standard of care; and
(2) enters into a patient-provider agreement that meets the criteria in subdivision 5.

(b) No physician, advanced practice registered nurse, or physician assistant, acting in good faith and based on the needs of the patient, shall be subject to disenrollment or termination by the commissioner of health solely for prescribing a dosage that equates to an upward deviation from morphine milligram equivalent dosage recommendations or thresholds specified in state or federal opioid prescribing guidelines or policies, including but not limited to the Guideline for Prescribing Opioids for Chronic Pain issued by the Centers for Disease Control and Prevention and Minnesota opioid prescribing guidelines.

(c) A physician, advanced practice registered nurse, or physician assistant treating intractable pain by prescribing, dispensing, or administering a controlled substance in Schedules II to V of section 152.02 that includes but is not limited to opioid analgesics must not taper a patient's medication dosage solely to meet a predetermined morphine milligram equivalent dosage recommendation or threshold if the patient is stable and compliant with the treatment plan, is experiencing no serious harm from the level of medication currently being prescribed or previously prescribed, and is in compliance with the patient-provider agreement as described in subdivision 5.

(d) A physician's, advanced practice registered nurse's, or physician assistant's decision to taper a patient's medication dosage must be based on factors other than a morphine milligram equivalent recommendation or threshold.

(e) No pharmacist, health plan company, or pharmacy benefit manager shall refuse to fill a prescription for an opiate issued by a licensed practitioner with the authority to prescribe opiates solely based on the prescription exceeding a predetermined morphine milligram equivalent dosage recommendation or threshold. Health plan companies that participate in Minnesota health care programs under chapters 256B and 256L, and pharmacy benefit managers under contract with these health plan companies, must comply with section 1004 of the federal SUPPORT Act, Public Law 115-271, when providing services to medical assistance and MinnesotaCare enrollees.

Subd. 3. Limits on applicability. This section does not apply to:

(1) a physician's, advanced practice registered nurse's, or physician assistant's treatment of an individual a patient for chemical dependency resulting from the use of controlled substances in Schedules II to V of section 152.02;

(2) the prescription or administration of controlled substances in Schedules II to V of section 152.02 to an individual a patient whom the physician, advanced practice registered nurse, or physician assistant knows to be using the controlled substances for nontherapeutic or drug diversion purposes;

(3) the prescription or administration of controlled substances in Schedules II to V of section 152.02 for the purpose of terminating the life of an individual a patient having intractable pain; or

(4) the prescription or administration of a controlled substance in Schedules II to V of section 152.02 that is not a controlled substance approved by the United States Food and Drug Administration for pain relief.
Subd. 4. **Notice of risks.** Prior to treating an individual a patient for intractable pain in accordance with subdivision 2, a physician, advanced practice registered nurse, or physician assistant shall discuss with the individual patient or the patient's legal guardian, if applicable, the risks associated with the controlled substances in Schedules II to V of section 152.02 to be prescribed or administered in the course of the physician's, advanced practice registered nurse's, or physician assistant's treatment of an individual a patient, and document the discussion in the individual's patient's record as required in the patient-provider agreement described in subdivision 5.

Subd. 5. **Patient-provider agreement.** (a) Before treating a patient for intractable pain, a physician, advanced practice registered nurse, or physician assistant and the patient or the patient's legal guardian, if applicable, must mutually agree to the treatment and enter into a provider-patient agreement. The agreement must include a description of the prescriber's and the patient's expectations, responsibilities, and rights according to best practices and current standards of care.

(b) The agreement must be signed by the patient or the patient's legal guardian, if applicable, and the physician, advanced practice registered nurse, or physician assistant and included in the patient's medical records. A copy of the signed agreement must be provided to the patient.

(c) The agreement must be reviewed by the patient and the physician, advanced practice registered nurse, or physician assistant annually. If there is a change in the patient's treatment plan, the agreement must be updated and a revised agreement must be signed by the patient or the patient's legal guardian. A copy of the revised agreement must be included in the patient's medical record and a copy must be provided to the patient.

(d) Absent clear evidence of drug diversion, nonadherence with the agreement must not be used as the sole reason to stop a patient's treatment with scheduled drugs. If a patient experiences difficulty adhering to the agreement, the prescriber must evaluate the patient for other conditions, including but not limited to substance use disorder, and must ensure that the patient's course of treatment is appropriately adjusted to reflect any change in diagnosis.

(e) A patient-provider agreement is not required in an emergency or inpatient hospital setting.