
MN Requesting Your Assistance with PBM-Pharmacy Problems during COVID-19

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Tue, Mar 31, 2020 at 10:58 AM

To: "monique@truthrx.org" <monique@truthrx.org>

Cc: "Kolkind, Hali (GOV)" <Hali.Kolkind@state.mn.us>, "Arnold, Grace (COMM)" <grace.arnold@state.mn.us>

Hello,

While the Board of Pharmacy has had concerns about some of the business practices of PBMs, the Board does not regulate them. A law was passed in 2019 that gives regulatory authority for PBMs to the Minnesota Department of Commerce. The Board has no authority to do the things that you ask, in relationship to PBMs. If requested, we would work with Commerce on this issue. (Two of our Board Members – and a former Board Member – are currently members of a Dept. of Commerce PBM advisory committee).

In regards to the other issues that you mention:

- Pharmacists in Minnesota have been able to administer vaccines for the past twenty years or so. About five years ago, the Board worked to get that authority expanded. (See [Minn. Stats. §151.01, subd. 27](#)). All national and regional chains operating in Minnesota have their pharmacists provide vaccinations – and many independent pharmacies do as well.
- The Board has posted a COVID-19 FAQ document on its [Web site](#). One of the questions explains how pharmacists working under protocol can do things like conduct rapid strep tests and then issue legally valid prescriptions. (Just one example, pharmacists have also been using protocols with practitioners for about a 20 years to be involved in a wide variety of such activities).
- In regards to COVID-19 testing, I have contacted the Minnesota Department of Health and, at this time, they don't need pharmacists to be involved in such testing – but I am sure they will contact me if that changes.

If you review the Board's COVID-19 FAQ document, I think you will find that the Board has taken many actions that should help pharmacists and pharmacies better cope with the pandemic – by allowing them to use alternative means to serve their patients while reducing the risk of the spread of the virus.

Feel free to contact me if you have additional questions.

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From: MN_HLB_Pharmacy Board <Pharmacy.Board@state.mn.us>
Sent: Tuesday, March 31, 2020 7:07 AM
To: Wiberg, Cody (HLB) <cody.wiberg@state.mn.us>
Subject: FW: MN Requesting Your Assistance with PBM-Pharmacy Problems during COVID-19

From: Monique Whitney <monique@truthrx.org>
Sent: Monday, March 30, 2020 7:43 PM
To: MN_HLB_Pharmacy Board <Pharmacy.Board@state.mn.us>
Subject: MN Requesting Your Assistance with PBM-Pharmacy Problems during COVID-19

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2 attachments

 **Wiberg C.pdf**
432K

 **PUTT Plan for Engaging Pharmacies to Fight COVID19.pdf**
77K



Frequently Asked Questions: COVID-19
(April 2, 2020 – changes from the 3/31/20 version are in red)

Approved by the Board of Pharmacy on March 26, 2020 during an emergency meeting held in accordance with Minnesota’s Open Meeting Law. Those provisions that effectively grant variances, or for which the Board is exercising enforcement discretion, are only approved for the duration of the Peacetime Emergency declared by Governor Tim Walz in Emergency Executive Order 20-01, issued on March 13, 2020 or until the Board withdraws approval, whichever occurs first. The Board will notify licensees and registrants when this FAQ document is withdrawn or when the Peacetime Emergency is ended. However, it is the responsibility of licensees and registrants to know when the variance waivers and enforcements discretion allowed by this document are no longer in place. Changes made subsequent to March 26, 2020 have been made after review by the Board’s President and/or Vice President.

The Minnesota Board of Pharmacy is committed to protecting the health and safety of Minnesotans during the COVID-19 outbreak. The Board has been receiving many questions concerning the impact that the COVID-19 pandemic is having, or may have, on our licensees and their patients. This document provides answers to those questions– and to questions that we anticipate receiving. This document is available on the Board’s General FAQ Webpage which can be accessed at: <https://mn.gov/boards/pharmacy/resourcesfaqs/faqs/generalfaqs.jsp>. Questions should be submitted to the Board’s general e-mail: pharmacy.board@state.mn.us. Any notification that the Board is asking licensees to submit, as described in the FAQs, can also be sent to that e-mail address.

The COVID-19 pandemic is fluid and evolving. And while we have tried to anticipate the questions that we will receive, we expect to receive questions that had not occurred to us. Therefore, this document will most likely be frequently updated as the situation changes. PLEASE CHECK OFTEN FOR UPDATES.

GENERAL INFORMATION RESOURCES

- **From the Board.** COVID-19 Information will be posted at:
<https://mn.gov/boards/pharmacy/resourcesfaqs/faqs/generalfaqs.jsp>

- **From the Minnesota Department of Health**
 - **Main page:** <https://www.health.state.mn.us/diseases/coronavirus/index.html>
 - **Downloadable posters, handouts, and other materials:**
<https://www.health.state.mn.us/diseases/coronavirus/materials/index.html>
- **From the U.S. Centers for Disease Control and Prevention (CDC)**
<https://www.cdc.gov/coronavirus/2019-ncov/index.html>
- **From the Drug Enforcement Agency (DEA)**
 - The DEA has recently updated their own FAQs regarding multiple topics including prescription validity, registration requirements, and temporary policy guidance during the emergency. <https://www.deadiversion.usdoj.gov/coronavirus.html>
- **From the Center for Medicare and Medicaid Services (CMS)**
 - The CMS has recently offered new waivers and flexibility related to the emergency as well as created guidance regarding Hospitals Without Walls, Telehealth, and Workforce availability. <https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Current-Emergencies-page>

OPERATING OR CLOSING PHARMACIES

Q: Given the COVID-19 pandemic, can we completely close our pharmacies?

A: With one exception, Minnesota Statutes and rules do not actually require a licensed pharmacy to be open for a minimum number of hours or days per week. Minnesota Rules 6800.7400, subp. 2 does state: “A pharmacist providing pharmaceutical services to a hospital maintaining an on-site pharmacy shall be engaged by the hospital and shall provide at least part-time, five-day-per-week services.” This creates an expectation that hospital pharmacies will be open at least part of the day, five days per week.

The Board hopes that pharmacies in Minnesota do not close entirely unless they have no choice – for example, because all of their staff have been exposed to or infected by COVID-19. To minimize the risk of staff and patient exposure or infection, the Board will allow pharmacists and technicians to work from home to the extent that they can. (See below for additional information on remote prescription processing). Community/outpatient pharmacies might consider the following:

- have patients call in for refills or submit refill requests electronically; encourage prescribers to transmit new prescriptions to pharmacies electronically, by FAX, or verbally by telephone;

- have some staff work remotely to verify prescriptions, complete data entry of prescriptions, certify the accuracy of data entry, conduct profile reviews and prospective drug utilization reviews;
- have some staff on duty in the pharmacy to fill and label prescription vials – and then mail them or deliver them to patient’s homes (or have patients come through drive-throughs or a curbside pick-up area, if the pharmacy has one).

With these procedures in place, the pharmacy might be closed to most (or all) walk-in business, but prescriptions could still be processed. Pharmacies are health care facilities and pharmacists are licensed health care professionals. If pharmacies simply close entirely, the crisis will be compounded by people with uncontrolled diabetes, hypertension, seizure disorders, heart failure, other infections, etc.

Q: What are the Board’s expectations if a pharmacy has to close entirely?

A: If a pharmacy is going to be entirely closed:

- The pharmacist-in-charge or other authorized representative should notify the Board prior to the closing, or as soon as possible after a closing - if prior notification is not possible.
- Patients should be notified prior to the closing, or as soon as possible after closing - if prior notification is not possible.
- Clinics, hospitals, and prescribing practitioners from which the pharmacy receives most prescriptions should be notified.
- Notifications mentioned above should indicate the anticipated reopening date.
- Notifications to patients should provide information about how patients can have their prescriptions transferred (if the pharmacy will be able to transfer prescriptions – see below) or instruct patients that they will need to obtain new prescriptions from their providers and have them filled at a different pharmacy.

Q: Does the Board have recommendations for pharmacies that continue operating?

A: In addition to the recommendations elsewhere in this document related to having staff work remotely, pharmacies should consider the following actions when staff are working in a pharmacy that remains open to the public:

- Encourage people to buy over-the-counter medications (without hoarding) and to refill prescriptions before they become exposed to or infected with COVID-19, so they do not have to do so after they are exposed or infected. (**Realizing that individuals do not always know if they have been exposed or infected**).

- Establish a process for reducing or eliminating the amount of time people wait in line to pick up filled prescriptions – especially those who are at most risk such as older adults, pregnant women, and people with chronic health conditions.
- Implement infection control procedures:
 - When possible, staff should maintain a distance of 6 feet from patients or other staff members.
 - Regularly clean and disinfect counters, waiting areas, and other spaces - especially where public interaction occurs.
 - Place alcohol-based hand sanitizer next to the cash register or check out area so people can sanitize their hands after using common items like pens.
 - Staff should wash hands with soap and water frequently and for at least 20 seconds. (Hand-washing posters can be downloaded from the MDH Web site listed on the first page of this document).
 - Staff should avoid touching eyes, nose, and mouth.
 - Staff should cover cough and sneeze with tissue and discard.
 - Monitor all staff for sickness regularly. Staff members should stay home if they have symptoms of a respiratory infection.

DELIVERIES OF FILLED PRESCRIPTIONS (INCLUDING BY OUT-OF-STATE PHARMACIES)

Q: Our pharmacy provides a home delivery service. Our drivers may be exposed to COVID-19 if they have to enter a home to get someone to sign for the delivery of the prescription. Do we have to get the signature?

A: No. Pharmacies are not required to make deliveries to the residences of patients. (However, see elsewhere in this document for options that pharmacies can follow to process prescriptions while minimizing contact with individuals who may be infected with COVID-19, which may involve increasing the use of deliveries or mail service). If a delivery service is offered, the Board’s rules don’t require that someone sign for the receipt of the prescription (although pharmacy benefit managers probably have such requirements). So, not getting a signature for the receipt of a prescription would not be a violation of Board rules. The Board does not regulate PBMs but hopes PBMs will waive signature requirements for deliveries. The Board will send correspondence to the Minnesota Department of Commerce, which does regulate PBMs, asking if that department can encourage PBMs to relax any policies that might make it difficult for pharmacies to respond to this crisis.

Q: Our pharmacy sometimes delivers filled prescription to the workplace of the patient or to a caregiver's workplace – (e.g. a parent's workplace when the patient is a child). Do the filled prescriptions have to be delivered directly to the patient or caregiver, or can they be dropped off at a central location, like a reception desk?

A: The Board's delivery rule (6800.3000), subp. 1) has additional requirements when a filled prescription is delivered to a patient's workplace (or caregiver's place of business – for example a parent's workplace if the patient is a child). The rule requires that filled prescriptions be delivered directly to the patient or caregiver of the patient. Until further notice, the Board will waive that requirement and allow a prescription to be dropped off at a central location at the workplace – provided that the patient or caregiver has given at least verbal authorization to do so. Efforts should be made to deliver the filled prescription in a package that does not reveal which medication(s) is/are in the package. (For example, placing the filled prescriptions and any accompanying paperwork in an opaque and sealed bag). Controlled substances prescriptions should not be delivered to a central location. As an alternative, patients or their caregivers can be offered the alternative of having filled prescriptions mailed to their residences.

Q: Our pharmacy delivers filled prescriptions to patients who reside in assisted-living facilities. Some of those facilities have asked that filled prescriptions be dropped off at a central location, staffed by a registered nurse or licensed practical nurse. Can we do that?

A: Yes. For assisted-living facilities that have registered nurses or licensed practical nurses on duty, pharmacies can deliver filled prescriptions to a central location staffed by a nurse. The nurse should sign for the delivery. If the filled prescriptions are normally delivered directly to a patient, the patient should give at least verbal authorization to have the filled prescriptions handled by the facility staff.

Q: We are a pharmacy located in another state that is not currently licensed by the Minnesota Board of Pharmacy. One of our patients is in Minnesota and is unable to return to our state for a COVID-19 related reason. Can we mail or deliver a prescription to that patient without applying for a license from the Board?

A: Yes. For emergency situations, the Board has previously allowed pharmacies located in another state, but not licensed by the Board, to mail or deliver filled prescriptions to one of their patients who is temporarily in Minnesota. Those situations have involved the mailing or delivery of a limited number of prescriptions for a limited period of time. The Board will allow this for COVID-19 related reasons.

DISPENSING PRESCRIPTIONS AND COUNSELING

Q: We have a patient who is out of refills for a medication. We have been unable to get a refill authorization because the prescribers at the patient’s clinic have themselves been infected with or exposed to COVID-19. Can we refill the prescription without an authorization?

A: Yes. Due to a change made by the Minnesota Legislature during the 2019 Session, pharmacists can sometimes refill prescriptions even when the refills have run out, as described below. Pharmacists are 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.

Q: A patient came to my pharmacy to get a prescription filled because the patient's regular pharmacy is closed down indefinitely due to COVID-19. I have been unable to contact the other pharmacy or the prescriber. Can I fill the prescription without getting the required transfer or a new prescription from the prescriber?

A: Yes, provided that:

- The pharmacist has enough information to accurately fill the prescription – for example, the patient presents with a labeled prescription vial or a printout from an online health record system of prescription information;
- In the professional judgement of the pharmacist, the prescription must be filled because the drug is essential to sustain the life of the patient or to continue therapy for a chronic condition and failure to dispense the drug to the patient would result in harm to the health of the patient. Pharmacists must use extra precaution when considering whether or not to dispense controlled substances in this manner; and
- No more than a 30-day supply is dispensed. However, 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. (For example, vials of insulin or boxes of insulin pens).

Q: Can we set up a "curbside delivery" service, with patients being asked to drop off written prescriptions and pick up their filled prescriptions outside of the pharmacy building?

A: Yes. If the prescription requires counseling, patients should be told that a pharmacist will contact them by telephone to provide the counseling.

Q: Will the Board relax counseling requirements?

A: Providing counseling to patients about their prescriptions is very important. However, the COVID-19 pandemic makes it necessary to take precautions designed to slow the spread of the virus. Direct contact with patients presents a risk for potential exposure to the virus that causes COVID-19.

Existing rules already allow pharmacists to exercise professional judgment when determining whether or not to provide counseling for refills. Those rules also currently require pharmacists to initiate counseling on all new prescriptions. The Board will allow pharmacists to exercise judgment in determining when verbal counseling for new prescriptions is necessary – and the Board will allow counseling on new prescriptions to be completed in other than a face-to-face manner. For example, when a pharmacist determines that counseling needs to include a conversation with the patient, the pharmacist can have that conversation by telephone. If verbal counseling for new prescriptions is not provided, pharmacists should make sure that written materials are provided to the patient. Pharmacies should also make sure that patients understand that they can call the pharmacy with any questions they have about their medications.

Due to the need to minimize the risk of exposure to the COVID-19 virus, and given that the Board is allowing more discretion concerning counseling for new prescriptions, the Board is suspending the requirement that refusals for counseling be documented on a log.

Q: Will the Board relax the requirement for quality assurance found in M. Rules 6800.3950, subp. 4 (which is often referred to as the “second check”).

A: QA is a very important process that prevents dispensing errors from harming patients. The Board will not give blanket authorization for pharmacies to skip quality assurance. Pharmacies are reminded that pharmacists can complete quality assurance remotely from other pharmacies. During the COVID-19 pandemic, the Board will also allow QA to be completed remotely by pharmacists working from home.

If, for COVID-19 related reasons, a pharmacy does not have enough pharmacists available (working either within the pharmacy or from a remote location) to both dispense prescriptions and complete the QA, the pharmacy will be allowed to not complete the QA, as long as it notifies the Board before it stops performing the QA and explains why the QA can't be completed. The Board is also relaxing the requirement that QA must be done within 72 hours and will allow it to be completed within seven days.

Q: Can a pharmacist that is licensed and in good standing in another state perform work inside Minnesota, or remotely from the other state?

A: The Board will not give blanket authorization for this to occur. A pharmacy that cannot adequately meet its staffing needs through the allowed use of licensed pharmacists, working by remote access (see below), can contact the Board's Office. Note that this may change if an Executive Order is issued to allow health professionals licensed in other states to participate within Minnesota or to practice remotely. If that occurs, this FAQ will be updated with details.

WORKING BY REMOTE ACCESS

Q: Will the Board allow pharmacists and technicians to work remotely from home in order to complete duties that would normally have to occur within a licensed pharmacy?

Examples: data entry of prescriptions and orders; verification of prescriptions; certification of data entry; certification of the finished prescriptions (commonly called the product check); profile reviews; prospective drug utilization reviews; stage-checking for compounding. If so, does the pharmacy need to submit variances or policies for approval?

A: Yes, the Board will allow for such duties to be performed remotely, **without** the need to submit any documents for approval, provided that:

- The computer software and hardware that is used:
 - Is adequate for the tasks being performed. For example, product checks and stage-checking would require the use of two-way, real-time audiovisual links (not just audio links). Certification of filled prescriptions cannot be done through the use of photographed, scanned or faxed images.
 - Keeps adequate records of filled prescriptions as required by Minnesota Rules 6800.3950 and is capable of identifying the staff involved in the processing of prescriptions.
 - is secure and, preferably, also encrypted.
- Staff working at home take precautions to safeguard protected health information, including the use of appropriate physical and technological means.
- The pharmacies involved notify the Board's Office and provide a description of the processes involved (approval will not be necessary, but Board staff may contact the pharmacies with instructions for changes).

Q: Can pharmacists and technicians working in a pharmacy be remotely involved in the dispensing process of another pharmacy. Example, can a technician working in one pharmacy, do remote data entry for another pharmacy? Another example, can a

pharmacist working in one pharmacy certify the accuracy of data order entry performed by a technician working in a different pharmacy?

A: Actually, many pharmacy chains and health-systems already have approved variances that allow these types of activities to occur. Those pharmacies can continue to operate as allowed by their variances. Pharmacies that do not have approved variances can engage in such activities, provided that:

- The computer software and hardware that is used:
 - Is adequate for the tasks being performed. For example, product checks would require the use of two-way, real-time audiovisual links (not just audio links). Certification of filled prescriptions cannot be done through the use of photographed, scanned or faxed images.
 - Keeps adequate records of filled prescriptions as required by Minnesota Rules 6800.3950 and is capable of identifying the staff involved in the processing of prescriptions.
 - is secure and, preferably, also encrypted.
- The pharmacies involved notify the Board's Office and provide a description of the processes involved (approval will not be necessary, but Board staff may contact the pharmacies with instructions for changes).

PHARMACY SERVICES FOR LONG-TERM CARE FACILITIES

Q: We service automated drug distribution systems (ADDs) in nursing homes and other long-term care facilities. We have a facility that will not allow our staff to enter the facility in order to load drug cannisters into the ADDs. Can staff at the facility load the cannisters instead?

A: No. There is no reason for that to occur. The Board's Executive Director confirmed with the Minnesota Department of Health (which regulates long-term care facilities) that no directive has been given to long-term care facilities to ban all individuals, other than patients and facility staff, from such facilities. Since pharmacy staff servicing the ADDs are performing functions that further the operations of the facilities and that are necessary for patients to receive care, they can be allowed in the facilities. If a facility refuses to allow pharmacy staff in to service the ADDs, they facility will not be able to use the ADDs.

TECHNICIANS

Q: Will the Board allow pharmacies to exceed the technician-to-pharmacist ratio?

A: Yes, but only if exceeding the ratio is necessary due to an actual impact of the COVID-19 virus on the pharmacy, facility or staff involved. For example, some pharmacists must be quarantined at home due to their exposure to COVID-19 or are ill with the virus – but there are technicians that can work in the pharmacy. Pharmacies do not need Board approval to exceed the ratio but should notify the Board if it is expected that the ratio will be continuously exceeded for more than five days.

Q: Will the Board relax the requirement found in M. Rules 6800.3850, subd.2 that states: pharmacy technicians shall be supervised by a licensed pharmacist stationed within the same work area who has the ability to control and is responsible for the action of the pharmacy technician?

A: Yes, given that the Board is allowing both pharmacists and technicians to work remotely, as described above, the Board will allow supervision of pharmacy technicians to occur remotely. The supervision should be done in an appropriate manner. For example, as mentioned above, product certification for dispensing and stage-checking for compounding would require the use of two-way audiovisual equipment.

PHARMACISTS AND TECHNICIANS AS HEALTHCARE WORKERS

Q: I am a pharmacist (or pharmacy technician or pharmacist intern) and I have good reason to believe that I have been exposed to someone who has COVID-19 and I am also exhibiting symptoms of the infection. However, I am being told that I can't be tested because I am not considered to be a "healthcare worker." Is that true?

A: No, that is not true. Board staff has checked with the Minnesota Department of Health and pharmacists, pharmacy technicians, and pharmacist interns are healthcare workers for the purposes of being tested when guidelines call for a healthcare worker to be tested.

QUESTIONS RELATED TO PHARMACIST SCOPE OF PRACTICE, PROTOCOLS

Q: Will the Board be temporarily expanding the scope of practice for pharmacists so that they can perform functions like conducting rapid strep tests and prescribing appropriate antibiotics as necessary?

A: While the Board has the authority to issue variances to its rules and can also exercise *limited* enforcement discretion for statutes, it cannot expand the scope of practice for pharmacists. For certain emergencies related to communicable diseases, the Commissioner of Health has the authority to waive some of the statutes and regulations under the

authority of the Board that are related to the distribution, prescribing, and dispensing of drugs used for such diseases. The Board will keep in contact with MDH to determine what special role, if any, MDH would like pharmacists to have in addressing the pandemic. That will include determining if MDH wants pharmacists to have a role in performing COVID-19 testing.

Under *existing* law, pharmacists **can** issue legally valid prescriptions when working under protocol with practitioners, including physicians, advanced practice registered nurses, and physician assistants. So, pharmacists working under protocol can already conduct rapid strep testing and issue legally valid prescriptions for appropriate antibiotics. This is just one example – protocols can cover a wide range of drugs and related tests.

Q: Can a pharmacist continue to administer vaccinations without a current CPR certification?

A: Yes. Pharmacists must normally follow the guidelines issued by the Advisory Committee on Immunization Practices – and those guidelines call for immunization providers to be certified in CPR. However, the Board understands that entities that provide CPR certification have not been able to provide training and issue certification renewals. Pharmacists whose CPR certification expires during the duration of the Peacetime Emergency declared by the Governor may continue to administer vaccinations.

SAFETY FOR PHARMACY PERSONNEL

Q: Can the Board recommend resources that can be used to help ensure the safety of pharmacy personnel?

A: There are recommendations in several other sections of this document that address measures that pharmacies can take to minimize contact between patients and pharmacy staff members.

Pharmacies are reminded that they have an obligation to follow all statutes and rules that pertain to the operation of their facilities. That includes federal and Minnesota occupational safety and health statutes and rules. The Minnesota Department of Labor and Industry (DLI) has a page that includes information about MNOSHA compliance for COVID-19. (<https://www.dli.mn.gov/business/workplace-safety-and-health/mnosha-compliance-novel-coronavirus-covid-19>).

In addition, the federal Occupational Safety and Health Administration has issued a *2020 Guidance on Preparing Workplaces for COVID-19*, which is available at:

<https://www.osha.gov/Publications/OSHA3990.pdf>. Since this is a guidance document, pharmacies do not have to follow all of processes listed, unless an action is required by a federal or state law, rather than being a recommendation.

CONTROLLED SUBSTANCES

Q: Has the United States Drug Enforcement Administration (DEA) provided any information concerning controlled substances that takes into consideration the COVID-19 pandemic?

A: Yes. The DEA has a *COVID-19 Information Page* which can be accessed at:
<https://www.deadiversion.usdoj.gov/coronavirus.html>

Q: Minnesota law states that Schedules II through V controlled substance prescriptions can't be dispensed without requiring the person purchasing the controlled substance to present valid photographic identification, unless the person purchasing the controlled substance is known to the dispenser. It also requires pharmacies to check IDs when selling pseudoephedrine-containing products. Does the Board have any guidance on these requirements, given the COVID-19 pandemic? Also, is it true that pseudoephedrine products can't be sold to customers through our drive-up window?

A: Yes. It has come to the Board's attention that Minnesotans are having a difficult time renewing driver's licenses, state ID cards, and other forms of identification. First, note that *you do not have to check an ID for prescriptions if the purchaser is known to you*. For both prescriptions and pseudoephedrine, you may also rely on an expired driver's license, state ID card, or other form of identification to meet this requirement.

It is NOT true that pseudoephedrine-containing products can't be sold to a customer through a drive-up window. Minnesota statutes require pharmacies to ensure that all packages of such products be "displayed behind a checkout counter where the public is not permitted and are offered for sale only by a licensed pharmacist, a registered pharmacy technician, or a pharmacy clerk." The law also requires the buyer of a product to "provide photographic identification showing the buyer's date of birth" and to "sign a written or electronic document detailing the date of the sale, the name of the buyer, and the amount of the drug sold."

The law does NOT state that the purchaser can't pick the pseudoephedrine up at a drive through window. Also, unlike some other states, Minnesota does not require the use of the National Precursor Log Exchange (NPLEx) system for the purchase of pseudoephedrine-containing products. Having the purchaser sign a paper log is satisfactory.

Q: I am concerned that patients who need opiate analgesics may have difficulty obtaining them. Can the Board supply information about how those drugs can be prescribed and dispensed?

A: Here is some information that should be useful to prescribers, pharmacists and patients:

- Minn. Stats. §151.37 does state that prescriptions for controlled substances are not valid unless the patient has had an in-person physical examination. It was put in place a dozen years ago to deal with illegitimate Web sites that were allowing people to purchase narcotics online. However, the requirement for an examination can be met as follows:
 - the prescribing practitioner examines the patient at the time the prescription or drug order is issued;
 - the prescribing practitioner has performed a prior examination of the patient;
 - another prescribing practitioner practicing within the same group or clinic as the prescribing practitioner has examined the patient;
 - a consulting practitioner to whom the prescribing practitioner has referred the patient has examined the patient; or
 - the referring practitioner has performed an examination in the case of a consultant practitioner issuing a prescription or drug order when providing services by means of telemedicine.

So, a chronic pain patient who has been previously examined by the prescriber, or any other prescriber working within the same practice group, would not legally need an in-person examination. Of course, the prescriber may have a valid clinical reason for wanting the person to come in for another examination.

- On March 31, 2020, the DEA published [a prescribing diagram](#) on its COVID-19 Web page. When a patient has not been previously examined by the prescriber, the DEA is now permitting an evaluation of the patient in one of the following ways:
 - in person, or
 - via telemedicine using a real-time, two-way, audio-visual communications device.

Consequently, the Board is exercising enforcement discretion and allowing prescriptions for controlled substances to be issued when the evaluation has occurred by telemedicine using a real-time, two-way, audio-visual communications device – even if the requirements in Section 151.37 for an in-person examination are not met.

- The Governor signed into law a bill that primarily addressed the COVID-19 pandemic. However, it included a section related to this question. The bill removed 30-day time limits for filling prescriptions for opiate analgesics. That means that for Schedule III and IV drugs like Tylenol with Codeine and tramadol, prescribers can once again authorize five refills for up to six months at a time – and those refills do not need to be filled within 30 days of the previous fill. For Schedule II prescriptions,

they can write out three one-month prescriptions and give them to the patient – with instructions that the second and third prescriptions be filled at one-month intervals. Also, federal and state laws are such that, *if a prescriber thought it prudent*, a prescription for Schedule III and IV drugs could be written for a six-month quantity. (e.g. – if a patient was taking one tablet per day, the prescription could actually be written for 180 tablets). Prescriptions for Schedule II drugs can be issued for a 12-month quantity at one time. (Of course, insurance would typically pay for no more than a 90-day supply at one time). As always, pharmacists must use their professional judgment in determining whether or not dispensing large quantities of opiate analgesics is clinically appropriate.

- Pharmacies have been able to deliver or mail prescriptions to patients for a very long time. There are no federal or state restrictions on the mailing or delivery of filled controlled substance prescriptions. Other areas of this document encourage pharmacies to increase the delivery and mailing of prescriptions as a means of limit contact between pharmacy staff and patients.
- There is no federal or state legal requirement that patients go into a clinic to pick up written prescriptions for controlled substances. Actually, Minnesota law is such that all prescriptions are supposed to be issued via electronic prescribing – even those for controlled substances. However, it is the Board’s understanding that many prescribers are not equipped to issue controlled substance prescriptions electronically. As an alternative, they can mail written prescriptions to the patient’s home or pharmacy. For Schedule III and IV prescriptions, they can phone the order into a pharmacy.

POSSIBLE DRUG AND MEDICAL SUPPLY SHORTAGES

Q: Is it true that Governor Walz issued an Executive Order that included a provision related to the dispensing of chloroquine and hydroxychloroquine?

A: Yes. On March 27, 2020, Governor Walz issued Emergency Executive Order 20-23, which includes the following authorization (emphasis added):

“I authorize the Minnesota Board of Pharmacy, established pursuant to Minnesota Statutes 2019, section 151.02, to enforce the following medication dispensing limitations, until termination of the peacetime emergency declared in Executive Order 20-01. **A prescription drug order for chloroquine or hydroxychloroquine must contain a diagnosis appropriate for the use of these medications and be dispensed for no more than 30 days at a time.**”

Q: What guidance does the Board have concerning the dispensing limitations of Emergency Executive Order 20-23?

A: The Board's guidance is as follows:

- Concerning the phrase “diagnosis appropriate for use”
 - It includes any FDA-approved indication for the drug being dispensed.
 - The FDA has not approved either of these drugs for the treatment of COVID-19. However, in one of its own [FAQs about COVID-19](https://www.fda.gov/oc/questions-and-answers/coronavirus-2019-ncov), the FDA notes the U.S. Centers for Disease Control has information for health care providers about potential treatments for COVID-19, including chloroquine and hydroxychloroquine: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/therapeutic-options.html>. In deciding whether or not to dispense one of these drugs for a diagnosis of infection with the SARS-CoV-2 virus that causes COVID-19, pharmacists should consider any recommendations made by the FDA and the CDC that are current at the time that the decision is being made.
- The 30-day quantity limit applies to all diagnoses. If the amount that is being prescribed for a 30-day period exceeds the amount that would typically be dispensed for the diagnosis in question, the pharmacist should contact the prescriber to discuss the need for the higher-than-normal dose. (Unless the patient has previously been prescribed the higher dose).
- If a patient tries to refill prescriptions too soon or tries to fill multiple prescriptions for these drugs within the 30-day period, pharmacists should handle such requests as they would normally handle such requests for any prescription – and determine if there is a clinically valid reason for honoring the request.
- If the prescriber has not either written a diagnosis on a paper prescription, placed it on a faxed prescription, or provided it for an electronic prescription, the pharmacist **does not** need to have the prescriber reissue a new prescription. The pharmacist may contact the prescriber by fax, telephone or other appropriate means to obtain the diagnosis. The pharmacist should write the diagnosis on the prescription or otherwise indicate it in the patient's profile.
 - Note that if the patient has been receiving prescriptions for one of these drugs on an ongoing basis and the pharmacist knows the diagnosis for which the patient has been prescribed the drug, the pharmacist does not need to contact the prescriber but should write the diagnosis on the prescription or otherwise indicate it in the patient's profile.

Q: How can pharmacists respond to requests to fill prescriptions for drugs such as chloroquine, hydroxychloroquine, and azithromycin when it appears that the intended use is to treat COVID-19? Can pharmacies legally sell such medications to prescribers for office use?

A: Pharmacists are required to fill prescriptions that pharmacists are reasonably expected to fill. However, a pharmacist can refuse to fill a prescription if, in the pharmacist's professional judgment, the prescription is not legally valid or clinically appropriate. As with any drug, pharmacists can consider what evidence might be available to support the use of a drug for a particular diagnosis, recommendations from public health agencies, potential side-effects of a drug, potential drug interactions, and the items that they are supposed to consider when conducting a prospective drug utilization review as required by Minn. Rules 6800.3110, subp. 4. Pharmacists are reminded that if they are concerned about potential inappropriate prescribing on the part of a practitioner, they are permitted to report their concerns to the health licensing Board that licenses the prescriber.

Pharmacies are allowed to sell only *minimal* quantities of prescription drugs to practitioners for office use without being licensed as a drug wholesaler. Therefore, pharmacies are *always* prohibited from ordering any drugs from manufacturers and wholesalers and then selling them in more than minimal quantities to practitioners. In the case of any drug, it is permissible for pharmacists to inquire about the need for and intended use of the drugs before selling even minimal quantities for office use. In addition, while pharmacists are required to fill prescriptions that pharmacists are reasonably expected to fill, pharmacies and pharmacists are *not* required to sell any medication to practitioners for office use.

Q: How can pharmacists respond if consumers are asking to purchase large quantities of over-the-counter drugs or medical supplies?

A: While pharmacies and pharmacists are legally required to fill any prescription that a pharmacist would reasonably be expected to fill in a licensed pharmacy, there is no legal requirement to even stock over-the-counter (OTC) drugs (although, of course, all pharmacies do). Consequently, pharmacies can limit the quantity of OTC drugs that a consumer is allowed to purchase.

Neither the Board, nor any other Minnesota agency, regulates the sale of medical supplies or devices. Pharmacies can limit the quantity of medical supplies that a consumer is allowed to purchase.

Q: How can a pharmacist respond if a patient wants to get a quantity of a medication that is greater than the quantity prescribed. For example, if a prescriber has written a prescription for a 30-day supply of a maintenance drug and the patient wants me to dispense a six-month supply. Can I do so without getting the permission of the prescriber?

A: No. Except has noted below, a pharmacist can never dispense a quantity greater than the quantity indicated on the prescription by the prescriber. Exception: after a patient has obtained an initial 30-day supply of a prescription drug, and the patient returns to the pharmacy to obtain a refill, a pharmacist may dispense up to a 90-day supply of that prescription drug to the patient when the following requirements are met:

- the total quantity of dosage units dispensed by the pharmacist does not exceed the total quantity of dosage units of the remaining refills authorized by the prescriber; and
- the pharmacist is exercising the pharmacist's professional judgment.

The initial 30-day supply requirement mentioned above is not required if the prescription has previously been filled with a 90-day supply.

This exception does not apply, and a pharmacist may not exceed the number of dosage units authorized by a prescriber for an initial prescription or subsequent refills if:

- the prescriber has specified on the prescription that, due to medical necessity, the pharmacist may not exceed the number of dosage units identified on the prescription; or
- the prescription drug is a controlled substance.

COMPOUNDING

Q: Does the Board have any recommendations concerning the possibility of shortages of sterile compounding garb?

A: Yes. See below.

There may be a shortage of sterile compounding garb due to the fact that much of the garb is produced in China (specifically Wuhan, the epicenter of the pandemic).

The Board has adopted USP General Chapter <797> *Pharmaceutical Compounding – Sterile Preparations*, by reference into its rules. USP published a document on March 18, 2020 titled *USP Response to Shortages of Garb and Personal Protective Equipment (PPE) for Sterile Compounding During COVID-19 Pandemic*, which is available at:

<https://www.usp.org/sites/default/files/usp/document/about/public-policy/usp-covid19-garb-and-ppe.pdf>).

Strategies used to conserve garb may result in a pharmacy being out of compliance with USP Chapter 797. The Board will exercise enforcement discretion during this time of limited supplies if your pharmacy can demonstrate it complied with best practices during a period of documented supply limitations. If your pharmacy decides to implement any strategies to conserve garb, and implementation results in noncompliance with USP Chapter 797, you must develop and maintain a policy demonstrating compliance with best practices. One way to do so is to follow the recommendations made by USP. Critical Point has also made recommendations concerning this issue.

Additional resources include:

- CDC's Interim Guidance on preventing COVID-19 from spreading, which includes Strategies for Optimizing the Supply of N95 Respirators at <https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/>
- Healthcare Supply of Personal Protective Equipment at <https://www.cdc.gov/coronavirus/2019-ncov/hcp/healthcare-supply-ppe.html>
- FDA's Surgical Mask and Gown Conservation Strategies - Letter to Healthcare Providers at <https://www.fda.gov/medical-devices/letters-health-care-providers/surgical-mask-and-gown-conservation-strategies-letter-healthcare-providers>
- Critical Point (requires *free* subscription) - <https://peernetwork.criticalpoint.info/>

Q: Will the Board relax prohibitions against the compounding of products that are essentially copies of commercially available products in the event of shortages of commercially available products?

A: The expectation is that the compounding of products that are essentially copies of commercially available products will not occur unless:

- there is a change, made for an identified individual patient, that produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product;
- there is a shortage of the commercially available product, as determined by the FDA

If these conditions do not exist, a pharmacy may compound a product that is essentially a copy of a commercially available product only if it can document that it has attempted and failed to obtain the commercially available product.

Q: Given shortages of hand sanitizer, can pharmacies and outsourcing facilities compound and sell hand sanitizer products?

A: Yes. As long as the pharmacy or outsourcing facility follows the relevant guidance document issued in March 2020: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-temporary-compounding-certain-alcohol-based-hand-sanitizer-products-during-public-health> (Click on the “Download the Final Guidance Document” button to access the guidance) and the hand sanitizer is compounded using USP grade ingredients (ethanol 96% or Isopropyl Alcohol 99.8%), resulting in final hand sanitizer concentrations of ethanol 80% or isopropyl alcohol 75% respectively, consistent with World Health Organization (WHO) recommendations. (Note: the use of different ingredient strengths or quantities may impact the quality of the final product and concentration, potentially making it ineffective against COVID-19).

Q: Can a registered nurse temporarily perform sterile product admixture in a licensed pharmacy space?

A: Not at this time. The Board may revisit this issue, however.

PRESCRIPTION MONITORING PROGRAM (PMP)

Q: The law requires a PMP user (e.g. prescriber or pharmacist) who uses a delegate to access PMP data, to audit the delegate’s use of the PMP - at least quarterly - to ensure that the delegate is not using the PMP inappropriately. Will the Board relax that requirement due to the COVID-19 pandemic?

A: Yes. The requirement to audit a delegate’s use of the PMP is suspended at this time. Notification will be sent when this suspension is lifted.

In the meantime, we still recommended conducting an audit, *if time permits*. If the delegate is found to have inappropriately accessed the MN PMP data, the account holder must immediately remove access for that delegate and notify the Prescription Monitoring Program within seven calendar days. A copy of this suggested process and expectations are available on the MN PMP website at www.pmp.pharmacy.state.mn.us.

If you have additional questions, please email them to minnesota.pmp@state.mn.us

OPERATIONS OF THE BOARD'S OFFICE

GENERAL OPERATIONS

Q: Will the Board of Pharmacy remain open for business and will the hours of operation remain the same?

A: Yes. Given recommendations from the U.S. Center for Disease Control and the Minnesota Department of Health in regard to social distancing, the Board encourages licensees, registrants, and members of the public to conduct business with the Board remotely. However, the Board will *not* close its office to the public entirely unless directed to do so by the Governor. But many of the Board's staff members will be working remotely. All staff members have the equipment necessary to work remotely. The Pharmacy Surveyors, Executive Director, and Deputy Director will continue to respond to questions received by e-mail or voice message from pharmacists, pharmacies, and other licensed facilities. The rest of the staff will continue to respond to the types of questions that they handle. We will be changing procedures for facility license renewals as noted below.

BOARD MEETINGS

Q: Will the Board's regularly scheduled meetings (Full Board, Variance and Policy Review Committee, Committee on Professional Standards) continue to be held?

A: *At the April 1, 2020 full Board meeting, which was held by telephone conference, the Board decided to cancel the May 6, 2020 Variance and Policy Review Committee meeting. The Board also cancelled the May 20, 2020 meeting. Please see below for information on the handling of requests for variances and policy reviews.*

NEW LICENSES AND RENEWALS

Q: Will facilities already licensed by the Board be allowed to continue operating if the Board is unable to process renewals (for example, if absence of Board staff due to infection with or exposure to COVID-19 delays processing of applications)?

A: The Board will try to ensure that licenses are renewed on time. However, if Board staff can't process renewal applications in a timely manner, a facility will be allowed to continue operating until the license can be renewed. No late fees will be assessed if a license renewal is delayed for this reason. The Board will notify affected licensees as soon as possible.

Q: Will facilities already licensed by the Board be allowed to continue operating if, due to COVID-19, their staff is unable to submit license renewal applications in a timely manner?

A: Yes, but facility licensing staff should notify the Board that COVID-19 is causing a delay in submission of applications – and indicate when the application will most likely be submitted. The Board will consider waiving late fees if a license renewal is delayed for this reason, depending on the length of delay.

Q: Will the Board process applications for new licenses and registrations in a normal manner?

A: The Board will make every effort to process applications for new licenses and registrations in the usual manner. However, there may be delays if Board staff members are unable to work due to infection with or exposure to COVID-19.

Normally, licenses for new in-state facilities are not issued until the facility has passed an inspection conducted by a Pharmacy Surveyor. It is possible that Pharmacy Surveyors may work with facility staff to obtain information remotely (for example, having facility staff submit videos or photographs of the facility). That may allow preliminary approval of a license. Note that full inspections of facilities might be scheduled for a later date.

VARIANCES AND POLICY REVIEWS

Q: Will the Board continue to process variance requests and review policies that need Board approval?

A: The Board considered this issue at its April 1, 2020 meeting. Businesses and individuals can continue to submit new requests for variance and policy reviews. However, if Board staff members are unable to work due to infection with or exposure to COVID-19, processing of variance requests and policy reviews may be delayed. If a delay is necessary for variance requests, the individual or business submitting the request may be asked to agree to defer consideration of the variance. The Board's Executive Director received a temporary delegation of authority to approve or deny submitted requests for variances or policy reviews – and to temporarily extended the expiration dates for existing variances for up to 90 days. The Board's Deputy Director will have that same delegated authority in the event that the Executive Director is incapacitated.

Q: Our facility has an existing variance that is due to expire. Can we continue using the variance if the Board is unable to process the renewal request before the expiration date?

A: Yes, unless you are notified by the Board that you can't do so. (But only provided that you have submitted the renewal request - or notified the Board that the submission will be

delayed for a reason related to the COVID-19 pandemic). As noted above, the Board's Executive Director now has delegated authority to temporarily extended the expiration dates for existing variance for up to 90 days.