



## Frequently Asked Questions: COVID-19 (March 16, 2020)

**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. These FAQs are being e-mailed to all licensees and registrants. They will also be placed on the Board’s General FAQ Web page which can be accessed at: <https://mn.gov/boards/pharmacy/resourcesfaqs/faqs/generalfaqs.jsp>. Questions can be submitted to the Board’s general e-mail: [pharmacy.board@state.mn.us](mailto: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>

## **OPERATING OR CLOSING PHARMACIES**

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

A: With one exception, Minnesota Statutes and rules actually do not 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 with at least 60% isopropyl alcohol or ethyl alcohol 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**

**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 (6800.300, 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.

## **DISPENSING PRESCRIPTIONS**

**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 (e.g. – the pharmacists at the other pharmacy have all been infected with or exposed to COVID-19). I also can't contact the prescriber because of a COVID-19 related issue. (e.g. - the clinic is closed due to COVID-19). 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; and
- 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.

**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: 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.

### **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).
  - is secure and, preferably, also encrypted.
- Staff working at home take precautions to safeguard protected health information.
- 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 have the appropriate hardware and software to exchange the data that is necessary to safely perform the tasks.
- 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.

### **TECHNICIAN-TO-PHARMACIST RATIOS**

**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 a couple of days.

## **EXPANSION OF PHARMACIST SCOPE OF PRACTICE VS. 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.

## **HOARDING OF DRUGS**

**Q: Consumers are asking to purchase large quantities of over-the-counter drugs, such as acetaminophen, ibuprofen, cough medicine, etc. We are worried about running out of these medications. Some are also asking to purchase large amounts of medical supplies, such as face masks and sterile gloves. What can we do?**

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: A patient wants to get a quantity of a medication that is greater than the quantity prescribed. For example, a prescriber has written a prescription for a 30-day supply of a maintenance drug. 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.

### *Sterile Compounding Garb*

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 following recommendations may be useful in helping compounding pharmacies to conserve garb while still taking precautions that minimize the risk of the production of contaminated products.

Please note that engaging in some of these recommendations may result in being out of compliance with USP Chapter 795, 797, and 800. 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 of the following recommendations during a shortage period, and implementation results in noncompliance with USP Chapter 797, you must develop and maintain a policy demonstrating compliance with best practices (e.g., if reusing face masks, you must develop a policy and procedure for identification, storage, and handling of face masks subject to reuse). In addition to the recommendations below, please refer to:

- 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>

#### Recommendations:

- Assess your current supply and how long that supply is expected to last. If your supply is running low, try to order more. Do not try to order large amounts (i.e. – do not hoard). If your supply (existing plus what you believe you can order and receive) will not last for at least two months, consider immediately implementing one or more of these strategies for conservation.
- Limit exposure and limit use of garb:
  - Limit entry into the clean room
    - exclude anyone exhibiting signs of any illness (who should probably not be at work at all)
    - reduce the number of staff engaged in compounding activities
    - stage supplies outside the compounding area
    - minimize trips into the clean room
  - Limit contamination
    - ensure personnel hygiene (which should be occurring even in normal circumstances)
    - wear freshly laundered scrubs every day
    - thorough disinfection

- walk slowly and deliberately in the clean room,
  - re-sanitize frequently
  - staff should not talk while compounding
  - staff should not touch their face mask after donning
- For a shoe cover shortage
  - Use cleanable, facility-dedicated shoes that are not worn outside the compounding area.
  - Source alternative shoe covers, such as those used on construction sites.
  - Use dedicated shoes in Hazardous Drug (HD) compounding areas and reduce use to one set of covers.
  - Do not reuse shoe covers, including turning them inside out for reuse.
  - Develop systems to deliver materials to compounding staff to reduce HD garb change required when entering the HD space. The use of pass-throughs and dedicated carts should be formalized and maximized.
- For a mask shortage
  - If available, substitute N-95 masks for clean room masks. When using an N-95 mask for non-HD sterile compounding procedures, fit testing is not required.
  - Consider limited reuse of face masks used in non-HD compounding.
    - Store the mask in a new, paper bag (or something clean and breathable) after each use. Masks should never be shared between employees.
    - Retained masks should be stored where they are donned, individually identified, donned prior to hand washing, and not touched after proper placement.
    - Retained masks should be replaced when the mask condition is questionable, the mask is visibly soiled, or after a period of time as determined in facility policy.
- For a gown shortage
  - Decrease the number of employees in the sterile compounding area to reduce use.
    - Consider using already garbed compounding staff for facility cleaning/disinfecting activities, rather than utilizing more garb for environmental services employees.
  - Retain and reuse gowns for an entire shift/day.
  - If gowns are reused for longer periods of reuse (no more than 1 week), store them on individual hooks. Do not store them inside out. Deliberate and careful removal is recommended.
    - Gowns should be stored on the clean side of the ante room away from the sink.

- Gowns should be discarded when they are visibly soiled or after a period of time as determined in facility policy.
    - Gowns used for cleaning or HD compounding should not be retained or reused.
  - When gowns are reused, add disposable sleeve covers (sterile or non-sterile are permitted).
- Use of sleeve covers
  - Sleeve covers should be opened in the buffer room/SCA area after handwashing procedures and the gown is donned.
  - Sleeve covers should be placed over the donned gown sleeve and should close tightly at the wrist.
  - Sterile gloves should be donned last and cover the wrist of the sleeve cover.
- Response to hand sanitizer shortage
  - Consider limiting hand sanitizer use to glove change procedures only.
  - Alcohol-based hand sanitizer not intended for clean room or surgical use may be utilized as a replacement.
- IF you have implemented any of the above recommended conservation strategies, implement additional environmental monitoring in the PEC used for sterile compounding.
  - Weekly, dynamic microbial surface sampling inside the PEC on the Direct Compounding Area (DCA).
    - If growth occurs, consider changes to supply cleaning/disinfecting procedures, changes to the procedure for material transfer into the PEC, or increasing the frequency of DCA sanitation procedures. Further testing growth to genus level would only be expected when growth exceeds action levels.
    - If a growth occurs that exceeds action levels, retrain staff, resample the site, and potentially decrease the BUD until a compliant sample is obtained.
  - While weekly, dynamic microbial surface sampling inside the PEC is preferred, if this is not possible, BUDs must be limited to Category 1 compounding (12 hours at room temperature or 24 hours under refrigeration).
- When a garb shortage affects Personal Protective Equipment (PPE) used for HD compounding
  - The current recommendation is that garb used in HD compounding should not be reused.
  - Implement process changes that reduce the use of PPE, such as:
    - Grouping HD compounding together,

- Designating a time when HD compounding is performed,
- Adjusting personnel schedules to limit to the extent possible the number of HD compounding personnel,
- Encouraging HD handling in PECs (per Assessments of Risk (AoRs), PPE including respiratory protection may be required when handling occurs outside a PEC, but some may not be required when using a PEC), and/or
- Considering the use of other respiratory protection such as a PAPR (Powered Air Purifying Respirator), if available, when an N95 mask is otherwise required.

**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.

**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.

## **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 licenses renewals as noted below. Unless exposed to or infected with COVID-19, at least one of the Board's three managers will be in the office every day.

### **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: The Board is currently planning to hold the March 16, 2020 Variance and Policy Review meeting and the April 1, 2020 full Board meeting. At the April 1, 2020 full Board meeting, the Board will decide whether and when to conduct future meetings. Any meetings that are held, will be held as remotely as possible. A limited number of staff members may be located in the Board's conference room – but the Board Members, individuals representing licensees, and members of the public will be asked to participate by telephone. The agendas for meetings will be limited to those things that the Board must act on in a timely manner. The Board may postpone disciplinary conferences – or conduct them remotely if possible.

## 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 will consider this issue at its April 1, 2020 meeting. The Board will likely encourage licensees and registrants to delay the submission of *new* variance requests for a period of time. 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. See above for information about how Variance and Policy Review Committee meetings will be conducted, if they are held.

**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).