



Frequently Asked Questions: COVID-19
(September 15, 2020 – changes from the 8/25/2020 version are in red)

This document was 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 (and extended by Emergency Executive Orders 20-35, 20-53, 20-75 and 20-83) 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 The Board will notify licensees and registrants when this FAQ document is withdrawn or when the Peacetime Emergency is ended.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)**
 - **General resources:** <https://www.cdc.gov/coronavirus/2019-ncov/index.html>
 - **Specific resources for pharmacists:** <https://www.cdc.gov/coronavirus/2019-ncov/healthcare-resources/pharmacies.html>
 - **Cleaning and Disinfecting Your Facility:** <https://www.cdc.gov/coronavirus/2019-ncov/community/disinfecting-building-facility.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 United States Pharmacopeia:** <https://www.usp.org/compounding>
- **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>
- **From the Joint Commission**
 - The Joint Commission created a [resource page](#) to support health care professionals and organizations on the front lines of the COVID-19 pandemic.

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 that staff and patient are exposed to an infected with the COVID-19 virus, 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:
 - Wear suitable masks.
 - When possible, staff should maintain a distance of at least six 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 indicative of a COVID-19 infection.

Q: Does the Board have guidance concerning the use by pharmacies of temporary satellite locations for the storage and use of medications during the COVID-19 pandemic?

A: Yes. Although it seems less likely than it did at the beginning of the pandemic, it may be necessary for pharmacies to provide drugs and services at locations that are not currently licensed by the Board. (For example, a pharmacy might be called upon to provide drugs and services to a temporary field hospital). Therefore, the Board has published a guidance on its Web site: <https://mn.gov/boards/pharmacy/licenseregistration/pharmacy.isp>

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. Board staff has heard from some PBMs that they are waiving such requirements.

Q: Our pharmacy sometimes delivers filled prescriptions 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. However, if the patient(s) is/are staying in Minnesota for more than a limited period of time, the pharmacy will need to obtain a license from the Board.

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.
- Staff must be licensed or registered by the Minnesota Board of Pharmacy and must normally work within the state, either in a licensed pharmacy or a hospital.
- 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 pharmacies involved are licensed by the Minnesota Board of Pharmacy and are located within the state.
- Pharmacists are licensed Minnesota pharmacists
- Technicians are registered with the state of Minnesota
- 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.

Q: If pharmacy staff members have fevers, should they get tested and stay home until the results come in? If the results are positive for Covid, should the rest of the staff be tested?

A: The Minnesota Department of Health has a document dedicated to health care workers and COVID-19 that may help answer these questions. It is available at:

<https://www.health.state.mn.us/diseases/coronavirus/hcp/hcwrecs.pdf>.

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.

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 pharmacists be involved in any type of testing for COVID-19?

A: Pharmacists may now be involved in certain types of COVID-19 testing – *per state law* (however, see below for an update concerning an Advisory Opinion issued by the Federal Department of Health and Human Services (HHS) that expands the sort of testing that pharmacists can be involved in). The FDA clarified in April 2020 that, when it grants an Emergency Use Authorization (EUA) for a *point-of-care test*, the test is deemed to be CLIA-waived. That is an important clarification because, pursuant to Minn. Stats. §151.01, subd. 27, pharmacists can only be involved in CLIA-waived tests.

Given the FDA clarification pharmacists can take part, *under existing state law*, in COVID-19 testing that involves the use of *point-of-care tests* that have an Emergency Use Authorization approved by the FDA. A list of COVID-19 tests that have obtained EUAs from the FDA is available at:

<https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>

Pharmacies are reminded that in order to do any CLIA-waived testing they must have a CLIA Certificate of Waiver. That has been a long-standing requirement. Information about obtaining the Certificate of Waiver can be found on the MDH Web site:

<https://www.health.state.mn.us/facilities/regulation/clia/index.html> (See the FAQ section).

Only pharmacists, and pharmacist interns under the immediate supervision of a pharmacist, can perform the allowed tests. Pharmacy technicians can only be involved in completing required paperwork, including the required reporting to MDH, as noted below. Before they can perform tests, pharmacists and pharmacist interns must have appropriate training. ***Pharmacies must also provide staff with appropriate personal protective equipment.***

The Minnesota Department of Health (MDH) has a page named *Reporting COVID-19/SARS-CoV-2 Infections*. <https://www.health.state.mn.us/diseases/coronavirus/hcp/report.html>. ***Pharmacists conducting COVID-19 tests are subject to the reporting requirements specified on that Web page.*** Both positive and negative tests must be reported. A reporting form is available on the MDH reporting Web page.

MDH also has a Web page devoted to *Evaluating and Testing for Coronavirus Disease 2019 (COVID-19)*: <https://www.health.state.mn.us/diseases/coronavirus/hcp/eval.html>

Additional information from the FDA about COVID-19 testing is available at:

<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2>

On May 19, 2020, HHS issued [Advisory Opinion 20-02 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration Under the Act](#) that includes this statement “we conclude that the PREP Act, in conjunction with the Secretary’s March 10, 2020 declaration, preempts any state or local requirement that prohibits or effectively prohibits a pharmacist from ordering and administering a COVID-19 diagnostic test that the Food and Drug Administration (FDA) has authorized.” The advisory also mentions that a previous advisory authorized “licensed pharmacists to order and administer COVID-19 tests, *including serology tests* that the Food and Drug Administration (FDA) has authorized. (emphasis added).

Given this new HHS Advisory, pharmacists can now order and administer *any FDA authorized COVID-19 test*, even serology tests. But note that the HHS Advisory states:

“Persons seeking PREP Act immunity are responsible for determining whether their products are covered countermeasures, whether a person or entity is a covered person, whether reasonable precautions have been taken to facilitate the safe use of covered countermeasures, and in general, whether immunity applies to them and their activities.”

Consequently, the Board still expects pharmacies to establish testing procedures that will safeguard both staff and patients, including the provision of appropriate personal protective equipment to staff involved in the testing. Another “reasonable precaution” is to require that pharmacists involved in testing receive adequate training concerning the tests that are used. Per the HHS Advisory, pharmacies have a responsibility to make sure that any test used has, in fact, been approved by the FDA.

Finally, it is not inconsistent with the HHS Advisory to continue requiring pharmacies to report tests results to MDH – as described above.

Q: Can pharmacists administer any vaccines other than those allowed under Minn. Stats. §151.01, subd. 27 (6)?

A: On August 19, 2020, the Federal Department of Health and Human Services issued the [Third Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19](#) that supersedes state laws and that allows state-licensed pharmacists to order and administer, and pharmacy interns to administer, vaccines that the Advisory Committee on Immunization Practices (ACIP)

recommends to *persons ages three through 18 according to ACIP's standard immunization schedule*. (Pharmacy interns must act under the supervision of a licensed pharmacist and the pharmacy intern must be licensed or registered by his or her State board of pharmacy). Minnesota licensed pharmacists, and the Minnesota registered pharmacy interns under their supervision, are qualified persons **only if the following requirements are met**:

- The vaccine must be FDA-authorized or FDA-licensed.
- The vaccination must be ordered and administered according to ACIP's standard immunization schedule.
- The licensed pharmacist must complete a practical training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE). This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines. (The Board interprets "practical training program" to include immunization training offered as part of the curriculum of an ACPE-accredited school or college of pharmacy or an immunization training program offered by an ACPE-approved continuing education provider. Under Minnesota statutes, the Board can approve other type of immunization training programs. However, the Board will *not* be able to approve other types of immunization training programs for the purposes of this Federal HHS amendment).
- The registered pharmacy intern must complete a practical training program that is approved by the ACPE. This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines. (The Board interprets "practical training program" to include immunization training offered as part of the curriculum of an ACPE-accredited school or college of pharmacy or an immunization training program offered by an ACPE-approved continuing education provider. Under Minnesota statutes, the Board can approve other type of immunization training programs. However, the Board will not be able to approve other types of immunization training programs for the purposes of this Federal HHS amendment).
- The licensed pharmacist or registered pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation. (The answer to the next question in this document includes this statement: "Pharmacists whose CPR certification expires during the duration of the Peacetime Emergency declared by the Governor may continue to administer vaccinations." While that still applies to the vaccinations that pharmacists have been able to administer under Minnesota law, it does **not** apply to the vaccinations authorized by the HHS amendment, which appears to pre-empt state laws).

- The licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each State licensing period. (Minnesota law does not require pharmacists to complete immunization CE during every two-year cycle. Given that the current cycle ends on September 30, 2020, pharmacists will not have to complete this CE for this cycle. However, pharmacists will have to complete this CE during the next cycle that starts on October 1, 2020 if they want to vaccinate children covered by the HHS amendment).
- The licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including informing the patient’s primary-care provider when available, submitting the required immunization information to the State or local immunization information system (vaccine registry), complying with requirements with respect to reporting adverse events, and complying with requirements whereby the person administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine. (Pharmacists can find information concerning these requirements for Minnesota at):
 - https://mn.gov/boards/assets/MNPharmacyImmPractice_2017_December_tcm21-389957.pdf and at
 - <https://www.health.state.mn.us/people/immunize/hcp/pharmacists.html>.
- The licensed pharmacist must inform his or her childhood-vaccination patients and the adult caregiver accompanying the child of the importance of a well-child visit with a pediatrician or other licensed primary-care provider and refer patients as appropriate. *The Board expects pharmacists to provide this information in writing.* Here is an example of the type of written information that might be provided:
 - “You have taken an important step in protecting yourself and your family from infectious disease by being vaccinated. Your pharmacist is an important part of your health care team.

But it is also important for children to have routine checkups performed by a physician, physician assistant, or advanced practice registered nurse. During “well care” checkups, the provider may perform a physical examination, order laboratory tests, do vision and hearing screenings, etc. These checkups can detect medical problems so that they can be treated. You can find additional information on the Minnesota Department of Health Web site at: Child and Teen Checkups Information for Families. <https://www.health.state.mn.us/people/childreneyouth/ctc/families.html>.”

Under Minnesota statutes, pharmacists must enter into a protocol with a physician, advanced practice registered nurse, or a physician assistant to administer any vaccines. However, the HHS amendment allows pharmacists to “order and administer” vaccines down to the age of three. That means that pharmacists will not need to amend their protocols to administer vaccines to children – they can order the vaccines on their own.

Nothing in the HHS amendment changes the requirement that pharmacists and pharmacies must ensure equal access to immunizations for children (defined as individuals through 18 years) enrolled in a Minnesota Health Care Program (MHCP), which includes children enrolled in Minnesota Medical Assistance (MA), MinnesotaCare, or Prepaid Medical Assistance Programs (PMAPs). This can be done by enrolling in the Minnesota Vaccines for Children (MnVFC) program. The MnVFC program will provide enrolled pharmacies with vaccines to be given to children that are in a MHCP, uninsured, or American Indian/Alaskan Native. For children enrolled in a MHCP, the pharmacy can bill the MHCP for the vaccine administration fee. More information on the MnVFC program can be found at www.health.state.mn.us/mnvfc.

If a pharmacist is not enrolled in the MnVFC program and is providing vaccines to privately insured children or to children who are cash customers, a pharmacist *must also provide the same vaccines to MHCP-enrolled children free of charge*. The pharmacy cannot charge MHCP-enrolled children for the cost of the vaccine or for an administration fee. Additionally, the pharmacy cannot bill the MHCP for the vaccine administration fee if they are not enrolled in the MnVFC Program. The Board is working with DHS and MDH to determine if HHS will issue any guidance on the impact that its amendment will have on the MnVFC.

The HHS Amendment was issued due to concern about significant gaps in vaccination coverage for children that have occurred due to COVID-19. The following is information from the Minnesota Department of Health concerning the vaccination gap and catch-up vaccination:

“As you are aware, significant gaps in immunization coverage have occurred as the result of the COVID-19 pandemic and Minnesota’s stay at home order from last spring. Even now months later, we continue to hear from families who are afraid to go back to their clinic for routine care and well-child check-ups. To monitor vaccination service delivery and raise awareness for this issue, we are maintaining data on our website for MMR administration by week for children under the age of 2 (<https://www.health.state.mn.us/people/immunize/hcp/vaxpan.html>). When

comparing doses administered in 2019 to the same weeks in 2020 in this age group, we see the gap has greatly diminished over time but there is still much catch-up vaccination yet to occur. Statewide, the total MMR doses given to this age group from January through July is behind by approximately 7,000 doses between the two years. We are also continuing to monitor trends in doses administered to school-age children (4-6 years) and adolescents (11-12 years). The gap for these aged children is more pronounced, the rebound has been slower, and the catch-up burden is great. Specifically, the current percentage decline for overall doses administered for children age 4-6 years is 29%, and for adolescents 11-12 years, it is 28%. These data suggest the pandemic continues to have an impact on vaccination. We want to make sure that partners are aware of resources that can help address the gap:

- Information on providing vaccination while protecting patients and staff: <https://www.health.state.mn.us/people/immunize/hcp/covidpediz.pdf>
- 30-second video PSA on childhood vaccinations during the pandemic: https://www.youtube.com/watch?time_continue=23&v=1AqZxijGwWo&feature=emb_logo
- MIIC training on reminder/recall functionality (in conjunction with MnAAP): <http://www.mnaap.org/work-groups/immunizations/>

MDH will continue to conduct a social media campaign on this topic and would appreciate amplification of the messaging from the organizations represented by MIPAC. We also plan to continue to do outreach to underserved communities about the importance of families returning to their clinics for routine preventive care. The key messages of this outreach include:

- Immunizations are important
- It is safe to go back to your clinic for well child visits
- Call your provider to schedule an appointment and learn about how to safely access care
- Get your immunization record by calling 612-201-3980 or visiting www.health.state.mn.us/immunize

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.

Q: Can a pharmacist give vaccinations outside of a pharmacy?

A: Nothing in Minnesota statutes or rules requires that pharmacists give vaccinations only within a licensed pharmacy. However, pharmacists on duty in licensed pharmacies are expected to supervise technicians, interns and other staff that work in the pharmacy. Minn. Rules 6800.2150, subp. 1 states:

“A pharmacy or satellite pharmacy shall have at least one licensed pharmacist on duty and physically present in the pharmacy at all times that the pharmacy is open for the transaction of business except for **brief** absences of the pharmacist arising out of and in the course of pharmacy practice. “

The length of time that it would take a pharmacist to leave the building to give a vaccination at curbside or in the parking lot would **not** be considered a brief absence. That would particularly be the case if the pharmacy were advertising an influenza vaccination “clinic” – where multiple patients might arrive for a vaccination.

Scheduling vaccination appointments or events in advance allows a pharmacy to continue providing this needed service to the public and to reduce potential exposure of certain staff to COVID-19. It also allows the site to anticipate and manage demand for pharmacist time so that proper scheduling and operation of the pharmacy, including supervision of technicians, can be maintained. The Board is aware of pharmacies that have opened early in order to give vaccinations at a time pre-announced to patients. Pharmacies are also scheduling vaccination events, having pharmacists and technicians on duty strictly for the event, with other pharmacists and technicians working in the pharmacy to dispense prescriptions.

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. The CDC has a Web page titled *Considerations for Pharmacies during the COVID-19 Pandemic*:

<https://www.cdc.gov/coronavirus/2019-ncov/healthcare-resources/pharmacies.html>

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>

That page has links to many different documents issued by the DEA, in which the DEA offers guidance to DEA registrants. The DEA is exercising enforcement discretion or otherwise relaxing a number of requirements related to controlled substances for the duration of the federally declared COVID-19 Public Health Emergency. Since Minnesota law concerning controlled substances is, for the most part, modeled after federal law – and often defers to federal law – the Board will allow pharmacies to follow the guidance given by the DEA until it is either rescinded by the DEA or for the duration of the Peacetime Emergency declared by Governor Tim Walz.

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: 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, please 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 & MEDICAL SUPPLY SHORTAGES (including drug wholesaling exceptions)

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.**”

However, Governor Walz issued Emergency Executive Order 20-84 on August 12, 2020, which includes the following:

“On March 27, 2020, I issued Executive Order 20-23, which authorized Minnesota health-related licensing boards to modify licensure requirements during the COVID-19 peacetime emergency. Executive Order 20-23 also authorized the Minnesota Board of Pharmacy to require that prescription drug orders for chloroquine or hydroxychloroquine must contain an appropriate diagnosis and be dispensed for no more than 30 days at a time. Although the modification of licensure requirements remains necessary during the pandemic, we no longer need to limit the use of chloroquine or hydroxychloroquine because these medicines have not been proven to be effective treatments for COVID-19 and are no longer in high demand. The authorization for the Minnesota Board of Pharmacy to implement dispensing limitations related to these medicines is no longer necessary and can be rescinded.”

“Paragraph 5 of Executive Order 20-23, which pertains to chloroquine and

hydroxychloroquine, is rescinded.”

Consequently, there are no longer any limitations related to the dispensing of chloroquine and hydroxychloroquine. A diagnosis code is no longer needed on prescriptions for these drugs and there are no longer any quantity limitations. However, as is always the case with any prescription, pharmacists need to exercise appropriate professional judgment when determining whether or not to dispense one of these drugs. Pharmacists should consider FDA and CDC recommendations, peer-reviewed studies, the medical conditions and history of the patient, and other pertinent information when considering the dispensing of one of these drugs to treat or prevent COVID-19.

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 as 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.

Q: Are there exceptions to drug wholesaling requirements that apply during the peacetime emergency declared by Governor Walz?

A: Yes, there are. Normally, prescription drugs in the possession of pharmacies, hospitals, clinics and other health care facilities can't be transferred to other health care facilities unless the facility that is transferring the drug is licensed as a drug wholesaler. (Except when the transferring and receiving facilities are under common ownership, in which case no wholesaler license is required).

However, Minn. Stats. §151.441, contains this exception to the definition of “wholesaling.”

- the distribution of a drug or an offer to distribute a drug for emergency medical reasons, including . . . a national security or peacetime emergency declared by the governor pursuant to section 12.31

Since the Governor has declared a peacetime emergency, prescription drugs that *are necessary for emergency medical reasons* can be transferred by one health care facility to other health care facilities, as long as the facility receiving the drug is legally allowed to possess prescription drugs. Such transfers can occur even if the facilities are not under common ownership. No drug wholesaling license is required when transfers are made for emergency medical purposes.

The facilities involved must follow DEA regulations if controlled substances are transferred. The Board recommends that the facilities keep appropriate records of all transfers.

COMPOUNDING PHARMACIES AND OUTSOURCING FACILITIES

Q: Does the Board have any recommendations for compounding pharmacies, given the shortages of sterile compounding garb and of other supplies necessary to engage in sterile compounding?

A: The Board is aware that there are shortages of compounding garb and other supplies needed for sterile compounding. The Board has adopted USP General Chapter <797> *Pharmaceutical Compounding – Sterile Preparations*, by reference into its rules. Strategies used to conserve garb and other supplies 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 or to deal with shortages of other supplies, 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 and the FDA. Critical Point has also made recommendations concerning this issue.

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>).

Also, the FDA issued a guidance on April 10, 2020 titled [Temporary Policy Regarding Non-Standard PPE Practices for Sterile Compounding by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency.](#)

Other resources include:

- Additional documents on the USP Web site: <https://www.usp.org/compounding>
- 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/>
The Web site has several relevant documents, including: *COVID-19: CriticalPoint Strategies to Cope with Garb and sIPA Shortages (updated 3/19/20)*

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 *general* 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; or
- there is a shortage of the commercially available product, as demonstrated by one of the following:
 - the drug is included on the [FDA's Drug Shortage List](#)
 - the drug was previously approved by the FDA but has been discontinued and is no longer marketed (unless removed from the market due to safety concerns or lack of efficacy).

However, even if these two situations **do not** apply, a pharmacy *may* compound a product that is essentially a copy of a commercially available product, *but only if it can document* that it has attempted and failed to obtain the commercially available product.

Q: Will the Board relax the “one-mile radius” provision that the FDA included in a previously issued guidance document and allow health-system compounding pharmacies to distribute compounded products to other healthcare facilities under common ownership – without first receiving patient-specific prescriptions?

A: The FDA has developed a [Compounding Activities/COVID-19 Web page](#) that appears to allow this. However, the FDA notes that it is “planning to issue a revision” to a previous guidance document. The Board will continue to monitor for any changes that the FDA makes to that guidance.

Unless the FDA states otherwise, the Board **will** allow health-system compounding pharmacies to distribute compounded products to other health facilities under common ownership – without first receiving patient-specific prescriptions. In addition, health-system compounding pharmacies will not be subject to the 5% limit on interstate distribution of compounded products if they distribute such products to other healthcare facilities under common ownership that are located in other states. (The FDA announced that the 5% limit will not be enforced at this time).

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.

Q: The FDA has issued COVID-19 guidance documents for the production of drugs by outsourcing facilities and by compounding pharmacies *not* registered as outsourcing

facilities. Will the Board allow the outsourcing facilities and compounding pharmacies that it licenses to follow those guidances when producing drugs for use within Minnesota?

A: Whenever possible, hospitals should first try to obtain FDA-approved, commercially manufactured drug products. If, that is not possible, hospitals should next try to obtain compounded/manufactured drug products from an outsourcing facility. Hospitals should only seek out compounded drugs from another pharmacy if they are unable to obtain the drug from a manufacturer or outsourcer. That being said:

- Outsourcing facilities may follow the FDA guidance titled [Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Outsourcing Facilities During the COVID-19 Public Health Emergency.](#)
- Compounding pharmacies not registered as outsourcing must submit a request to the Board before providing products to hospitals located within Minnesota. (send to pharmacy.board@state.mn.us). In the request, the compounding pharmacy must indicate the Minnesota hospital(s) that have requested services from the compounding pharmacy. The Board will not approve a request unless the pharmacy has been asked by a Minnesota hospital to provide services. The compounding pharmacy must wait until it receives an approval letter before providing products to Minnesota hospitals. If approval is given, the compounding pharmacy must follow all of the requirements of the FDA Guidance [Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency.*](#)

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 – but with no physical access to our office. 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. Note that the owner of the building in which the Board's Office is located has locked the outer doors of the building. Consequently, even though the Board has not closed its office to the public, it is not currently possible to come into our office. Some staff are working in the office to process licensing applications but many of the Board's staff members are 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: Yes. Meetings listed on the Board's Web site: <https://mn.gov/boards/pharmacy/board/> will be held. However, until further notice, the meetings will be held virtually, using WebEx. Details concerning each meeting will be published on the Board's Web site at least one week prior to each meeting. Information about how to access the meetings will be included. <https://mn.gov/boards/pharmacy/board/agenda.jsp>

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 possible 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. Since opening inspections are best done on-site and in coordination with the facility, the Board has received permission to have the Surveyors conduct on-site opening inspections. When on-site at the facility, Pharmacy Surveyors will wear masks and follow the facility's COVID-19 policies and procedures. The Surveyors may contact representatives of the facilities to obtain information in advance of the on-site visit. That may allow the on-site visit to be shorter.

Q: How will the Board be handling applications for licensure as a pharmacist?

A: Here are some changes that will be made to the requirements and processes for licensure as a pharmacist:

- Evidence of Completion of Internship. Several colleges of pharmacy have reported to the Board that students have not been able to complete their last advance pharmacy practice experiential rotations. The students have, however, completed *at least* the 1,440 experiential hours required by Accreditation Council for Pharmacy Education standards. (i.e. – the minimum hours required to be completed as part of the curriculum). Consequently, the Board will:

- Require applicants for initial licensure as pharmacists to complete the minimum of 1,600 hours of internship required by Minn. Rules 6800.5400, subp. 6; but
- The Board will waive the requirement that 800 hours (of the 1,600 required hours) involve traditional compounding, dispensing, and related patient counseling activities - as long as the applicant has completed all of the 1,440 experiential hours required as part of the curriculum.
- Changes to Criminal Background Check Procedures. During the COVID-19 pandemic, finding fingerprinting locations has been a challenge. The Minnesota Health-Related Licensing Boards, which includes the Board of Pharmacy, worked with Governor Walz’s office to find a solution that will facilitate licensing of healthcare professionals throughout the crisis. The Governor issued Emergency Executive Order 20-23 which allows CBCs to be do in an alternative manner. Additional information can be found on the Board’s Web site: https://mn.gov/boards/assets/CBC_During_State_of_Emergency_tcm21-427792.pdf.

VARIANCES AND POLICY REVIEWS

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

A: Yes. The Board will be conducting VPRC meetings remotely, using WebEx. The Schedules remains as posted at: <https://mn.gov/boards/pharmacy/board/committeemeetings.jsp>. The deadlines for submission of variance requests and policy reviews still apply.

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).