IMPORTANT NOTICE

The State of Minnesota Peacetime Emergency declared by Governor Walz ended on July 1, 2021. After the Peacetime Emergency was first declared, the Board approved blanket variances to some rules and decided to exercise enforcement discretion for some sections of Minnesota statutes. This document has included information on the variances and enforcement discretion.

Those provisions that effectively grant variances, or for which the Board is exercising enforcement discretion, were only approved for the duration of the Peacetime Emergency. Consequently, those provisions are no longer in effect. Those pharmacies still following such provisions have until July 16, 2021 to transition back to compliance with the relevant statutes and rules. (Except that pharmacies using a curbside pick-up/delivery service may continue using it until July 28, 2021. See below for additional details).

Please note that some actions taken by the Federal Government pre-empt state law and remain in effect. These items primarily concern COVID-19 testing and vaccinations and certain allowances made by the FDA related to compounding.

Since numerous changes have been made to this document, it is recommended that licensees and registrants review it in its entirety.
HISTORY

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. The Board also reviewed and approved this document at its November 18, 2020 meeting. 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 (most recently extended by additional Emergency Executive Orders) or until the Board withdraws approval, whichever occurs first. Those provisions that effectively granted variances, or for which the board was exercising enforcement discretion, are rescinded due to the end of the Peacetime Emergency declared by Governor Tim Walz in Emergency Executive Order 20-01, originally issued on March 13, 2020. As noted above, the board will allow licensees following provisions of the most recent FAQ published 5/21/2021 time to transition back to compliance with Minnesota Statutes and Minnesota Board of Pharmacy Rules by 7/16/2021.

Please note that some actions taken by the Federal Government pre-empt state law and remain in effect. These items primarily concern COVID-19 testing and vaccinations and certain allowances made by the FDA related to compounding.

The Board will notify licensees and registrants when this FAQ document is withdrawn or when the Peacetime Emergency is ended. The State of Minnesota Peacetime Emergency has ended. It is the responsibility of licensees and registrants to know when that the variance waivers and enforcements discretion previously allowed by this document are no longer in place except as described in this document. Changes made after November 18, 2020 have been made after review by the Board’s 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. While we have tried to anticipate the questions that we will receive, we expect to receive questions that had not occurred to us. In addition, various other state and federal agencies may make announcements, change policies, or
exercise enforcement discretion in relation to the pandemic. Therefore, this document will be regularly updated as the situation changes. PLEASE CHECK OFTEN FOR UPDATES.

On 4/2/2021, after over a year of multiple versions of the document, it was reformatted for both content and accessibility. Content changes were made based on the current pandemic conditions. Multiple items have also been removed entirely. We hope you find this version easier to utilize and reference. Click on the links to navigate to the item category or question within the document or to the internet sources embedded.
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A list of suggested links to resources or references that may be useful

### Board of Pharmacy Operations
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### Review and Revision History
Summarizes document section changes and updates.
Resources

A list of links to resources or references that may be useful from outside organizations.

STATE OF MINNESOTA SPECIFIC RESOURCES

- From the Board of Pharmacy. 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

GENERAL RESOURCES

- From the National Association of Boards of Pharmacy
  - News, Vaccine Resources, and What Pharmacists Should Know
  - https://nabp.pharmacy/coronavirus-updates/

- From the U.S. Centers for Disease Control and Prevention (CDC)
  - COVID Vaccine Toolkit;
  - CDC COVID-19 Vaccination Page
  - Vaccine Resources for Healthcare Professionals

- From the United States Pharmacopeia:
  - Compounding Standards: https://www.usp.org/compounding
  - COVID-19 Vaccine Beyond Use Dates: From the COVID-19 Vaccine Handling Toolkit

- From the Drug Enforcement Agency (DEA)
  - The DEA has FAQs regarding multiple topics including prescription validity, registration requirements, and temporary policy guidance during the emergency.
    https://www.deadiversion.usdoj.gov/coronavirus.html

- From the Center for Medicare and Medicaid Services (CMS)
  - The CMS has recently offered waivers and other guidance regarding Hospitals Without Walls, Telehealth, and Workforce availability.
Board of Pharmacy Operations

Questions pertaining to the operations of the board including information on hours, variances, licenses and similar. Click on the question to review the current guidance.

1. **Will the Board of Pharmacy remain open for business and will the hours of operation remain the same?**

2. **Will the Board’s regularly scheduled meetings (Full Board, Variance and Policy Review Committee, Committee on Professional Standards) continue to be held?**

3. **Will the Board continue to process variance requests and review policies that need Board approval?**

4. **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?**

5. **Is it true that the Board will allow University of Minnesota College of Pharmacy students to work as interns before the completion of their first year of training?**

6. **How will the Board be handling applications for licensure as a pharmacist?**

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

8. **Where can I go for the most up to date resources on COVID-19 specifically for pharmacists?**  Redacted 7/1/21, see resources for NABP link.
Q1: **Will the Board of Pharmacy remain open for business and will the hours of operation remain the same?**

Yes. Note that the owner of the building in which the Board’s Office is located has currently locked the outer doors of the building so there is no public access. The office continues to be operational in a temporary space* during this transition phase while it prepares to move to a new location. This move is unrelated to the public emergency. The temporary space does not have a public reception area at this time.

All licensees are encouraged to transact business remotely via telephone, email, by fax, or though the licensing portal.

*All mail and correspondence should remain unchanged at this time and be directed to:

Minnesota Board of Pharmacy
2829 University Avenue SE, Suite 530
Minneapolis, MN 55414

Q2: **Will the Board’s regularly scheduled meetings (Full Board, Variance and Policy Review Committee, Committee on Professional Standards) continue to be held?**

Yes. Meetings listed on the Board’s Web site: [https://mn.gov/boards/pharmacy/board/](https://mn.gov/boards/pharmacy/board/) will be held. However, until further notice, the meetings will still 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](https://mn.gov/boards/pharmacy/board/agenda.jsp). The Board plans to resume in-person meetings in September, after it is fully moved into its new office.

Q3: **Will the Board continue to process variance requests and review policies that need Board approval?**

Yes. The Board will be conducting VPRC meetings remotely, using WebEx. The schedule remains as posted at: [https://mn.gov/boards/pharmacy/board/committeemeetings.jsp](https://mn.gov/boards/pharmacy/board/committeemeetings.jsp) The deadlines for submission of variance requests and policy reviews still apply. The Board plans to resume in-person meetings in September, after it is fully moved into its new office.

Q4: **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?**

This is no longer an issue; the Board will process all variance requests and policy reviews in a timely manner – provided all required materials are submitted by the deadline for submission.
Q5: Is it true that the Board will allow University of Minnesota College of Pharmacy students to work as interns before the completion of their first year of training?

Yes. First-year students during the 2021-2022 academic year will be allowed to work as interns. However, these students will not be registered as interns. Consequently, they will only be allowed to work as interns when they are taking part in the College’s experiential education program. Pharmacies will not be allowed to hire or utilize them as interns, outside of the College’s experiential education program until the students have successfully completed the entire first-year of education and have been registered as interns.

The College has provided information to preceptors about the students who will be involved.

Q6: How will the Board be handling applications for licensure as a pharmacist?

The Board has resumed its normal processes for issuing licenses.

Q7: Can a pharmacist that is licensed and in good standing in another state perform work inside Minnesota, or provide support remotely from the other state?

No. (Please see other areas of this document for information about administration of vaccines by pharmacists licensed in other states).

Q8: Redacted 7/1/2021
Pharmacy Operations

Questions pertaining to daily operations in a pharmacy including information on deliveries, counseling, staffing, technician ratios, remote dispensing, centralized functions and similar. Click on the question to review the current guidance.


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

11. If pharmacy staff members have fevers, or COVID signs and symptoms 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?

12. Does the Board have recommendations for pharmacies that continue operating?

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

14. 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?

15. 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?

16. 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?
17. Will the Board relax counseling requirements?

18. 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”).

19. 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?

20. 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?

21. Will the Board allow pharmacies to exceed the technician-to-pharmacist ratio?

22. 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?

23. 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?

24. Has the United States Drug Enforcement Administration (DEA) provided any information concerning controlled substances that takes into consideration the COVID-19 pandemic?
25. 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?

26. 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?

27. 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? Redacted 7/1/21.

28. How can pharmacists respond to requests to fill prescriptions for drugs such as for unapproved indications including the treatment of COVID-19? Redacted 7/1/21.

29. Can the Board recommend resources that can be used to help ensure the safety of pharmacy personnel?
Q9: Redacted 5/21/21.

Q10: Are there exceptions to drug wholesaling requirements that apply during the peacetime emergency declared by Governor Walz?
Now that the Peacetime Emergency has ended drug wholesaling must be done pursuant to the relevant Federal and State statutes and rules.

Q11: If pharmacy staff members have fevers, or COVID signs and symptoms should they get tested and stay home until the results come in? Who should be tested?
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:


Q12: Does the Board have recommendations for pharmacies that continue operating?
Pharmacies should review the most recent guidance from the CDC, and the Minnesota Department of Health for recommendations Concerning infection prevention and control.

Q13: Our pharmacy provides a home delivery service. Our drivers may be exposed to the COVID-19 virus if they must enter a home to get someone to sign for the delivery of the prescription. Do we have to get the signature?
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 the COVID-19 virus, 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 may 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.

Q14: 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?
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 option of having filled prescriptions mailed to their residences.

Q15: 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? 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.

Q16: 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? Yes, until July 28, 2021, which is the date of the Board’s next business meeting. At that time, the Board will consider whether or not to continue allowing pharmacies to use a curbside delivery service.

If the Board does allow continued use of such a service, it will likely only be until the Board’s September 15, 2021 meeting. That would give pharmacies time to submit a variance request to M. Rules 6800.3000, subp. 1 (A), which currently does not permit curbside delivery. Pharmacies that want to continue using curbside delivery are advised to start the process of applying for a variance as soon as possible because the deadline for submitting a variance request for issues that will be heard at the September Board meeting is August 6, 2021. A policy and procedure document that details how the service works should be submitted with the variance request. That document should include, among other things, a description of how required counseling is conducted.

Q17: Will the Board relax counseling requirements? No. Given the end of the Peacetime Emergency, pharmacies must return to normal counseling procedures, as required by the Board’s rules.

Q18: 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”). No. Given the end of the Peacetime Emergency, pharmacies must return to normal quality assurance procedures, as required by the Board’s rules.
Q19: 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?

No. Given the end of the Peacetime Emergency, pharmacies must return to normal dispensing procedures, as required by the statutes and the Board’s rules. Pharmacists, pharmacy technicians, and pharmacist interns involved in the dispensing process must return to working within a licensed pharmacy.

Q20: 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?

No – unless the pharmacies involved already have approved variances and central service policies and procedures.

Q21: Will the Board allow pharmacies to exceed the technician-to-pharmacist ratio?

No. Given the end of the Peacetime Emergency, pharmacies must follow the ratios found in the statutes and rules.

Q22: 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?

No. Given the end of the Peacetime Emergency, pharmacies must follow the requirements of this rule.

Q23: 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?

No. The Board didn’t expand the scope of practice even during the Peacetime Emergency because it does not have the authority to do so.

Q24: Has the United States Drug Enforcement Administration (DEA) provided any information concerning controlled substances that takes into consideration the COVID-19 pandemic?

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

That page contains links to many different documents issued by the DEA, in which the DEA offers guidance to DEA registrants including enforcement discretion on a number of requirements related
to controlled substances. The Board will allow pharmacies to follow the guidance for the duration of the federally declared COVID-19 Public Health Emergency or until the DEA rescinds the guidance.

Q25: 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?

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.

- Pharmacies have been able to deliver or mail prescriptions to patients for a very longtime. 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.

Q26: 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?

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, pharmacies may no longer 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.

Q27: Redacted 7/1/2021

Q28: Redacted 7/1/2021

Q29: Can the Board recommend resources that can be used to help ensure the safety of pharmacy personnel?

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

Section Contents

Compounding

Questions pertaining to compounding, BUD, PPE, and similar items. Click on the question to review the current guidance.

30. 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?

31. 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?

32. 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?


34. 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 guidance items when producing drugs for use within Minnesota?

v2.23 on 7.1.2021

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35. **Can a pharmacy compound products that contain remdesivir using the active pharmaceutical ingredient?**

Q30: 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?

Given the end of the Peacetime Emergency, the Board expects that sterile compounding will be complaint with USP Chapter 797.

Q31: 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?

No. Given the end of the Peacetime Emergency, the Board expects that compounding will be compliant with USP Chapters 795 and 797, Title I of the federal Drug Quality and Security Act, and relevant provisions in Minnesota Statutes Chapter 151.

Q32: 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?


Q33: Redacted 7/1/2021.

Q34: 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?

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.*

**Q35: Can a pharmacy compound products that contain remdesivir using the active pharmaceutical ingredient?**

Not unless certain conditions are met. Veklury (remdesivir) was approved by the FDA in two versions: remdesivir for injection, 100 milligrams (mg), a sterile, preservative-free lyophilized powder; and remdesivir injection, 100 mg/20 milliliters (mL) (5 mg/mL), a sterile, preservative-free solution.

The Board considers all compounded, injectable remdesivir products to be essentially copies of the commercially available product. Minn. Stats. §151.253 prohibits the compounding of products that are essentially copies of commercially available products – 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.

However, pharmacists must always use their own professional judgment when evaluating a prescription for a compounded product and must have a sound reason to believe that the compounded product really will produce a significant difference. In making such a determination, a pharmacist would be well-advised to review the cautions and recommendations that the FDA has issued about the compounding of remdesivir products: [https://www.fda.gov/drugs/human-drug-compounding/fda-alerts-health-care-professionals-and-compounders-potential-risks-associated-compounding?utm_medium=email&utm_source=govdelivery](https://www.fda.gov/drugs/human-drug-compounding/fda-alerts-health-care-professionals-and-compounders-potential-risks-associated-compounding?utm_medium=email&utm_source=govdelivery)
Testing and Treatment

Questions pertaining to administration of COVID-testing, individuals involved, and COVID treatment prescription considerations.

Click on the question to review the current guidance.

36. Can pharmacists and pharmacy interns be involved in testing for COVID-19?

37. Can pharmacy technicians be involved in COVID-19 testing?

38. What training is required for a pharmacist, intern, or technician to be involved in COVID-19 testing?

39. What reporting is required for results of COVID-19 testing? Are pharmacists conducting COVID-19 tests subject to any specific reporting requirements?

40. Can a pharmacist order COVID-19 tests or is a collaborative practice agreement and protocol required?

41. Can pharmacists, pharmacy interns, and pharmacy technicians conduct COVID-19 testing or administer vaccines to patients at a long-term care facility?

42. Has the board expanded technician duties to allow for point of care testing, vaccine administration, or other tasks?
Q36: Can pharmacists and pharmacy interns be involved in testing for COVID-19?
Pharmacists may be involved in certain types of laboratory testing as authorize Minn. Stats. §151.01 Subd. 27 (3), including performance of CLIA waived testing. 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.

Pharmacies are reminded that in order to do any CLIA-waived testing they must have a CLIA Certificate of Waiver. 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).

Numerous Federal HHS guidance and other items issued as Advisory Opinions from U.S. Department of Health and Human Services (USDHHS) also allow Interns and Qualified Pharmacy Technicians the same privilege under conditions noted in that document.

Q37: Can pharmacy technicians be involved in COVID-19 testing?
Under state law, only pharmacists and pharmacist interns under the immediate supervision of a pharmacist can perform the allowed tests. Under state law, pharmacy technicians can only be involved in completing required paperwork, including the required reporting to MDH, as noted below. However, please review the PREP Act and guidance issued by the USDHHS that pre-empts state law and allows pharmacy technicians to administer COVID-19 tests when the conditions in the guidance are met. The board reminds all parties that observation of supervision rules and competency are also required.

Q38: What training is required for a pharmacist, intern, or technician to be involved in COVID-19 testing?
Before performing tests, pharmacists, pharmacist interns, and pharmacy technicians must have appropriate training that meets criteria of the PREP Act requirements. The pharmacy must have a policy in place that details how COVID-19 testing will be administered and how records will be kept.

Q39: What reporting is required for results of COVID-19 testing? Are pharmacists conducting COVID-19 tests subject to any specific reporting requirements?
The Minnesota Department of Health (MDH) has a page dedicated to this topic:
https://www.health.state.mn.us/diseases/coronavirus/hcp/report.html

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:
https://www.health.state.mn.us/diseases/coronavirus/hcp/eval.html
Q40: Can a pharmacist order COVID-19 tests or is a collaborative practice agreement and protocol required?

On May 19, 2020, HHS issued *Advisory Opinion 20-02 on the Public Readiness and Emergency Preparedness Act (PREP Act)* and the Secretary’s Declaration Under the Act states “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).

Pharmacies must establish testing procedures that will safeguard both staff and patients, including the provision of appropriate personal protective equipment to staff involved in the testing. Pharmacists involved in testing must receive adequate training concerning the tests that are used. A protocol within a collaborative practice agreement is also allowed by state law.

Q41: Can pharmacists, pharmacy interns, and pharmacy technicians conduct COVID-19 testing or administer vaccines to patients at a long-term care facility?

Yes – subject to the conditions, limitations, and requirements listed elsewhere in this document. *Pharmacy interns and pharmacy technicians must be personally and directly supervised by a pharmacist who is on site at the long-term care facility.*

Q42: Has the board expanded technician duties to allow for point of care testing, vaccine administration, or other tasks?

Under state law, pharmacy technicians cannot perform any duty that requires professional judgment or that is specifically reserved for pharmacists. The PREP Act declaration issued by the federal HHS department authorizes "qualified" pharmacy technicians and state-authorized pharmacy interns to administer COVID-19 tests, including serology tests, as well as administer certain (NOT ALL) vaccines. This is subject to the conditions and requirements noted in the PREP Act declaration and subsequent amendments.
Section Contents

Vaccination

Questions pertaining to administration of COVID-19 vaccines.
Click on the question to review the current guidance.

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

44. Can pharmacists and pharmacy interns administer COVID-19 vaccines?

45. Redacted. Combined with Q46.

46. Can pharmacy technicians administer COVID-19 vaccinations?

47. Can a retired pharmacist administer vaccines?

48. Are there opportunities for pharmacists to volunteer to give COVID-19 vaccines?

49. How do I dispose of vaccine packaging and vials?

50. Where can I find information on valid identification (ID) requirements for vaccination?

51. What does the expanded EUA to include adolescents age 12-15 for Pfizer’s COVID-19 vaccine mean to pharmacies?

52. Is a protocol for COVID-19 vaccines required for pharmacists?

53. What are a pharmacist’s obligations and expectations for MIIC review and reporting?

54. What label information is required for prepared vaccines?
Q43: Can pharmacists and interns administer any vaccines other than those allowed under Minn. Stats. §151.01, subd. 27 (6)?

PREP Act declarations issued by the federal HHS department authorize pharmacists and interns to administer FDA-licensed and ACIP-recommended vaccines to persons ages 3 through 18 as well as COVID-19 vaccines. Minn. Stat. §151.01 Subd. 27 (6) defines additional vaccination administration that is permitted by state law.

MIIC information now found in Q53

Q44: Can pharmacists and pharmacy interns administer COVID-19 vaccines?

Administration of COVID-19 vaccine is permitted by Pharmacists and qualified interns. The Board has long allowed pharmacy interns to administer vaccines as long as they are appropriately trained, have a basic CPR certification, and work under the direct and personal supervision of a pharmacist.

_COVID-19 vaccines must be administered according to CDC schedules and guidelines. The administration of the second dose of the Pfizer COVID-19 vaccine should not be routinely scheduled for 28 days after the first dose administration date. The CDC has published the following information on its Web site:_

The second dose of Pfizer-BioNTech and Moderna vaccines should be administered as close to the recommended interval as possible, but not earlier than recommended (i.e., 3 weeks [Pfizer-BioNTech] or 1 month [Moderna]). However, second doses administered within a grace period of 4 days earlier than the recommended date for the second dose are still considered valid. If it is not feasible to adhere to the recommended interval and a delay in vaccination is unavoidable, the second dose of Pfizer-BioNTech and Moderna COVID-19 vaccines may be administered up to 6 weeks (42 days) after the first dose. Currently, only limited data are available on efficacy of mRNA COVID-19 vaccines administered beyond this window.

The Board has checked with the Minnesota Department of Health and the CDC, and all three agencies agree that routinely scheduling the second dose of the Pfizer COVID-19 vaccine for 28 days should not be happening. Whenever possible, the second dose should be given 21 days after the first dose.

Q45: Redacted; combined with Q46.

Q46: Can pharmacy technicians administer COVID-19 vaccinations?

Qualified technicians may conduct COVID-19 vaccine administration and diagnostic testing to the extent allowed by the PREP Act declarations - by meeting all conditions of the declarations, and guidance offered in this document.

Remote supervision of pharmacy technicians who are engaged in immunizations is not permitted. If technicians are used to conduct COVID-19 testing or to administer any authorized vaccine, they must be directly and personally supervised by a pharmacist no matter where that testing, or vaccine administration occurs.
This means that pharmacy technicians cannot give vaccinations outside of a licensed pharmacy unless accompanied by a licensed pharmacist who will supervise the technician. (Note that technicians can administer vaccines in the area \textit{immediately} outside of the licensed area. e.g. – many pharmacies have a screened-off area right outside the pharmacy, or a room immediately adjacent to the pharmacy, where vaccinations are given).

Training, competence, and direct supervision are required. The pharmacy, the pharmacist-in-charge, and the supervising pharmacist are responsible for ensuring that these conditions are met. The supervising pharmacist must be allowed to decide whether or not a particular technician is able to safely administer vaccines.

\textbf{Q47: Can a retired pharmacist administer vaccines?} 
Retired pharmacists who have let their license lapse recently can reinstate their license. The Board will consider waiving the continuing education requirement for reinstatement for pharmacists who have recently let their license lapse. The March 12, 2021 (Seventh) Amendment to the PREP Act Declaration added pharmacists whose licenses or registrations have expired within the last 5 years to the list of qualified persons who can administer COVID-19 vaccines in any jurisdiction. Pharmacists must meet the conditions in the PREP Act Declaration and amendments which are listed there.

\textbf{Q48: Are there opportunities for pharmacists to volunteer to give COVID-19 vaccines?} 
Yes. In response to an anticipated need for volunteers to support Minnesota’s vaccine administration effort, the Minnesota Department of Health (MDH) established the State Vaccination Group (SVG) within Minnesota Responds. The SVG will enroll, verify, train, and deploy volunteers to provide staffing surge support to Local Public Health and state-run vaccination clinics when requested.

Enrollment in the SVG is now open. At this time, the program is enrolling currently licensed and active physicians, physician assistants, nurses, pharmacists, paramedics, podiatrists, and others authorized to draw and inject COVID-19 vaccinations.

\begin{itemize}
  \item If the individual has never registered in Minnesota Responds and is interested in enrolling, go to the Minnesota Responds website at https://mnresponds.org and choose the “Online Registration” link. Complete the membership enrollment information.
  \item If the individual has already applied with another unit, they should login, select the organization tab, select all, and choose the SVG.
\end{itemize}

MDH has assigned staff to work with professionals volunteering to support this important public health mission. Part of that support will involve manually verifying professional licenses and ensure volunteers have taken the CDC COVID-19 vaccination training.

The demand for volunteers will vary and is dependent on the amount of vaccine Minnesota receives from the federal government. The number of requests the state receives for volunteers from local vaccination groups will also vary and may not occur until later spring or summer.
Q49: How do I dispose of vaccine packaging and vials?

The following information from the 4/22/21 update of Minnesota Department of Health’s Interim COVID-19 Vaccine Provider Guide:

It is no longer recommended to dispose of COVID-19 vaccine and vials as normal solid waste. Due to the increased threat of fake or counterfeit vaccines, CDC convened an interagency working group of medical professionals, suppliers, and law enforcement. The working group recommends vaccination sites take appropriate steps to properly dispose of empty vaccine vials and product packaging. The following recommended actions will protect empty COVID-19 vaccine vials and packaging from counterfeit efforts:

- Action 1 (preferred method): Treat vials and packaging similarly to medical waste by placing in red sharps container; or
- Action 2: Deface all, or safely crush, materials so they cannot be reintroduced or reproduced. After the products are sufficiently defaced, dispose with regular waste.

Vaccines are only available and administered through state-authorized vaccination locations. Non-medical companies or private people are not authorized to provide, sell, or administer vaccines. Any offers related to the sale or use of COVID-19 vaccines, not from a medical provider, should be considered suspicious and reported to the appropriate state or jurisdiction. This may include: State or local department of health, the U.S. Department of Health and Human Services, the Office of the Inspector General (www.oig.hhs.gov) online or at 1-800-HHS-TIPS, or Submit a Tip (www.fbi.gov/tips) to the Federal Bureau of Investigation.

Requirements vary for other vaccines and pharmaceutical wastes. For more information, contact the Minnesota Pollution Control Agency (www.pca.state.mn.us) at 651-296-6300 or 800-657-3864 or email at info.pca@state.mn.us.

Q50: Where can I find information on valid identification (ID) requirements for vaccination?

There is no statute or rule in Minnesota that requires an ID for vaccine patients. The board of pharmacy has no requirement for valid ID for patients seeking vaccination. See also question 26 regarding ID’s for controlled substances which describes the board’s guidance and discretion surrounding valid identification.

Use of MIIC to screen for vaccine appropriateness does not require the use of a valid social security number or driver’s license number.

The CDC and MDH both indicate that eligible persons should be able to get vaccinated even if they can’t produce a government issued ID, and they shouldn’t be asked questions about their immigration or citizenship status. MDH does not have any requirements for ID.
Q51: **What does the expanded EUA to include adolescents age 12-15 for Pfizer’s COVID-19 vaccine mean to pharmacies?**

On 5/10/21 the [FDA approved expansion of the EUA](https://www.fda.gov) for the Pfizer-BioNTech COVID-19 Vaccine for the prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) to include adolescents 12 through 15 years of age. The [Fact Sheet for Recipients and Caregivers](https://www.fda.gov) was also revised to incorporate the change.


Minnesota Statutes §151.01 Subd. 27 (6) authorizes pharmacists to administer “vaccines approved by the United States Food and Drug Administration related to COVID-19 or SARS-CoV-2 to all eligible individuals six years of age and older” – pursuant to a protocol with a physician, physician assistant, or advanced practice registered nurse. When administering vaccines by protocol, pharmacists must, among other things, comply with guidelines for vaccines and immunizations established by the federal Advisory Committee on Immunization Practices (ACIP) in order to provide the vaccine.

As noted below in Question 52, pharmacists can also administer COVID-19 vaccines without a protocol as long as the administration complies with declarations and amendments issued under the Public Readiness and Emergency Preparedness Act (PREP Act).

Q52: **Is a protocol for COVID-19 vaccines required for pharmacists?**

Under Public Readiness and Emergency Preparedness Act (PREP Act) declarations and amendments, issued by the Secretary of the Department of Health and Human Services, pharmacists administering COVID-19 vaccines do not need to work under a vaccine protocol signed by a Minnesota licensed physician, physician assistant or advanced practice registered nurse. Pharmacists can independently order and administer COVID-19 vaccines to all age groups designated in COVID-19 vaccine EUAs and approved by the Advisory Committee on Immunization Practices (ACIP). Pharmacists utilizing their own authority to order the vaccine for individuals may continue to do so if they meet all other conditions of the PREP Act.

Pharmacists utilizing protocols with a practitioner to vaccinations to patients should discuss the EUA changes with the collaborating practitioner for any protocol revisions that may be needed. A pharmacist operating under such a protocol, would not be able to go outside of any protocol parameters established. See also question 40 containing similar guidance.

Q53: **What are a pharmacist’s obligations and expectations for MIIC review and reporting?**

A pharmacist is required to comply with the MIIC reporting requirement by reporting all administered vaccine doses in a timely manner. With some minor exceptions for flu vaccines, pharmacists are required to:

- View immunization history for each patient prior to vaccine administration.
- Review recommended vaccines based on patient’s exact age and immunization history before vaccine administration.
• Report all administered vaccine doses.
• Comply with the signed data use agreement for allowable uses and client privacy.

A pharmacist administering vaccinations by protocol or under their own authority has a legal and professional obligation for screening for vaccine appropriateness. See information from MDH in their Vaccine Provider Weekly Updates from May 6, 2021 regarding vaccinating only authorized age groups.

Previously, the board in coordination with MDH offered enforcement discretion that temporarily waived the requirement for pharmacists to review MIIC prior to giving COVID-19 vaccinations. As of the week of 4/12/21, both MDH and the Board removed that temporary waiver in part because of the large number of individuals who have been vaccinated.

It is the expectation that the licensed pharmacist administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine.

Q54: **What label information is required for prepared vaccines?**

As vaccination rates slow, there is a higher likelihood for wasted doses or multidose vials that are entered but not utilized before their beyond use date. Pharmacies are encouraged to standardize a process for the preparation of vaccines for administration including but not limited to:

• Appropriate assigning and communication of Beyond Use Dates for vaccine vials.
• Following Minnesota Rule 6800.3200 for prepackaging and labelling any pre-drawn syringes.
• Following all ACIP recommendations for vaccine administration.
## Review and Revision History

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<th>Date</th>
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<td>All content revised and document received additional formatting</td>
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<td>Vaccination</td>
<td>MDH and BoP require MIIC evaluation prior to vaccination Q43</td>
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<td>MDH recommendations for disposal of vaccine packaging/vials Q49</td>
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<td>Redaction Q9</td>
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<td>NEW ID requirements Q50, adolescent vaccine recipients Q51</td>
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