



Frequently Asked Questions - 2019 Legislation (July 16, 2019 Revision)

Legislation enacted during the 2019 Regular and Special Sessions contained many provisions that will have an impact on the Board's licensees and registrants. This document contains answers to anticipated questions. It will be updated as the Board receives additional questions. These FAQs will also be placed on the Board's FAQ Web page (under the appropriate categories) at: <https://mn.gov/boards/pharmacy/resourcesfaqs/faqs/generalfaqs.jsp>. Questions can be submitted to the Board's general e-mail: pharmacy.board@state.mn.us.

Opiates

Q: Do prescriptions for opiates have quantity limits?

A: Yes, but only as follows:

- When used for the treatment of **acute** pain, prescriptions for opiates or narcotic pain relievers listed in Schedules II through IV in section 152.02 can't exceed a **seven-day supply for an adult** and can't exceed a **five-day supply for a minor under 18 years of age**.
- However, when used for the treatment of **acute dental pain**, including acute pain associated with wisdom teeth extraction surgery or **acute pain associated with refractive surgery**, prescriptions for opiate or narcotic pain relievers listed in Schedules II through IV of section 152.02 can't exceed a four-day supply.
- For the purposes of this provision, "**acute pain**" means pain resulting from disease, accidental or intentional trauma, surgery, or another cause, that the practitioner reasonably expects to last only a short period of time. **Acute pain does not include** chronic pain or pain being treated as part of cancer care, palliative care, or hospice or other end-of-life care.
- Despite these limits, if, in the professional clinical judgment of the prescriber, more than the specified quantity is required to treat a patient's acute pain, the practitioner may issue a prescription for the quantity needed to treat the patient's acute pain.

Q: Do pharmacists have an obligation to determine if an opiate prescription is for acute pain?

A: When presented with a prescription for an opiate analgesic, pharmacists should make a reasonable effort to determine if the prescription is for acute pain. That could include

asking the patient or the patient's caregiver, contacting the prescriber, assessing the patient's medical record (when a pharmacist has access to the records), making inferences based on the way the prescription is written, etc. The key would be to use sound professional judgment in making the determination. Remember that Minn. Rules 6800.3110 has long required pharmacists to make a reasonable effort to obtain certain information, including "disease state or states" and the patient's "individual history."

Q: If a pharmacist determines that an opiate prescription is for acute pain and if the quantity exceeds the new limits, can the pharmacist fill the prescription? Does a pharmacist need to contact the prescriber to verify that the prescriber wants to prescribe a quantity in excess of the limits?

A: Yes, the pharmacist can fill the prescription. The pharmacist can use professional judgment in determining whether to call the prescriber. Pharmacists should use extra caution if a prescription for acute pain greatly exceeds the new limits. Remember that the federal Controlled Substances Act states that pharmacists have a corresponding responsibility to ensure that controlled substance prescriptions are dispensed for appropriate medical purposes.

Q: Do prescriptions for opiates have time limits for dispensing?

A: Yes. The 2019 Opioid Omnibus bill states:

- No prescription for an opiate or narcotic pain reliever listed in Schedules II through IV of section 152.02 may be initially dispensed more than 30 days after the date on which the prescription was issued.
- No subsequent refills indicated on a prescription for a Schedule III or IV opiate or narcotic pain reliever may be dispensed more than 30 days after the previous date on which the prescription was initially filled or refilled. After the authorized refills for Schedule III or IV opiate or narcotic pain relievers have been used up or are expired, no additional authorizations may be accepted for that prescription. If continued therapy is necessary, a new prescription must be issued by the prescriber.

Note: Prescriptions for Schedule III or IV opiates can still have up to five refills within six months. However, each refill must be dispensed no more than 30 days after the last refill was dispensed.

For example, if a prescription for tramadol, with five refills, is issued on July 1st, the patient has until July 31st to get the prescription filled. If the patient first presents to a pharmacy on August 1st, the prescription is no longer valid. But assume that the patient did initially fill the prescription on July 2nd. The patient then has until August 1st to get the first refill

dispensed. If the first refill is not dispensed by August 1st, all refills are void. If the patient does get the first refill dispensed on August 1st, then the second refill must be dispensed by August 31st – otherwise all remaining refills are void, and so forth.

Q: Does the 30-day time-period start on the date that the prescription is processed and/or adjudicated, or the date on which the prescription is sold to the patient? [NEW – 7/16/2019]

A: Since many pharmacies do not have their cash registers interfaced with their pharmacy dispensing software, it is based on the date that the prescription is processed and prepared for dispensing. Since the statute must apply to a variety of practice types and fulfillment scenarios, the measurement of this interval should be based on the date that the prescription is processed and prepared for dispensing rather than the point of sale or counselling. Nothing in statutes or rules currently references point of sale as the standard for when dispensing occurs. Generally, fill history is documented based on the date that the prescription is processed and prepared.

Q: If a patient requests a refill before the 30-day time limit is reached, can the patient come into the pharmacy to pick up the prescription after the 30-day limit is reached? [NEW – 7/16/2019]

A: Yes – but as mentioned in several other responses, a pharmacist has a corresponding responsibility to ensure that controlled substance prescriptions are dispensed for appropriate medical purposes. If a patient calls in for a refill on day 28 but picks it up on day 31, that is most-likely acceptable. But if a patient calls in for a refill on day 28 but then waits for several weeks before picking it up, the pharmacist should probably ask some questions to determine if it is still appropriate to dispense the prescription.

Q: Do the quantity and time limits apply to Naltrexone, Suboxone, loperamide, diphenoxylate with atropine, or promethazine with codeine? [NEW – 7/16/2019]

A: In most circumstances - no. The statutes specify that the limits apply to opiates or “narcotic pain relievers” listed in Schedules II – IV. The acute pain quantity limit provision clearly specifies that it applies when such drugs are used for the treatment of acute pain. The language creating the time limit for the filling or refilling of prescriptions is best interpreted so that it also applies only when such drugs are used for the treatment of pain.

- Although low-dose naltrexone might be used to treat certain types of pain, it is not a controlled substance. Loperamide is not used to treat pain and is also not a controlled substance. Since neither of these drugs is a controlled substance, the limits don’t apply.

- Suboxone used for the treatment of opiate addiction is not subject to the limits – even if the patient might also derive pain relief from it. The limits *do* apply to any formulation of buprenorphine that is being used to treat pain – including Suboxone used off-label for pain.
- Even though it is abused, unless promethazine with codeine (or any other codeine-containing cold/cough syrup) is being prescribed for pain (which would be clinically questionable) the limits would not apply.
- Diphenoxylate with atropine is in Schedule V and it should not be used for pain. Consequently, the limits do not apply.

Q: We have prescribers who authorize 90 day supplies of *opioid medications* as three separate prescriptions, each for a one-month supply, with start dates for each month. With the recent legislative changes, does this mean as of July 1, 2019 this practice will no longer be allowed and any prescriptions with start dates later than 30 days after the written date will no longer be valid?

A: That is correct – prescribers will no longer be able to write out prescriptions for Schedule II *opiates* in that manner. The federal DEA regs are such that Schedule II prescriptions must be dated with the date on which they are issued. Those regs allow prescribers to issue multiple CII prescriptions on a single day, with instructions for the earliest date on which the prescriptions can be filled. But the DEA has made it clear that each prescription is considered a new prescription – and not a refill. So, the Board can't consider the second and third prescriptions to be refills. And the new state law says that new opiate prescriptions must be filled within 30 days of the date on which they are issued. There is no exception that would allow a prescriber to issue multiple opiate prescriptions on a particular date and have some of them be filled more than 30 days after the issue date. *Note: controlled substances other than opiates are not affected by this change. For example, prescriptions for methylphenidate, Adderall and other drugs used for attention deficit hyperactivity disorder can still be issued in this manner.*

It is more work, of course, but the prescriber can issue additional prescriptions at 30-day intervals by issuing electronic prescriptions to the patient's pharmacy. (Or by mailing paper prescriptions to the patient). The patient does not have to physically come into a clinic to pick up a prescription. For Schedule III and IV opiates, the prescriber can authorize refills but specify that each fill must last 30 days.

Q: Can opiate analgesic prescriptions that are for 90 days be partially filled? [NEW – 7/16/2019]

A: Yes, but the Federal (DEA) partial refill rules need to be followed and pharmacists need to use sound professional judgment.

- *For Schedule III and IV drugs:* “Partial refills of schedules III and IV controlled substance prescriptions are permissible under federal regulations provided that each partial filling is dispensed and recorded in the same manner as a refilling (i.e., date refilled, amount dispensed, initials of dispensing pharmacist, etc.), the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed, and no dispensing occurs after six months past the date of issue.” Of course, for Schedule III and IV drugs, the prescriber could also just write for a 30-day supply, with refills. Partial fillings of Schedule III and IV opiate analgesics won’t be considered “refills” for the purposes of the new time limits enacted by the Legislature. However, pharmacists have a corresponding responsibility under the Federal Controlled Substances Act to ensure that controlled substances are dispensed for a legitimate medical purpose. In addition, state statutes require pharmacists to exercise sound professional judgment and to adhere to generally accepted standards of practice. As an example, if a patient has a prescription for a 90-day supply of tramadol and gets a two-week partial fill dispensed – and then doesn’t request another partial fill for two or three months, the pharmacist should be assessing whether the tramadol should still be dispensed.
- *For Schedule II drugs* partial fills are allowed as follows – but in no case can partial fills be dispensed more than 30 to 60 days following the issuance date of the prescription, depending on the circumstances:
 - The Comprehensive Addiction and Recovery Act of 2016 (“CARA”), allows a pharmacy to provide a partial fill of a Schedule II controlled substance prescription if: (1) state law does not prohibit partial fills of Schedule II prescriptions (Minnesota statutes and rules do **not** prohibit partial fills of this sort); (2) the prescription is written and filled in compliance with federal and state law; (3) the partial fill is requested by the patient or the prescriber; (4) the total quantity dispensed in all partial fills does not exceed the total quantity prescribed; and (5) **all of the partial refills are dispensed within 30 days**. So – a 90-day prescription for a Schedule II opiate analgesic can’t be partially filled after 30 days from the date it was issued, unless:
 - The patient is in a long-term care facility or is terminally ill, in which case M. Rules 6800.4300 applies. That rule (and DEA regs) specify that partial fills can be dispensed for up to *60 days* for such patients.
 - DEA regs also state that the “partial filling of a prescription for a controlled substance listed in Schedule II is permissible if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and he makes a notation of the quantity supplied on the face of the written prescription, written record of the emergency oral prescription, or in the electronic prescription record. The remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall

notify the prescribing individual practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.”

Q: In regard to the time limits for opiate dispensing, are controlled substance opiate prescriptions written prior to July 1, 2019 grandfathered?

A: No, they are not grandfathered. A prescription written on or before June 30, 2019 is subject to the new time limits for dispensing – both for initial fills and for refills.

Q: Do pharmacy chains or hospitals have to report intracompany distribution of opiates (i.e. the transfer of opiates between pharmacies or other facilities that are under common ownership)?

A: Yes – **but only in limited circumstances.**

- Reporting must occur if a pharmacy is located within Minnesota and it receives, in any manner, an opiate from another pharmacy or facility that is owned by the same company and that is located *outside* of Minnesota.
 - If the out-of-state facility is licensed by the Board as a wholesaler, it will need to report all opiate distributions into the state just as any other wholesaler has to do.
 - If the out-of-state facility is not licensed as a wholesaler, the facility will have to report in a manner that the Board will be developing. Instructions for reporting will be supplied well in advance of the March 1, 2020 deadline for the first round of reporting.
- Transfer of opiates from one pharmacy located within Minnesota to another pharmacy located within Minnesota will not have to be reported to the Board.

Q: Is it true that pharmacists will have to take continuing education courses concerning the appropriate prescribing and dispensing of opiates?

A: No, but prescribers will have to do so (except for veterinarians).

Q: Have licensing fees for the businesses licensed by the Board been increased to provide funds for programs that address the opioid abuse epidemic?

A: Yes. Except for pharmacies and third-party logistics providers, the fees for most businesses licensed by the Board were increased to \$5,260. The fees for opiate manufacturers was increased to \$55,260. The licensing fees for pharmacies and third-party logistics providers are \$260. (Effective date for these changes – July 1, 2019). See below for related FAQs.

Prescription Monitoring Program

Q: Is it true that pharmacists are now required to use the Prescription Monitoring Program in certain circumstances?

A: No. While prescribers are now required to use the PMP in certain circumstances, pharmacists are not required to do so. Of course, many pharmacy employers have their own internal requirements for checking the PMP.

Q: Are there new requirements pharmacists must follow if they have delegates who access the PMP on their behalf?

A: Yes, there are.

- A pharmacist who has a PMP delegate must audit the use of the PMP by each delegate on at least a quarterly basis. This audit is to ensure that the delegate has accessed the data only for permitted reasons. If a delegate is found to have inappropriately accessed data, the pharmacist must immediately remove PMP access for that individual and notify the board within seven days. Additional information about how the audits should be conducted will be supplied to pharmacists and other permissible users.
- A pharmacist must terminate a delegate's access to the PMP within three business days of the delegate leaving employment with the pharmacy. Pharmacists may want to do this even sooner, since pharmacists are responsible for their delegate's use of the PMP.

Q: Will the Board be conducting its own audits of PMP use?

A: Yes. The Board is now required to "conduct random audits, on at least a quarterly basis, of electronic access by permissible users . . . to ensure compliance with permissible use as defined in this section." If selected for an audit, the PMP user must "respond to an inquiry by the board, no later than 30 days after receipt of notice that an audit is being conducted." Failure to respond on the part of a pharmacist may result in deactivation of access to the PMP and referral to the Board's Complaint Review Panel for consideration of possible disciplinary action. Other permissible users who fail to respond will be reported to other agencies that regulate that type of user.

Pharmacist Administration of Drugs

Q: What drugs can pharmacists administer?

A: Pharmacists can administer the following drugs, as allowed under Minn. Stats. §151.01, subd. 27. The second and third bullet points are new. (See additional FAQs below):

- drugs for first dosage and medical emergencies;
- drugs by intramuscular and subcutaneous administration when the drugs are used for the treatment of alcohol or opioid dependence (e.g. Vivitrol); and
- drugs by intramuscular and subcutaneous administration when the drugs are used for treatment of mental illnesses; and
- vaccines.

Q: Do pharmacists have to administer drugs pursuant to a protocol or a collaborative practice agreement?

A: No. However, if a protocol or collaborative practice agreement is not in place, the pharmacist can only administer the drug after receiving a prescription or drug order from a practitioner that indicates that the pharmacist can administer the drug. Pharmacists can only enter into protocols and collaborative practice agreements with licensed practitioners who would be able to prescribe the drug in question within their scope of practice. For example, a pharmacist can't administer drugs used for the treatment of a human mental health disorder based on a protocol with a dentist, optometrist, podiatrist or veterinarian.

- Administration of drugs for first dosage and medical emergencies does not have to be done pursuant to a protocol or collaborative practice agreement. However, if there is no protocol in place allowing for such administration, the pharmacist would need a prescription or drug order, allowing the pharmacist to administer the drug, before administering it. In limited circumstances involving a life-threatening emergency, the Board would exercise enforcement discretion and not take action against a pharmacist who, in good faith, administers the first dose of a drug needed to treat the emergency, even if the pharmacist has no prescription or drug order for the patient. (e.g. administering adrenaline using an auto-injector to a patient the pharmacist reasonably believes is experiencing an anaphylactic reaction).
- Administration of drugs by intramuscular and subcutaneous administration, when the drugs are used for the treatment of alcohol or opioid dependence, does not have to be done pursuant to a protocol or collaborative practice agreement. However, if there is no protocol in place allowing for such administration, the

pharmacist would need a prescription or drug order, allowing for administration of the drug, before administering it.

- Administration of drugs by intramuscular and subcutaneous administration, when the drugs are used for treatment of mental illnesses, *does* require a protocol or collaborative practice agreement – unless the pharmacist receives “the order of a prescriber and the prescriber is notified after administration is complete.” In that case, the order must indicate that pharmacist can administer the drug.

Pharmacists and therapeutic substitution

Q: Is it true that pharmacists can now engage in therapeutic substitution, rather than just generic substitution?

A: Not in a manner that is any different than what pharmacists have been able to do under a protocol for at least the past ten years. The language below was included in the SF 278, PBM bill (emphasis added). That language was not part of the Board’s policy bills. Pharmacists have been able to enter into the type of protocols mentioned in this language since at least July 1, 2009. A key word in this provision is the underlined “the” in the highlighted language. Using “the”, rather than “a”, means that a pharmacist would need a protocol with each prescriber of each prescription in question. With this language, a protocol with just one prescriber can’t cover the prescriptions written by other prescribers. Pharmacists could enter into a protocol with each of the prescribers in a particular clinic, or perhaps with the medical director of a clinic who certifies that all prescribers at the clinic agree to the protocol. But, again, pharmacists have been able to do that since 2009. **Note: hospitals can continue to use their Pharmacy and Therapeutics Committee approved automatic substitution policies and procedures.**

Subd. 7a. **Coverage by substitution.** (a) When a pharmacist receives a prescription order by paper or hard copy, by electronic transmission, or by oral instruction from the prescriber, in which the prescriber has not expressly indicated that the prescription is to be dispensed as communicated and the drug prescribed is not covered under the purchaser's health plan or prescription drug plan, the pharmacist may dispense a therapeutically equivalent and interchangeable prescribed drug or biological product that is covered under the purchaser's plan, ***if the pharmacist has a written protocol with the prescriber*** that outlines the class of drugs of the same generation and designed for the same indication that can be substituted and the required communication between the pharmacist and the prescriber.

(b) The pharmacist must inform the purchaser if the pharmacist is dispensing a drug or biological product other than the specific drug or biological product prescribed and the reason for the substitution.

(c) The pharmacist must communicate to the prescriber the name and manufacturer of the substituted drug that was dispensed and the reason for the substitution, in accordance with the written protocol.

Compounding for Veterinary Office Use

Q: Can a pharmacy compound products for veterinary office use?

A: Yes, but only if the following conditions are met:

- the compounded drug product is needed to treat animals in urgent or emergency situations, meaning where the health of an animal is threatened, or where suffering or death of an animal is likely to result from failure to immediately treat;
- timely access to a compounding pharmacy is not available, as determined by the prescribing veterinarian;
- there is no commercially manufactured drug, approved by the United States Food and Drug Administration, that is suitable for treating the animal, or there is a documented shortage of such drug;
- the compounded drug is to be administered by a veterinarian or a bona fide employee of the veterinarian, or dispensed to a client of a veterinarian in an amount not to exceed what is necessary to treat an animal for a period of ten days;
- the pharmacy has selected the sterile or nonsterile compounding license category, in addition to the veterinary pharmacy licensing category; and
- the pharmacy is appropriately registered by the United States Drug Enforcement Administration when providing compounded products that contain controlled substances.

Note that pharmacies that do this type of compounding no longer have to also be licensed as drug wholesalers.

Illegal fee-splitting and kick back arrangements

Q: Can pharmacies enter into arrangements with prescribers, *other than veterinarians*, through which the prescriber can be involved in setting the price that the patient will pay for the dispensed drug product?

A: No. It is unprofessional conduct for a pharmacist or pharmacy to enter into any arrangement through which a pharmacy, in which the prescribing practitioner does not have a significant ownership interest, fills a prescription drug order and the prescribing practitioner is involved *in any manner, directly or indirectly*, in setting the price for the filled prescription that is charged to the patient, the patient's insurer or pharmacy benefit manager, or other person paying for the prescription. For example, a pharmacy should not enter into an arrangement through which:

- it receives a prescription from a prescriber;
- it fills the prescription;
- it bills the prescriber, rather than the patient;
- and the prescriber then bills the patient for a higher cost than the prescriber paid the pharmacy.

This is just one example, there are other possible arrangements that would also not be allowed.

Q: Can pharmacies enter into arrangements with veterinarians through which the prescriber can be involved in setting the price that the patient will pay for the dispensed drug product?

A: Yes. A veterinarian and a pharmacy may enter into such an arrangement provided that the client or other person paying for the prescription is notified, ***in writing and with each prescription dispensed***, about the arrangement, unless such arrangement involves pharmacy services provided for livestock, poultry, and agricultural production systems, in which case client notification would not be required. Effective July 1, 2019 any pharmacy licensed by the Board that has entered into any such arrangement with veterinarians who treat animals other than food-producing animals, must provide written notification about the arrangement with each prescription filled. The pharmacy is not required to provide *specific* information about the financial details of the arrangement. *However, the notification must explain that there is a **financial** relationship between the pharmacy and the veterinarian.* A notification on the Web site of a pharmacy, or a sign posted within the pharmacy, is not sufficient. Nothing in this provision prevents the client from asking about the arrangement and the amount of money received by both the pharmacy and the veterinarian.

Syringe/needle access

Q: Are prescriptions required for the sale of needles and syringes?

A: No. The Board had Minn. Stats. §151.40 amended to include this language (emphasis added): “a person who self-administers drugs pursuant to *either the prescription or the direction of a practitioner*, or a family member, caregiver, or other individual who is designated by such person to assist the person in obtaining and using needles and syringes for the administration of such drugs” may legally possess needles and syringes. This means that a practitioner may simply direct a patient to use needles and syringes to self-administer a drug, rather than having to issue a prescription. If no prescription is presented and the individual wants to buy more than ten (10) needles or syringes, the pharmacist should

determine if the individual was directed by a practitioner to use the needles or syringes. (Also see the next FAQ).

Q: Can a pharmacist sell needles and syringes to an individual when a prescriber has not issued a prescription or directed the individual to use the needles and syringes for self-administration of a drug?

A: Yes, but only as follows:

- In this situation, a pharmacy can sell up to ten (10) unused needles and syringes provided:
 - the needles and syringes are stored in a manner that makes them available only to authorized personnel and not openly available to customers (i.e. behind the counter);
 - the pharmacy notifies the Minnesota Department of Health that it participates in an activity that supports proper disposal of used hypodermic needles or syringes. Notification can be done at: <https://survey.vovici.com/se/56206EE3487564F2>. Pharmacies do not have to collect used needles and syringes but can instead provide information about proper disposal. Further information, and a printable customer education brochure that meets this requirement, can be obtained at: <https://www.pca.state.mn.us/living-green/disposing-needles-and-syringes>.
 - the prohibition on advertising the sale of up to ten (10) syringes in this manner has been removed – so pharmacies can now let the public know that they sell syringes in this manner.
- Pharmacies can also sell needles and syringes to a variety of other individuals and businesses that are allowed by law to possess them. (Although sources other than pharmacies are probably used by most of those individuals and businesses). A list can be found at: <https://www.revisor.mn.gov/statutes/cite/151.40>. Pharmacists should verify the credentials of these other individuals and businesses.

Emergency prescription refills

Q: If a prescription is out of refills, can a pharmacist still dispense the drug?

A: Yes, in some circumstances. Pharmacists will be allowed to refill prescriptions, even if no refills remain, provided that:

- the patient has been compliant with taking the medication and has consistently had the drug filled or refilled as demonstrated by records maintained by the pharmacy*~;

- the pharmacy from which the legend drug is dispensed has record of a prescription drug order for the drug in the name of the patient who is requesting it, but the prescription drug order does not provide for a refill, or the time during which the refills were valid has elapsed~;
- the pharmacist has tried but is unable to contact the practitioner who issued the prescription drug order, or another practitioner responsible for the patient's care, to obtain authorization to refill the prescription;
- the drug is essential to sustain the life of the patient or to continue therapy for a chronic condition;
- failure to dispense the drug to the patient would result in harm to the health of the patient; and
- the drug is not a controlled substance listed in section 152.02, subdivisions 3 to 6, except for a controlled substance that has been specifically prescribed to treat a seizure disorder, in which case the pharmacist may dispense up to a 72-hour supply.

Note that **pharmacists can use their professional judgment in determining the patient's compliance with therapy. A patient who has occasionally skipped a refill or who has occasionally filled a prescription "late" is **not** necessarily non-compliant.*

~ Pharmacists practicing in pharmacies that share a common, real-time, electronic database can consider refills for the same drug, that have been filled by other pharmacies using the database, when considering whether to dispense an emergency refill.

If those conditions are met, the amount of the drug dispensed by the pharmacist to the patient must not exceed a 30-day supply, or the quantity originally prescribed, whichever is less, except as provided for controlled substances (i.e. – only controlled substances used for seizure disorders and only a 72-hour supply). If the standard unit of dispensing for the drug exceeds a 30-day supply, the amount of the drug dispensed or sold must not exceed the standard unit of dispensing.

A pharmacist can't dispense or sell the same drug to the same patient, as an emergency refill allowed under this new provision, more than one time in any 12-month period.

The pharmacist must notify the practitioner who issued the prescription drug order not later than 72 hours after the drug is sold or dispensed. The pharmacist must request and receive authorization before any additional refills may be dispensed. If the practitioner declines to provide authorization for additional refills, the pharmacist must inform the patient of that fact.

The record of a drug sold or dispensed under this section shall be maintained in the same manner required for any other refills.

Insurers and PBMs are required to pay for these emergency refills – even though there were no refills remaining.

Receipt and processing of prescriptions outside of a licensed pharmacy

Q: Can pharmacists ever receive and process a prescription drug order when working outside of a licensed pharmacy?

A: Yes, but only in limited circumstances.

- *A licensed pharmacist or pharmacist intern working within a licensed hospital may receive a prescription drug order and access the hospital's pharmacy prescription processing system through secure and encrypted electronic means in order to process the prescription drug order, even when they are not in the actual licensed pharmacy. Although this has long been the standard of practice in hospital pharmacies, it was actually not legal until the law was changed during the 2019 Legislative Session.*
- A pharmacist, when that pharmacist is not present within a licensed pharmacy, may accept a written, verbal, or electronic prescription drug order from a practitioner – but only if certain conditions are met:
 - the prescription drug order is for an emergency where waiting for the pharmacist to travel to a licensed pharmacy to accept the prescription drug order would likely cause the patient to experience significant physical harm or discomfort;
 - the pharmacy from which the prescription drug order will be dispensed is closed for business;
 - the pharmacist has been designated to be on call for the licensed pharmacy that will fill the prescription drug order;
 - electronic prescription drug orders are received through secure and encrypted electronic means;
 - the pharmacist takes reasonable precautions to ensure that the prescription drug order will be handled in a manner consistent with federal and state statutes regarding the handling of protected health information; and
 - the pharmacy from which the prescription drug order will be dispensed has relevant and appropriate policies and procedures in place and makes them available to the board upon request.
- Orders received by a pharmacist, as allowed under the second bullet point above, can be processed (filled) only if:

- The pharmacist is accessing the pharmacy’s prescription processing system through secure and encrypted electronic means;
- the pharmacy from which the prescription drug order will be dispensed is closed for business;
- the pharmacist has been designated to be on call for the licensed pharmacy that will fill the prescription drug order;
- the prescription drug order is for a patient of a long-term care facility or a county correctional facility (which means the processing cannot occur for outpatients or for hospital inpatients);
- the prescription drug order is not being processed pursuant to section 151.58;
- the prescription drug order is processed pursuant to Chapter 151 and the rules promulgated thereunder; and
- the pharmacy from which the prescription drug order will be dispensed has relevant and appropriate policies and procedures in place and makes them available to the board upon request.

Taken together, these conditions mean that pharmacists can both receive and process emergency prescriptions, when working outside of a licensed pharmacy, only when the patient is in a long-term care facility or county correctional facility and the drug can somehow be accessed by a nurse or other allowed staff person working in such facilities. (For example, from an e-kit). Pharmacists working outside of a licensed pharmacy could receive prescriptions for other emergency situations but would have to go into the pharmacy to process them.

Drug wholesaler and third-party logistics providers

Q: Do Minnesota’s drug wholesaler and third-party logistic provider (3PL) laws conform to the Drug Supply Chain Security Act (DSCSA)?

A: Yes. Legislation was enacted during the 2019 Special Session that conforms Minnesota’s drug wholesaler and 3PL laws to the DSCSA, effective July 1, 2019.

Q: Do pharmacies need a drug wholesaler license in order to sell minimal quantities of prescription drugs to practitioners for office use?

A: No. The law excludes “the distribution of minimal quantities of a drug by a licensed retail pharmacy to a licensed practitioner for office use” from the definition of wholesale distribution. Consequently, pharmacies do not need a drug wholesaler license to make such sales. The law does not define “minimal quantities” so pharmacists will need to use professional judgment and common sense when making sales to practitioners for office

use. In Minnesota, a “retail” pharmacy is one licensed in the outpatient/community pharmacy category.

Q: If a pharmacy sells more than minimal quantities of drugs to licensed practitioners for office use, or if it sells drugs to entities or individuals other than licensed practitioners, does it need to obtain a drug wholesaler license?

A: Yes, but there are no longer any provisions in the statutes that allow pharmacies to wholesale drugs differently than any other entity licensed as a wholesaler. So, a pharmacy **must pay the full drug wholesaler registration fee (\$5,260)** and it **must comply with all the requirements that any wholesaler must comply with**, including the requirements that:

- **a fingerprint-based criminal background check of a facility manager or designated representative be conducted; and**
- **a surety bond of either \$25,000 or \$100,000 be submitted to the Board** (the amount depends on gross revenues of the wholesaler).

Q: Do third-party logistics providers (3PLs) need to be licensed in order to ship or transport drugs into and within Minnesota?

A: Yes, effective July 1, 2019 all 3PLs that ship or transport drug into or within Minnesota must be licensed by the Board. Until the Board can make changes to its licensing database, 3PLs will receive a license number that starts with “3” – like wholesalers do. However, they will be regulated as a 3PL and not as a wholesaler. Any 3PL that is currently licensed as a drug wholesaler will need to change their license type.

Q: Do drug manufacturers also need to be licensed as drug wholesalers?

A: No, not if they only engage in the wholesale distribution of their own drug products. Manufacturers who distribute the drugs *of other manufacturers* do need to be licensed as drug wholesalers. Any manufacturer that only distributes its own products and that still also holds a drug wholesaler license can drop the wholesaler license (or simply not renew it when it is up for renewal in May 2020).

Q: Will drug wholesalers have to provide a surety bond to the Board?

A: Yes. The Board will provide more information about the procedures at a later date. The surety bond does not have to be provided until the Board distributes the procedures. Details and exceptions are as follows:

- An applicant for initial or renewal licensure as a drug wholesaler, that is not a government owned and operated wholesale distributor, must submit a surety bond of

\$100,000, except that if the annual gross receipts of the applicant for the previous tax year is \$10,000,000 or less, a surety bond of \$25,000 is required.

- If a wholesale distributor can provide evidence satisfactory to the board that it possesses the required bond in another state, the requirement for a bond will be waived.
- A single surety bond satisfies the requirement for the submission of a bond for all licensed wholesale distributor facilities under common ownership.

Q: Will drug wholesalers have to have managers or authorized representatives undergo criminal background checks?

A: Yes. A facility manager or other authorized representative will have to undergo a criminal background check as provided in Minn. Stats. §214.075. The Board will provide more information to affected licensees after developing policies and procedures in conjunction with the Criminal Background Check Program of Minnesota's Health-Licensing Boards.

Fee increases

Q: Were the Board licensing and registration fees increased during the 2019 Session?

A: Yes, effective July 1, 2019, the fees will be (initial & renewal, unless otherwise noted):

- pharmacist, \$175; (increased from \$145)
- pharmacist licensed by reciprocity (application fee), \$275 (increased from \$240)
- pharmacy intern, \$50 (increased from \$37.50)
- pharmacy technician, \$50; (increased from \$37.50)
- pharmacy, \$260; (increased from \$225)
- third party logistics provider, \$260; (newly established fee)
- pharmacy professional corporation (new), \$150; (increased from \$125)
- pharmacy professional corporation (renewal), \$100 (increased from \$75)
- all drug and medical gas wholesalers: \$5,260 (increased from \$185 to \$235)
- Drug manufacturers (except for opioid manufacturers) and medical gas manufacturers: \$5,260 (increased from between \$185 to \$235, fee used to vary depending on the type of drugs manufactured)
- Medical gas distributors: \$5,260 (increased from \$110)
- Opioid drug manufacturers: \$55,260 (This is a new fee - it will be reduced to \$5,260 if the sunset provision kicks in).

In addition, opiate product manufacturers with Minnesota sales of more than 2 million units in a year will be required to pay an opiate product registration fee of \$250,000.

Q: Did the Board delay the renewal date for medical gas distributors? [NEW – 7/16/2019]

A: Yes. The Board can't grant a variance to the statutes enacted by the Legislature, so the Board can't change the amount of a fee. However, the date on which renewals is due is specified in the rules that are promulgated by the Board and variances can be granted to the rules. The Board acted to grant a blanket variance to medical gas distributors, delaying the due date for the next renewal from November 30, 2019 until June 1, 2020.

Sale of cannabidiol (CBD) products

Note that these FAQs **do not apply** to the sale of *food products* that contain CBD derived from hemp. The legislation enacted by the Minnesota Legislature during the 2019 Session did not address the sale of food products containing CBD derived from hemp. It is the Board's understanding that nothing in Minnesota statutes allow CBD to be added to food products. In addition, the U.S. Food and Drug Administration has stated that CBD cannot be added to foods and cannot be sold as a dietary supplement. Sellers may wish to contact the Minnesota Department of Agriculture for additional information about food products. Note also, that this FAQ does not apply to any products made by the manufacturers regulated by the Minnesota Department of Health (MDH) Medical Cannabis Program. The MDH Office of Medical Cannabis should be contacted about those products. Finally, sellers of these products may also wish to check with the U.S. Food and Drug Administration to determine if the sale of their products is allowed under federal law.

Q: Are products that contain CBD derived from hemp legal to sell under Minnesota state law?

A: Effective January 1, 2020, products containing CBD derived from hemp can be legally sold under Minnesota state law only if all the conditions below are met.

- The product has been tested by an independent, accredited laboratory (using generally accepted standards for herbal and botanical substances) to confirm that the product:
 - contains the amount or percentage of cannabinoids that is stated on the label of the product;
 - does not contain more than trace amounts of any pesticides, fertilizers, or heavy metals; and
 - does not contain a delta-9 tetrahydrocannabinol concentration that exceeds the concentration permitted for industrial hemp as defined in section 18K.02, subdivision 3.
- The product bears a label that contains, at a minimum:

- the name, location, contact phone number, and website of the manufacturer of the product;
- the name and address of the independent, accredited laboratory used by the manufacturer to test the product;
- an accurate statement of the amount or percentage of cannabinoids found in each unit of the product meant to be consumed; and
- a statement stating that the product does not claim to diagnose, treat, cure, or prevent any disease and has not been evaluated or approved by the United States Food and Drug Administration (FDA) unless the product has been so approved.
- The information required to be on the label must be prominently and conspicuously placed and in terms that can be easily read and understood by the consumer.
- The label must not contain any claim that the product may be used or is effective for the prevention, treatment, or cure of a disease or that it may be used to alter the structure or function of human or animal bodies, unless the claim has been approved by the FDA.

Q: What about CBD-containing products that don't meet the requirements? Are they illegal to sell?

A: Until January 1, 2020, all products containing CBD derived from hemp are illegal to sell under Minnesota state law. (However, prior to that date, the Board does not intend to take enforcement action against any products that already meet the new requirements listed above). After that date, any CBD-containing product (other than a food product) that does not meet the new requirements will be considered an illegal misbranded and/or adulterated drug. It is a crime (misdemeanor) to sell misbranded or adulterated drugs. County or city prosecutors can bring criminal charges against sellers of misbranded and adulterated products. The Board of Pharmacy can take administrative action, including:

- Embargo – prohibiting a business or individual from selling a product or removing it from the premises without permission from the Board or a court. A court might subsequently issue an order of condemnation, requiring the seller to destroy the product at its expense;
- Cease and desist order – ordering a business or individual to stop selling such products.

Q: Can pharmacies stock and sell products containing CBD derived from hemp?

A: The area within a business licensed by the Board as a pharmacy cannot stock or sell a product containing CBD derived from hemp unless the product meets the new requirements listed above. Prior to January 1, 2020, the Board will exercise enforcement

discretion to allow pharmacies to sell compliant products. After that date, pharmacies simply need to follow the new law, like any other business. Pharmacies may wish to check with the FDA about federal statutes and rules, with their legal counsels, and with their malpractice insurers. As with all products, the Board expects pharmacists to use sound professional judgment in making recommendations to patients.

Medication Repository and Lower Cost Prescription Drugs

Q: What will the Board be doing to help individuals who are having difficulty affording their medications?

A: The Board will be doing two things to help individuals who are having a hard time affording their medications:

- The Board will establish a drug repository program, through which donors may donate a drug or medical supply for use by lower income individuals who meets certain eligibility criteria. The board will issue a request for proposals to find an entity willing and qualified to serve as the central repository for the program. It will contract with the central repository to implement and administer the prescription drug repository program. More details about this program will be made available after the Board works with the selected central repository entity to fully develop the program.
- The Board of Pharmacy will develop a page on its Web site that provides information to pharmacists, practitioners, and the public about sources of lower cost prescription drugs. The Board will also develop handouts, posters, and other documents with information about such sources. The documents will be available on the Board's Web site for download. The Board of Pharmacy and the boards that license prescribing will be required to inform their licensees of the availability of this information. Licensees are required to provide the information to patients.

Pharmacy Benefit Managers

Q: Are pharmacy benefit managers now regulated by the Board of Pharmacy?

A: No. However, they will be licensed and regulated by the Minnesota Department of Commerce. Any questions about PBM licensure or regulation should be directed to that department. The sections related to PBMs that were in Chapter 151 have been moved to a new chapter of statutes – 62W.