Statutes, Rules and Guidances

Legislation Update

As reported at the last meeting, a number of bills have been introduced at the Legislature that are either under the jurisdiction of the Minnesota Board of Pharmacy or that might have an impact on the Board or its licensees and registrants. This document provides an update on some of those bills and provides links to the language in the bills.

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. This language was not included in the House Health and Human Services Omnibus bill (HF 4510) (Please note that the amendment to this bill that includes all of the policy provisions is not currently available on the Legislature’s Web site), nor in the Senate version of that bill (SF 4198). That means that it is unlikely to pass this Session.

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 the last 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.”
This language was included in the House Health and Human Services Omnibus bill (HF 4510), but not the Senate version of that bill (SF 4198). So, its fate is uncertain.

**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 intramuscular and subcutaneous drugs under a prescription drug order. Previously, the ability to administer such drugs was limited to 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).

If enacted, the Board would not have to complete any additional inspections, develop new forms, or track pharmacists who engage in this new activity. The Board might receive additional complaints, but the increase is expected to be minimal. Consequently, it is anticipated that the Board will be able to absorb any expenses related to an increase in complaints within its existing budget. If enacted, the Board would expect that pharmacists only administer those drugs, or place those medical devices, for which they have appropriate training.

Both the House and Senate bills were passed by the relevant committees and sent to the Floors for action. That means that it is very likely that the language will be enacted into law.

**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
This language was included in the House Health and Human Services Omnibus bill (HF 4510) (Please note that the amendment to this bill that includes all of the policy provisions is not currently available on the Legislature’s Web site), but not the Senate version of that bill (SF 4198). The House language appropriates $175,000 to the Board to pass along to the repository. So, its fate is uncertain.

**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.

This language was included in the House Health and Human Services Omnibus bill (HF 4510) (Please note that the amendment to this bill that includes all of the policy provisions is not currently available on the Legislature’s Web site), but not the Senate version of that bill (SF 4198). So, its fate is uncertain.

**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 to 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 inform 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.

At the Board’s March, 2022, the Board’s former Executive Director made the following recommendations, which were adopted by the Board:

“The Executive Director recommends 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 advocates for the bill did agree to make the changes that were recommended. The language was included in the Senate version of the HHS Omnibus bill, but not the House version. So, its fate is uncertain.

**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. If enacted as currently engrossed, this bill would:

• Address 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, that no THC could be present in an amount that exceeds 0.3%.

• Limit the sale of hemp-derived products meant for human consumption to individuals aged 21 and older.

• Allow manufacturer to supply information required to be on the label through the use of 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.

• Clarify 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. This bill may be amended to transfer the authority for edible cannabinoid products to the Board of Pharmacy and finally legalize them, provided that they meet the requirements of Minn. Stats. §151.72.

This language was included in the House Health and Human Services Omnibus bill (HF 4510) (Please note that the amendment to this bill that includes all of the policy provisions is not currently available on the Legislature’s Web site), but not the Senate version of that bill (SF 4198). So, its fate is uncertain.
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. Staff at the various agencies – and the Governor’s Office – who worked on this bill think that it makes sense to have such an agency so that regulatory authority is not spread among several different departments.

The Board went on record at its last meeting as supporting this legislation. It appears that the bill has not yet been introduced but the Governor’s Office does intend to have it introduced.