Iowa Board of Pharmacy

Frequently Asked Questions: COVID-19

Last update: February 15, 2022

The Iowa Board of Pharmacy is committed to protecting the health and safety of Iowans during the current COVID-19 pandemic. The Board and staff have received many questions relating to the pandemic and its effect on the provision of pharmacy services in Iowa.

As of February 16, 2022, there is **no** Proclamation of Disaster Emergency in place in the State of Iowa. At the same time, the federal PREP Act Declaration and several federal regulatory enforcement discretion positions are still in place and will be recognized in this state.

This document intends to provide information and answers to specific questions that the Board has received or anticipates receiving. These FAQs are being provided to all licensees and registrants. This information can also be found on the Board's website at pharmacy.iowa.gov on the home page under the "Health Resources and Links" section. **Please note that the Board cannot anticipate every scenario that might occur as it relates to adjusting pharmacy operations as a result of COVID-19 and the challenges that the novel coronavirus may present.** The Board anticipates pharmacists will exercise prudent professional judgment in determining how best to modify practice to provide quality pharmaceutical care to Iowans while protecting the public and pharmacy personnel.

Additional questions that are not addressed in this document may be directed to Board Compliance Staff. Staff will make every effort to provide a timely response.

New questions or updated answers are in red. Updates to questions relating to the extension of regulatory relief with extended Governor Proclamations are not highlighted.

GENERAL INFORMATION / RESOURCES

(Please note that, while a link shown below may still be active, the content or the position of the agency or organization may have since been changed or updated since its initial publication or posting. Pharmacies are strongly encouraged to verify the agency's or organization's most current policy or position.)

- Iowa Board of Pharmacy
  - Compounding Garb Limitations
  - Statement on Board Enforcement during COVID-19 Pandemic (Rescinded)
  - Response to Governor's March 22 Proclamation (March 27, 2020)
  - Response to Governor's April 2 Proclamation (April 6, 2020)
  - Response to Governor's April 27 Proclamation (April 29, 2020)
  - Response to Governor's May 26 Proclamation (May 27, 2020)
  - Response to Governor's June 25 Proclamation (June 26, 2020)
  - Response to Governor's July 24 Proclamation (July 24, 2020)
  - Response to Governor's August 21 Proclamation (August 24, 2020)
  - Response to Governor's September 18 Proclamation (September 24, 2020)
  - Response to Governor's October 16 Proclamation (October 19, 2020)
  - Response to Governor's November 10 Proclamation (November 10, 2020)
  - Response to Governor's December 9 Proclamation (December 10, 2020)
  - Response to Governor's January 7 Proclamation (January 8, 2021)
  - Response to Governor's February 5 Proclamation (February 8, 2021)
  - Response to Governor's March 5 Proclamation (March 8, 2021)
  - Response to Governor's April 2 Proclamation (April 5, 2021)
  - Response to Governor's April 30 Proclamation (May 5, 2021)
  - Response to Governor's May 27 Proclamation (June 1, 2021)
  - Response to Governor's June 25 Proclamation (June 29, 2021)
  - Response to Governor's July 23 Proclamation (July 26, 2021)
- Iowa Governor Kim Reynolds
  - State of Public Health Disaster Emergency (March 17, 2020)
  - Proclamation of Disaster Emergency (March 22, 2020)
  - Proclamation of Disaster Emergency (April 2, 2020)
  - Proclamation of Disaster Emergency (April 27, 2020)
  - Proclamation of Disaster Emergency (May 26, 2020)
  - Proclamation of Disaster Emergency (June 25, 2020)
  - Proclamation of Disaster Emergency (July 24, 2020)
  - Proclamation of Disaster Emergency (August 21, 2020)
  - Proclamation of Disaster Emergency (September 18, 2020)
  - Proclamation of Disaster Emergency (October 16, 2020)
  - Proclamation of Disaster Emergency (November 10, 2020)
  - Proclamation of Disaster Emergency (December 9, 2020)
  - Proclamation of Disaster Emergency (January 7, 2021)
  - Proclamation of Disaster Emergency (February 5, 2021)

    - Proclamation of Disaster Emergency (March 5, 2021)
    - Proclamation of Disaster Emergency (April 2, 2021)
    - Proclamation of Disaster Emergency (April 30, 2021)
    - Proclamation of Disaster Emergency (May 27, 2021)
    - Proclamation of Disaster Emergency (June 25, 2021)
    - Proclamation of Disaster Emergency (July 23, 2021)
    - Proclamation of Disaster Emergency (August 19, 2021)
    - Proclamation of Disaster Emergency (September 17, 2021)
    - Proclamation of Disaster Emergency (October 15, 2021)
    - Proclamation of Disaster Emergency (November 12, 2021)
    - Proclamation of Disaster Emergency (December 10, 2021)
    - Proclamation of Disaster Emergency (January 7, 2022)
    - Proclamation of Disaster Emergency (February 3, 2022)
- Iowa Department of Public Health
    - Novel Coronavirus (COVID-19)
    - Isolation Guidance for Essential Services Personnel
    - Isolation Guidance for Iowans
    - What is Self Isolation?
    - Iowa Statewide Emergency Registry of Volunteers (i-SERV)
    - COVID-19 Outbreak Guidance for Businesses (April 8, 2020)
    - IDPH Coronavirus information (to be decommissioned as of February 16, 2022)
    - IDPH COVID-19 Vaccine Information (October 1, 2020)
    - IDPH COVID-19 Therapeutics Information for Providers
- U.S. Centers for Disease Control and Prevention (CDC)
    - Coronavirus (COVID-19)
    - Interim US Guidance for Risk Assessment and Public Health Management of Healthcare Practitioners with Potential Exposure in Health Care Setting to Patients with Coronavirus Disease 2019 (COVID-19) (Updated March 2021)
    - Considerations for Pharmacies During the COVID-19 Pandemic (April 3, 2020)
    - Implementing Safety Practices for Critical Infrastructure Workers Who May Have Had Exposure to a Person with Suspected or Confirmed COVID-19 (April 8, 2020)
    - Considerations for Pharmacies during the COVID-19 Pandemic (April 14, 2020)
    - Guidance for Pharmacists and Pharmacy Technicians in Community Pharmacies during the COVID-19 Response (Updated May 28, 2020)
    - COVID-19 Vaccine: Quick Reference Guide for Healthcare Professionals (March 26, 2021)
    - Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States (March 5, 2021)
    - Resuming Business Toolkit (May 21, 2021)
    - Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic (September 10, 2021)
- Critical Point
    - Critical Point Peer Network

- National Center for Biotechnology Information, US National Library of Medicine
  - WHO Guidelines on Hand Hygiene in Health Care (hand sanitizer formulation)
- United States Pharmacopeia (USP)
  - Compounding Alcohol-Based Hand Sanitizer During COVID-19 Pandemic (Updated March 25, 2020)
  - USP COVID-19 Response Hand Sanitizer Information (May 4, 2020)
  - Operational Considerations for Sterile Compounding During COVID-19 Pandemic (December 15, 2020)
  - USP COVID-19 Vaccine Handling Toolkit (January 28, 2021)
- U.S. Drug Enforcement Administration (DEA)
  - COVID-19 Information Page
  - DEA Guidance re: Oral Emergency CII Prescriptions (March 27, 2020)
  - DEA Letter to Hospitals/Clinics, Manufacturers, and Distributors (April 10, 2020)
  - DEA Letter to Practitioners/Dispensers re: Temporary Suspension of 5% Distribution Regulation (April 13, 2020)
- U.S. Food and Drug Administration (FDA)
  - Coronavirus (COVID-19) Update: FDA Alerts Consumers About Unauthorized Fraudulent COVID-19 Test Kits (March 20, 2020)
  - Coronavirus (COVID-19) Update: FDA Provides Update on Patient Access to Certain REMS Drugs during COVID-19 Public Health Emergency (March 22, 2020)
  - Coronavirus (COVID-19) Update: FDA Helps Facilitate Veterinary Telemedicine During Pandemic (March 24, 2020)
  - Coronavirus (COVID-19) Update: FDA Takes Action to Increase U.S. Supplies through Instructions for PPE and Device Manufacturers (March 24, 2020)
  - FDA adds Hydroxychloroquine to Category 1 for Compounding with Bulk Drug Substances under 503B (March 25, 2020)
  - Emergency Use Authorization for Use of Chloroquine or Hydroxychloroquine Supplied from the SNS for Treatment of COVID-19 (March 28, 2020)
  - Safely Using Hand Sanitizer (March 30, 2020)
  - Coronavirus Disease 2019 (COVID-19) Frequently Asked Questions (March 30, 2020)
  - Coronavirus (COVID-19) | Drugs
  - Coronavirus (COVID-19) Update: Serological Tests (April 7, 2020)
  - Summary of Best Practices for Retail Food Stores, Restaurants, and Food Pick-Up/Delivery Services During the COVID-19 Pandemic (April 10, 2020)
  - Temporary Policy Regarding NonStandard PPE Practices for Sterile Compounding by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency (April 10, 2020)
  - Coronavirus (COVID-19) Update: FDA Issues Emergency Use Authorization to Decontaminate Millions of N95 Respirators (April 12, 2020)
  - 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 (April 20, 2020)

    - Temporary Policy on Repackaging or Combining Propofol Drug Products During the COVID-19 Public Health Emergency (April 22, 2020)
    - Coronavirus (COVID-19) Update: FDA Reiterates Importance of Close Patient Supervision for 'Off-Label' Use of Antimalarial Drugs to Mitigate Known Risks, Including Heart Rhythm Problems (April 24, 2020)
    - Exemption and Exclusion from Certain Requirements of the Drug Supply Chain Security Act During the COVID-19 Public Health Emergency (April 30, 2020)
    - Coronavirus (COVID-19) Update: FDA Issues Emergency Use Authorization for Potential COVID-19 Treatment (May 1, 2020)
    - Temporary Policy Regarding NonStandard PPE Practices for Sterile Compounding by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency (May 14, 2020)
    - 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 (Revised May 21, 2020)
    - Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Outsourcing Facilities During the COVID-19 Public Health Emergency (Revised May 21, 2020)
    - Medical Device Shortages During the COVID-19 Public Health Emergency (August 14, 2020)
    - Beware of Fraudulent Coronavirus Tests, Vaccines and Treatments (September 21, 2020)
    - A Closer Look at COVID-19 Diagnostic Testing (November 16, 2020)
- U.S. Environmental Protection Agency (EPA)
    - EPA Announces Enforcement Discretion Policy for COVID-19 Pandemic (March 26, 2020) - NOTE: Policy terminated August 31, 2020
- U.S. Occupational Safety and Health Administration (OSHA)
    - Protecting Workers: Guidance on Mitigating and Preventing the Spread of COVID-19 in the Workplace (June 10, 2021)
- U.S. Dept of Health and Human Services (HHS), Assistant Secretary for Preparedness and Response (ASPR)
    - COVID-19: 2019 Novel Coronavirus Disease
- Iowa Poison Control Center
    - POISON ALERT: Serious Toxicity from Chloroquine and Hydroxychloroquine (March 25, 2020)
- Iowa Pharmacy Association (IPA)
    - COVID-19 Resources
- National Community Pharmacists Association
    - NCPA Coronavirus Information (Updated June 2021)
- American Pharmacists Association (APhA)
    - COVID-19 Resources and Training For You
    - COVID-19: Practice Resources
    - COVID-19 Testing In Pharmacies (July 2021)

- The Joint Commission
    - Coronavirus (COVID-19) Information and Resources
- National Council for Prescription Drug Programs (NCPDP)
    - NCPDP Emergency Preparedness Information
- Centers for Medicare & Medicaid Services (CMS)
    - Medicare Pharmacies and Other Suppliers May Temporarily Enroll as Independent Clinical Diagnostic Laboratories to Help Address COVID-19 Testing (May 8, 2020)
    - CMS and CDC announce provider reimbursement available for counseling patients to self-isolate at time of COVID-19 testing (July 31, 2020)

OPERATING OR CLOSING PHARMACIES

Question: Can our pharmacy adjust our hours of operation?

Answer: Yes. The Board's rules do not mandate that your pharmacy be open a minimum number of hours or days. It is highly recommended that you provide updated information as far in advance and to the extent possible to your patients. For a telepharmacy operation, the hours of operation of the telepharmacy site are required to be in the agreement with the managing pharmacy, so the sites are encouraged to be in communication with each other and patients to modify hours of operation.

Question: Can our pharmacy convert to a closed-door or delivery-only operation temporarily?

Answer: Yes. The Board's rules do not require a general pharmacy license to be open to the public. The pharmacy is encouraged to provide advanced notice, to the extent possible, to the pharmacy's patients and prescribers, as well as signage on the pharmacy exterior to provide information to customers.

Question: What are the Board's expectations if a pharmacy has to close entirely?

Answer: If a pharmacy is going to close entirely:

- The pharmacist-in-charge or owner should notify Board staff prior to the closing, or as soon as possible after closing (if prior notification is not reasonably possible).
- Patients should be notified prior to the closing, or as soon as possible after closing (if prior notification is not reasonably possible). The notification should provide information about how patients can have their prescription(s) transferred or instruct that they will need to obtain new prescriptions from their provider to be filled at a different pharmacy.
- Clinics, hospitals, and prescribing practitioners from which the pharmacy receives prescriptions should be notified to the extent reasonably possible.
- If the pharmacy plans to reopen at a later date, the above notifications should include the anticipated reopening date.

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

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

- Encourage customers to buy over-the-counter medications (without hoarding) and to refill prescriptions before they become exposed to or infected with COVID-19 (keeping in mind that *individuals do not always know if they have been exposed or infected*).
- Establish a process for reducing or eliminating the amount of time customers wait in line to pick up filled prescriptions - especially those who are at most risk. Suggestions include:
    - Maximize (or require) use of drive-through window(s) or implement curbside pick up options
    - Initiate an appointment process for prescription pick up
    - Limit the number of patients that can be in the pharmacy area at one time
    - Initiate prescription delivery services (note that prescription delivery is a task that does not require Board registration)
- Implement infection control procedures:
    - When possible, staff should maintain a distance of 6 feet from patients or other staff members; some pharmacies have placed tape on the floor in 6-foot increments to distance customers from each other
    - Require patient mask use if observed to be symptomatic
    - 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 warm water frequently and for at least 20 seconds. (You can download and print: IDPH Hand Washing Sign)
    - Staff should avoid touching eyes, nose, and mouth.
    - Staff should cover coughs and sneezes with a tissue and discard.
    - Regularly monitor all staff for illness. Staff members should stay home if they have symptoms of any respiratory infection.
    - Some businesses have put in place temporary barriers to limit transmission when customer distance cannot be at least 6 feet, such as plexiglass barriers and hanging clear plastic shower liners.
    - Consider limiting the number of patrons allowed in the store at any given time.
- Identify staffing contingency plans sooner than later to identify temporary staff that could be called to work in the event existing staff is unavailable due to illness.
- Ensure pharmacy policies and procedures are current and readily available should temporary personnel be utilized and current staff is not available to provide needed information.
- Review CDC COVID-19 web page for the most current recommendations.
- Review Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic for updated guidance from CDC.

Question: Can an out-of-state pharmacy which is NOT licensed in Iowa ship prescriptions to patients located in Iowa without obtaining a license? (Updated February 15, 2022)

Answer: No. A pharmacy intending to ship prescriptions to Iowans in this state must hold an Iowa pharmacy license.

Question: Can an out-of-state wholesaler or drug distributor which is NOT licensed in Iowa ship prescription drug products into Iowa?

Answer: No. A distributor intending to distribute drug products into this state must hold an appropriate license. A manufacturer must hold a Limited Distributor license while a wholesaler (if it meets the federal definition of a wholesaler) must hold a Wholesale Distributor license. The Board is acutely concerned about the potential for black or gray market operations which may be engaged in the distribution of counterfeit drug products and will take all necessary actions to prohibit those operations in Iowa.

PRESCRIPTION DISPENSING / DELIVERY

Question: 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?

Answer: No. The Board's rules do not require a patient's signature at delivery. The pharmacy may need to inquire with the patient's third-party payer to determine signature requirements. The Iowa Pharmacy Association may also have additional information as it relates to insurer issues. Visit Iowa Pharmacy Association's website for more information. Additional information relating to Medicare and CMS actions can be found at CMS Newsroom.

Question: Our pharmacy sometimes delivers filled prescriptions to the workplace of the patient or to a caregiver's workplace. 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?

Answer: The Board adopted an amendment to 657 IAC 8.15 for delivery of prescriptions. The amended rule, effective April 29, 2020, says:

> **657—8.15(155A) Delivery of prescription drugs and devices.** A prescription order may be delivered to a patient at any location licensed as a pharmacy. Alternatively, a pharmacy may use the mail, a common carrier, or personal delivery to deliver a prescription order to any location requested by the patient. A pharmacy that delivers prescription orders by one or more alternate methods shall have policies and procedures to ensure patient confidentiality, prescription order accountability, and proper storage of prescription orders during delivery. When counseling is required pursuant to rule 657—6.14(155A), oral counseling shall be provided before the prescription order is delivered to the patient. Documentation of the delivery of prescription orders shall be maintained by the pharmacy for at least two years from the date of delivery. The term "patient" includes the patient and the patient's authorized representatives.

As such, pharmacies may implement procedures as allowed by the amended rule to provide prescription delivery services to patients as they request, ensuring patient confidentiality, accountability, and proper storage of the medication(s).

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

Answer: Yes. Under the Board's adopted amendment to 657 IAC 8.15 (see previous question for text of amended rule) for prescription delivery, the pharmacy can deliver a patient's prescription to any location of the patient's choice, as long as the pharmacy can ensure patient confidentiality, accountability, and proper storage of the medication(s).

Question: Can my pharmacy 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?

Answer: Yes. The pharmacy needs to ensure the adjusted procedures ensure patient confidentiality, accountability, and proper storage of medication(s). If a patient requires counseling and the counseling was not provided in advance of the patient picking up the medication (preferable), staff working the "curbside delivery" location must gather from the patient a phone number at which the patient may be contacted for the pharmacist to call to provide counseling.

PHARMACY PRACTICE (Prescription limitations, Patient Counseling, Substitution)

Question: We have a patient who is out of refills for a medication. We have been unable to get a response from the patient's prescriber. Can we refill the prescription without authorization?

Answer: Unless it's a controlled substance, yes. Iowa Code section 155A.29 currently authorizes pharmacists to exercise professional judgment by refilling a prescription one time without prescriber authorization *if all of the following are true*:

a. The pharmacist is unable to contact the prescriber after reasonable effort.
b. Failure to refill the prescription might result in an interruption of therapeutic regimen or create patient suffering.
c. The pharmacist informs the patient or the patient's representative at the time of dispensing, and the practitioner at the earliest convenience, that prescriber reauthorization is required.

Answer: If it's a controlled substance, federal regulation has not been amended or lifted, to date, to allow renewal of a controlled substance prescription without prescriber authorization.

Question: A patient has come to my pharmacy to get a prescription filled because the patient's regular pharmacy has closed indefinitely. My staff has also been unable to contact the prescriber due to their clinic being closed. Can I fill the prescription without getting the required transfer or new prescription from the prescriber?

Answer: Unless it's a controlled substance, yes. Iowa Code section 155A.29 currently authorizes pharmacists to exercise professional judgment by refilling a prescription one time without prescriber authorization *if all of the following are true*:

a. The pharmacist is unable to contact the prescriber after reasonable effort.
b. Failure to refill the prescription might result in an interruption of therapeutic regimen or create patient suffering.
c. The pharmacist informs the patient or the patient's representative at the time of dispensing, and the practitioner at the earliest convenience, that prescriber reauthorization is required.

Question: Can our pharmacy discontinue provision of face-to-face counseling?

Answer: Yes, as long as the pharmacy has some equivalent method to provide the needed information to the patient. Board rule 8.15 requires oral counseling to occur before a prescription order is delivered to a patient in situations where counseling is required pursuant to rule 6.14.

Question: Is a pharmacist authorized to engage in therapeutic interchange of a medication when or if the prescribed medication is not available, without contacting the prescribing physician for authorization?

Answer: No. This regulatory relief provision terminated June 30, 2021.

Question: How do I handle prescriptions which are subject to REMS laboratory testing?

Answer: Please review Coronavirus (COVID-19) Update: FDA provides update on patient access to certain REMS drugs during COVID-19 public health emergency for guidance.

Question: My pharmacy has been presented with a prescription issued by a practitioner who is not currently licensed in Iowa. Is this a legal prescription?

Answer: As of February 16, 2022, all emergency provisions relating to the licensure of practitioners practicing or treating patients in this state have been rescinded; as such, any practitioner who is practicing within Iowa or who is treating patients who are located in Iowa, including via telehealth services, must hold an Iowa license with the appropriate licensing authority.

Question: Is the electronic prescribing mandate waived during this state of emergency?

Answer: No; however Iowa Code provides a number of exemptions for the mandate, including an emergency. Under current Board rule, an emergency is defined as including, *but not being limited to*, issuing a prescription to meet the immediate care needs of a patient after hours when a prescriber may not have access to their electronic prescribing system. In keeping with the current

exemption for emergency situations, a practitioner may transmit a prescription via other than electronic methods in a situation that they deem is an emergency, including when they may not be able to access their electronic prescribing system. Prescribers are encouraged to seek additional guidance from their professional licensing board as those boards are tasked with enforcement of the mandate.

Question: Did Governor Kim Reynolds suspend the rules relating to procedures for authentication of verbal orders and standing orders?

Answer: Previously, but the provision has expired. The current regulatory provisions are reinstated and enforceable.

CONTROLLED SUBSTANCES

Question: Is my pharmacy allowed to skip the signature requirement for over-the-counter sales of pseudoephedrine or over-the-counter dispensing of schedule V cough syrups?

Answer: No. Further, DEA Guidance relating to the signature requirement for pseudoephedrine logbooks continues to require the signature of the purchaser.

Question: I heard the DEA has relaxed some of the regulations on phoned-in emergency CII prescriptions?

Answer: Yes, on March 27, 2020, the DEA published Guidance relating to oral emergency CII prescriptions which provides temporary exemptions to two required components of an oral emergency CII prescription. The Guidance allows prescribers to 1) submit the follow-up prescription to the pharmacy within 15 days (current regulation requires 7 days) and 2) submit the follow-up prescription via alternate methods, such as via facsimile or by a photograph or scan of the prescription sent to the pharmacy. Note that emergency prescriptions still must be transmitted directly from the prescriber to a pharmacist and that the follow-up prescription must still include all the required elements, including the notation “Authorization for Emergency Dispensing.” Pharmacists are encouraged to solicit the intended method of submission for the follow-up prescription from the prescriber during the initial phone call and document the relevant information for subsequent verification (e.g., ask the prescriber to identify how the follow-up prescription will be submitted and document the fax number or email address from which the prescription will be provided for subsequent verification).

Question: I heard that the DEA has temporarily paused its regulation which limits distribution of controlled substances to another registrant to 5% of the registrant’s annual dispensing/distribution?

Answer: Yes, due to the COVID-19 pandemic and the challenges posed, DEA has issued this Letter to DEA Practitioners on April 13, 2020 in which it grants a temporary exception to 21 CFR 1307.11. If a registrant is compliant with all other aspects of distribution (such as security,

recordkeeping, etc.), the DEA will not limit a registrant's distribution to 5% of its annual dispensing/distribution. The temporary authorization is backdated to January 1 and extends through the end of the national disaster emergency declaration. Upon the expiration of the national disaster emergency, the registrant will only have to count any distribution from that point through the end of the calendar year in its annual distribution calculation. Pharmacies should note that any distribution of prescription drug products, including controlled substances, are subject to the federal drug supply chain security act conditions, unless the distribution is an exempted transaction (such as to meet a specific patient need or in response to a public health emergency).

Question: I heard that the DEA has temporarily authorized DEA-registered hospitals and clinics to have controlled substances delivered to and handled by a satellite hospital/clinic which is not DEA-registered?

Answer: Yes, under very specific parameters, DEA will allow a DEA-registered hospital/clinic, under its existing DEA registration, to handle controlled substances at a satellite hospital/clinic location (one or more). The parameters include, but are not limited to, the satellite hospital/clinic was set up to provide temporary services connected to the public health emergency resulting from the COVID-19 pandemic, certain records are maintained, and that physical security and effective controls against diversion are maintained. Hospitals or clinics which may be subject to the DEA allowance must review and maintain compliance with the DEA Letter to Hospitals/Clinics, Manufacturers, and Distributors (April 10, 2020).

Question: Can registered pharmacies postpone DEA biennial controlled substance inventories during the nationwide public health emergency declared by the Secretary of Health and Human Services on January 31, 2020, as a result of the Coronavirus Disease 2019 (COVID-19)?

Answer: No. A biennial inventory is required under the Controlled Substances Act (CSA) as enacted by Congress. **21 U.S.C. 827**(a)(1) requires that "every registrant under [Subchapter I-Control and Enforcement] shall, on May 1, 1971, or as soon thereafter as such registrant first engages in the manufacture, distribution or dispensing of controlled substances, and every second year thereafter, make a complete and accurate record of all stocks thereof on hand, except that the regulations prescribed under this section shall permit each such biennial inventory (following the initial inventory required by this paragraph) to be prepared on such registrant's regular general physical inventory date (if any) which is nearest to and does not vary by more than six months from the biennial date that would otherwise apply." As such, the statutory text of the CSA requires registrants engaged in the manufacture, distribution, and dispensing of controlled substances to conduct an inventory no less often than biennially. DEA's regulations implementing this provision permit such registrants to conduct the inventory "on any date which is within two years of the previous biennial inventory date," but the regulations, like the statute, do not permit the inventory to be delayed beyond two years. **21 CFR 1304.11**. No waiver or exemption is currently in effect to excuse general compliance with this requirement for dispensers, including pharmacies. Any questions about the applicability of these requirements to a registrant's particular situation should be directed to the Diversion Control Division Policy Section at (571) 362-3260.

REMOTE PROCESSING

Question: 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?

Answer: Previously, but with the discontinuation of the regulatory relief in Governor Reynolds' Proclamations of Disaster Emergency and the Board's withdrawal of its statement on enforcement discretion, pharmacies are now expected to comply with all laws and rules relating to the practice of pharmacy, including the pharmacist supervision of technicians. The Board will be reviewing the issue and assessing a potential rule change to allow this practice in the future.

Question: Can pharmacists and technicians working in a pharmacy be remotely involved in the dispensing process of another pharmacy?

Answer: Yes, as long as the pharmacies involved have the appropriate hardware and software to exchange the necessary data to safely and securely perform the tasks and that work completed by technicians that would otherwise be verified by a pharmacist continues to be verified by a pharmacist.

CONTINUING EDUCATION / TRAINING

Question: My CPR certification is due to expire soon and the training organization has indefinitely suspended all in-person training. Will I have to discontinue administering immunizations until I can complete certification?

Answer: No. Federal HHS issued a 4th amendment to its PREP Act to specifically identify that the CPR training requirement in its authorizations for immunizations may be satisfied by an online program which has achieved accreditation by the ACPE, American Nurses Credentialing Center, or Accreditation Council for Continuing Medical Education. The board will recognize CPR certification with at least one of these accreditation credentials for the period of the CPR certification. While the Board's preference is that an immunizer receive a hands-on competency evaluation (some programs offer these remotely) per its rules, it will exercise enforcement discretion for individuals who attain CPR certification per the guidelines of the HHS under the PREP Act.

PHARMACY PERSONNEL / LICENSING ISSUES

Question: Can the pharmacy utilize store employees who are not currently registered with the Board in any capacity to assist with duties normally handled by registered pharmacy support persons, such as entering the pharmacy to assist with handling payment transactions for prescriptions?

Answer: No.

Question: Can a pharmacist that is licensed and in good standing in another state perform work inside Iowa or remotely from another state?

Answer (non-IA-licensed RPh working in out-of-state pharmacy): Pharmacists who work in an Iowa-licensed non-resident pharmacy may provide pharmacist services for Iowa patients without specifically holding an Iowa pharmacist license.
Answer (non-IA-licensed RPh working in Iowa pharmacy): A pharmacist who is working in an Iowa pharmacy shall hold an active Iowa pharmacist license.

Question: A member of my staff is believed to be infected with COVID-19. When can they return to work?

Answer: Refer to current CDC guidance.

Question: What are the recommendations for pharmacy personnel who believe they have been exposed to coronavirus?

Answer: Refer to IDPH Isolation Guidance for Essential Services Personnel (March 22, 2020).

Question: Is the Board waiving licensure requirements for manufacturers to ship COVID-19 point-of-care test kits into Iowa?

Answer: The Board has not relaxed licensure requirements for entities part of the drug supply chain, as part of the Board's mission to protect the health, safety and welfare of Iowans. That said, a manufacturer which does not qualify as a wholesale distributor under federal law would be covered under the Board's Limited Distributor Licensure requirements. If the distribution is limited to "distribution of medical devices exclusively to a health care practitioner for use in the normal course of professional practice ("professional use")", licensure is optional.

Question: Can my pharmacy or hospital order COVID-19 testing kits from a wholesale distributor that is not licensed in Iowa?

Answer: If the wholesaler's distribution into Iowa is limited to medical devices (such as COVID testing kits) to a health care practitioner for use in the normal course of professional practice ("professional use"), yes. This distribution activity is covered under the Board's "optional licensure" with a Limited Distributor License. The wholesaler would not be authorized to distribute any prescription drug product (such as albuterol inhalers, etc.) without prior licensing as a wholesale distributor in Iowa.

Question: Can my pharmacy engage a nurse to assist with COVID vaccine administration?

Answer: Yes, with some considerations.

Delegation: Since a pharmacist does not have the authority to delegate medication administration to a nurse, the pharmacy should be vaccinating under Dr. Stilley's (formerly Dr. Pedati's) standing order which delegates vaccine administration to a nurse (a registered nurse only, unless a registered nurse is on site to supervise a licensed practical nurse). Alternatively, if a nurse

registers as a technician trainee, a pharmacist can delegate the task of administering immunizations to a technician trainee in accordance with rule 3.17.

Board registration: If the nurse will be allowed access to the pharmacy, the nurse will need to be registered by the board as a pharmacy support person or a technician.

PHARMACIST SCOPE OF PRACTICE and PROTOCOLS

Question: Will the Board be temporarily expanding the scope of practice for pharmacists so that they can perform functions like conducting COVID-19 or rapid strep tests *with subsequent prescribing of appropriate antibiotics*?

Answer: On July 1, 2021, SF 296 became effective, which authorizes pharmacist to order and administer point-of-care testing and treatment for influenza, streptococcus A, and COVID-19 to patients ages six years and older pursuant to statewide protocols developed by the board in consultation with the department of public health.

The Board's approved statewide protocols for point-of-care test and treat can be found HERE for influenza and strep.

A SWP for COVID-19 test and treat is not currently under consideration by the Board, but pharmacists are authorized under the 9th amendment of the PREP Act Emergency Declaration to order and administer certain COVID-19 therapeutics (monoclonal antibodies, etc.).

Question: If a vaccine is approved by FDA and available for administration to prevent the novel coronavirus, will pharmacists be authorized to administer the vaccine under the Board's statewide protocol?

Answer: Yes. When a vaccine is approved by FDA and added to the ACIP recommendation guidelines, a pharmacist is authorized to administer the vaccine to a patient pursuant to the Board's statewide protocol for immunizations. Under the Board's statewide protocol, a pharmacist is authorized to administer to patient's six months of age and older "other immunizations in response to a public health emergency." Beyond the federal public health emergency, COVID vaccines would be authorized only via a patient-specific prescription or the board-approved statewide protocol for the specific age-related vaccinations.

On September 29, 2020, the Iowa Department of Public Health issued a letter to all health care providers about enrollment in the COVID-19 Vaccination Program. Any health care provider who wishes to participate in the Vaccination Program must complete the CDC COVID-19 Vaccination Program Provider Agreement. At the link to the Provider Agreement, a health care provider can access a PDF version of the Agreement, but note that the Provider Agreement may only be submitted via the online survey. All providers who participate in the Vaccination Program are required to submit documentation of the administration to the state's vaccine registry. The Provider Agreement provides more information about the parameters of participating in the

Program. The Board encourages pharmacies to participate in the COVID-19 Vaccination Program to the extent possible, if the pharmacy has appropriate resources to do so. A statewide standing order for COVID vaccinations can be found HERE. Interim Director Garcia has issued a vaccine shortage order which can be found HERE.

More information about the COVID-19 Vaccination Program can be found at IDPH COVID-19 Vaccine Information.

The Board encourages pharmacies to review their emergency kit to ensure adequate supplies of non-expired medications are available for adverse reactions to an immunization and encourages pharmacies to ensure patients remain under observation for an adequate period of time to ensure no emergency adverse reaction occurs.

Question: Following administration of a COVID vaccine, am I required to report the administration to the patient's primary care practitioner?

Answer: It depends.

- If the administration is pursuant to Dr. Stilley's order, the pharmacist/pharmacy is **not** required to report the administration of the vaccine (due to being for a public health emergency). *See* 657 IAC 39.10(7)"b"
- If the administration is pursuant to the Board's statewide protocol or the HHS order authorizing pharmacists to order and administer the vaccine, state law must be followed which requires reporting to the primary care practitioner, if known, "as soon as reasonably possible". *See* Iowa Code 155A.46(2)"b" and 657 IAC 39.11(5)

Question: Can my pharmacy conduct COVID-19 diagnostic and/or serologic tests?

Answer: Yes. The PREP Act and subsequent HHS Guidance authorize pharmacists to order and administer COVID testing, including serology tests, authorized by FDA. This authority provides pharmacists with the independent authority to order and administer a test without a specific order from a prescriber to do so. This authority extends only through the federal government's designation of the public health disaster. Pharmacist administration of COVID testing beyond the federal public health disaster must be pursuant to an order by a licensed healthcare practitioner authorized to prescribe.

The HHS Guidance authorizes pharmacists to order and administer COVID tests *which are authorized by FDA*. The pharmacist must ensure that the test to be administered is authorized by FDA either under a normal approval process or through the FDA's Emergency Use Authorization process. *Pharmacists are not authorized to order and administer a COVID-19 test which has not received FDA authorization, even if it may be available in the marketplace.*

Delegation of tasks to technicians

As pharmacists consider engaging in any type of COVID-19 testing, they should continue to comply with laws and rules relating to pharmacist responsibilities for dispensing, delegation of

tasks, and supervision of pharmacy personnel. Pharmacists are authorized to independently order and administer COVID-19 tests, and to dispense a test ordered by another provider, including another pharmacist. Pharmacists may delegate appropriate non-clinically judgemental tasks associated with testing to pharmacy personnel who are appropriately trained and working under pharmacist supervision.

On October 20, 2020, HHS issued Guidance that authorizes qualified pharmacy technicians and State-registered pharmacy interns to administer COVID-19 tests. The Board issued this Guidance to provide further information to licensees.

Laboratory information

- *Point-of-care testing (POCT)*: If a pharmacy intends to order and administer POCT, it must first have a current CLIA Certificate of Waiver to conduct CLIA-waived tests, such as POCT for COVID-19. A pharmacy that does not have a CLIA Certificate of Waiver may complete the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (CMS Form 116) and submit to the:

  Iowa CLIA Laboratory Program
  State Hygienic Laboratory
  University of Iowa Research Park
  2490 Crosspark Road
  Coralville, IA 52241
  (319) 335-4500 or (800) 421-IOWA
  FAX: (319) 335-4174
  Email: shl.clia@uiowa.edu

  On the application for a CLIA Certificate of Waiver, the pharmacy may be required to identify the specific CLIA-waived test(s) intended to be administered at the pharmacy.

- *Moderate- or High-Complexity testing*: Pharmacy collection of patient specimens (respiratory for diagnostic, venous blood for serologic) for subsequent moderate- or high-complexity lab analysis must identify and coordinate with a laboratory for such testing. No CLIA Certificate of Compliance or Waiver is required for specimen collection. Possible laboratory options may include, but cannot be guaranteed by the Board:
    - Quest Diagnostics
    - ARUP
    - LabCorp
    - State Hygienic Lab

Policies and Procedures

The pharmacy must ensure that, depending on the test(s) to be conducted, a complete policy and procedure is established and followed which includes but is not limited to:

- Notification of the pharmacy's intent to order and administer COVID-19 tests via updating the pharmacy's online profile with the Board via View User Profile and Update Demographics to identify "COVID-19 Diagnostic" or "COVID-19 Antibody" testing as an available pharmacy service;
- Notification to the test kit manufacturer and FDA (via email at CDRH-EUA-Reporting@fda.hhs.gov) of any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the test kit;
- Patient screening parameters prior to ordering and administering a test, including identification of testing priority groups;
- Personnel training required prior to engaging in specimen collection and testing, including review and understanding of the test kit manufacturer instructions / package insert;
- Strict adherence to the testing procedure identified in the test kit manufacturer instructions / package insert;
- Appropriate use of personal protective equipment (PPE);
- Environmental security measures that will be in place to prevent the spread or transmission of the coronavirus by a potentially infected individual presenting to the testing site;
- Evaluation of test results;
- Dissemination of test results to the patient, the patient's primary care practitioner, and the local public health agency; and
- Patient guidance to be provided based on the test type (diagnostic or serologic) and test result (positive or negative).

Personnel Training

Pharmacy personnel who will be conducting COVID-19 testing must be properly trained on the testing policy and procedures, proper specimen collection, proper use of personal protective equipment (PPE), and evaluation of test results prior to engaging in specimen collection and/or testing. Documentation of completed training, and documented observed competency for specimen collection and use of PPE, for each individual involved in specimen collection and/or testing must be maintained in the pharmacy and available for inspection and copying by the Board or its authorized representative.

Supplies for Collection of Patient Specimens

A pharmacy engaged in COVID-19 testing, either at POC or collection of specimens for moderate- or high-complexity laboratory testing, which is having difficulty obtaining supplies for collecting patient specimens should review the FDA website Contacts for Medical Devices During the COVID-19 Pandemic for more information.

Test Result Reporting

A pharmacy engaged in ordering or analyzing COVID-19 tests (including at POC, collection of specimens for moderate- or high-complexity laboratory testing, or ordering a test for a patient's at-home specimen collection and submission to a moderate or high-complexity laboratory) must provide all test results to the patient, the patient's primary care practitioner (if identified), and all positive test results to the Iowa Department of Public Health (electronically through the Iowa Disease Surveillance System, preferred, or via fax to 515-281-5698). If the pharmacy is only involved with overseeing specimen collection but is not the ordering practitioner or lab conducting the test analysis, the pharmacy is not required to report test results.

The pharmacy, regardless of the pharmacy's level of involvement in testing, must update the pharmacy's online profile with the Board via View User Profile and Update Demographics to identify the pharmacy's service(s) of "COVID-19 Diagnostic" and/or "COVID-19 Antibody" testing. Within approximately 48 hours, the pharmacy will receive via email a survey to connect with the IDSS for submission of positive test results, if the pharmacy is required to report based on the pharmacy's level of involvement in testing. If the pharmacy has not received the template within 72 hours, please contact sue.mears@iowa.gov.

Treatment Following a Positive COVID-19 Test Result

At this time, there is no Board-approved statewide protocol for test and treat for COVID-19. However, under the 9th Amendment to the PREP Act Emergency Declaration, pharmacists are authorized to order and administer approved or authorized COVID-19 therapeutics that are administered subcutaneously, intramuscularly, or orally in accordance with the EUA. Note that Evusheld, monupiravir, and Paxlovid specifically limit the prescribers who are authorized to order these medications and pharmacists are **not** included in the list of authorized practitioners.

Billing to CMS

The US Centers for Medicare & Medicaid Services (CMS) recently published information allowing pharmacies to temporarily enroll as an independent clinical diagnostic laboratory for the purpose of reimbursement for COVID-19 testing. Note that the information and subsequent enrollment does not impact or override the CLIA requirements for laboratories. Pharmacies would still be limited to conducting tests that are authorized for their level of CLIA certification.

On July 31, 2020, CMS and CDC announced that provider reimbursement is available for counseling patients to self-isolate at the time of the COVID testing. Providers who are eligible to bill CMS for counseling services will be able to use existing evaluation and management (E/M) payment codes for reimbursement. Further information and resource links are available in the Counseling Check List PDF.

Final Reminder

A pharmacy engaged in COVID-19 testing must continue to be aware of current recommendations and authorizations for such testing. While the HHS Guidance issued April 8, 2020 provides

pharmacists immunity from damages as a result of conducting COVID-19 countermeasures, the Board's expectation is that pharmacists are conducting these tests under strict policy and procedures and adhering to the test kit product insert.

Question: With the recent change in the Emergency Use Authorization for REGEN-COV monoclonal antibodies (mAb) and the HHS 9th PREP Act amendment, can my pharmacy administer REGEN-COV to patients?

Answer: Yes. The HHS 9th Amendment to the PREP Act Declaration authorizes pharmacists to order and administer and technicians and interns to administer any COVID-19 therapeutic that is approved or authorized by the FDA which is administered orally, intramuscularly or subcutaneously.

- Training. The pharmacist, technician or intern who is administering the COVID-19 therapeutic must complete an ACPE-approved practical training program which includes:
    - Hands-on injection technique,
    - Clinical evaluation of indications and contraindications of COVID-19 therapeutics,
    - Recognition and treatment of emergency reactions to COVID-19 therapeutics, and
    - Any other training identified by FDA.
- Supervision. A supervising pharmacist must be readily and immediately available to the technician.
- CPR certification. The pharmacist, technician or intern must hold a current certification in basic cardiopulmonary resuscitation.
- Recordkeeping and reporting.
    - Pursuant to Iowa Code 155A.46, subsection 2, paragraphs (a) and (b), the pharmacy must retain records of the medication ordered and administered and notify the patient's primary care provider.
    - Pharmacies must report the administration to HHS weekly via https://teletracking.protect.hhs.gov
- Board notification. A pharmacy intending to order and administer COVID-19 therapeutics must update its online board pharmacy profile (link HERE) and indicate "Yes" to the pharmacy service "Statewide Protocol - COVID-19 Test and Treat" (regardless of administration under the HHS PREP Act authority or a board-approved SWP, if available).
- Product availability. As of September 13, 2021, mAb distribution is being handled via federal and state-level allocation and distribution. Pharmacies that wish to be an approved provider of mAbs must complete the IDPH COVID-19 Monoclonal Antibody Provider Request Form.

Question: When FDA authorizes a COVID-19 test for point-of-care use, does that mean it is CLIA-waived?

Answer: Yes. When the FDA issues a Letter of Authorization to a company to authorize a COVID-19 test under an Emergency Use Authorization, the letter will include the settings in which the EUA-authorized test may be performed. When FDA authorizes point-of-care tests (including for

SARS-CoV-2) under an EUA, such tests are deemed to be CLIA-waived and can be performed in a patient care setting that is qualified to have the test performed there as a result of operating under a CLIA Certificate of Waiver.

Question: Would my pharmacy be authorized to perform CLIA-waived COVID-19 testing at off-site locations?

Answer: Yes. Information provided in How to Obtain a CLIA Certificate of Waiver information, CLIA-waived tests can be provided at temporary locations.

Question: I am finding a lot of COVID-19 antibody (serology) tests available online for health care professionals to order. Can my pharmacy administer these antibody tests?

Answer: While there are several COVID-19 antibody tests authorized for use by FDA under an Emergency Use Authorization ("EUA"), the vast majority of which are only authorized for use in a moderate or high-complexity laboratory. FDA has relaxed its regulatory framework for development of these tests, allowing companies to develop and market test kits prior to receiving official approval from FDA. The companies are required to validate their test results prior to marketing their tests and are required to notify the FDA of their validation and intent to distribute. However, until a test kit has been authorized by FDA (either under the regular approval process or via an EUA), such test kit has not been assigned a CLIA designation. As such, *test kits which do not have FDA approval or FDA EUA that specifies use in a CLIA-waived lab are deemed to be conducted only in a high-complexity laboratory environment and, therefore, not approved for use at the point of care or patient care setting, such as in a pharmacy*.

Question: What is TestIowa.com?

Answer: TestIowa.com is an initiative by the State of Iowa to increase the rate of COVID-19 testing to expand access to testing and help stem the spread of the coronavirus. Iowans are encouraged to visit TestIowa.com to obtain a test kit (which may be picked up or delivered to your home). The sample is collected at the individual's home and the sample is returned to the state hygienic lab for processing.

Question: How can my pharmacy become a site to administer monoclonal antibodies and/or dispense COVID-19 antivirals?

Answer:

- A pharmacy that would like to provide administration of monoclonal antibodies may complete a survey HERE for consideration as an approved provider. Note, however, that as supplies are allocated in extremely limited quantities from the federal government, it is unlikely that the Department is in need of additional sites.
- A pharmacy that would like to dispense COVID-19 antiviral medications may send an email to C19therapeutics@idph.iowa.gov to express interest in becoming a dispensing site. Department personnel will be in contact with you for additional information if and when they are looking to expand its list of pharmacy partners.

Question: My hospital has been allocated supplies of the COVID-19 antivirals. They are in 5-day course packs but the board's rule limits ED dispensing to no more than 72 hours. Do we need to submit a waiver?

Answer: No. The board's rule also provides a phrase "or the minimum quantity in suitable containers" which would cover the situation here. The ED may dispense the unit-of-use package of the complete 5-day treatment course.

HOARDING OF DRUGS / SUPPLY CHAIN ISSUES

Question: Are we authorized to limit sales of over-the-counter medications and supplies, such as acetaminophen, ibuprofen, cough medicine, etc.?

Answer: Yes. The Board has no mandate that the pharmacy sell these products, so it is entirely a business decision for the pharmacy to set purchase limitations if desired.

Question: Can I dispense more than the authorized quantity of a prescription, if refills are available?

Answer: Unless it is a controlled substance, yes. Iowa Code section 155A.27, subsection 6, authorizes a pharmacist to dispense "up to the total number of dosage units authorized by the prescriber on the original prescription and any refills of the prescription, not to exceed a 90-day supply." It is recommended, however, that pharmacists exercise professional judgment in making determinations on dispensing additional quantities of prescription drugs. While it is beneficial to limit the number of pharmacy visits for patients, there is also a concern about adding to the strain of the drug supply chain.

Question: Am I authorized to limit a quantity dispensed on a prescription if I am concerned about drug supply chain issues?

Answer: Yes, you can use your professional judgment to dispense partial quantities of prescription medications in order to prevent the situation of limited drug supplies.

Question: How should my pharmacy handle prescriptions being issued for hydroxychloroquine, chloroquine, ivermectin, or other medications anecdotally being used for treatment or prophylaxis of COVID-19?

Answer: The Board encourages you to use your best professional judgment in determining the legitimacy of these prescriptions and the likely intent. There is no mandate to fill a prescription and a pharmacist has a corresponding responsibility to ensure that a valid patient-prescriber relationship exists and that a prescription was issued for a legitimate purpose. Prescribers are authorized to prescribe medications that are "extra-label" or "off-label" and pharmacists are encouraged to review current scientific literature, and FDA and CDC resources to find the most up-to-date information about potential treatments for COVID-19.

Question: How should my pharmacy handle requests from practitioners who want my pharmacy to distribute stock supplies of chloroquine, hydroxychloroquine, or other prescription drugs anecdotally identified as potential treatment or prophylaxis for COVID-19 for their "office use"?

Answer: Pharmacies are strongly encouraged to limit distribution of these products to only another pharmacy to meet a specific patient need (legitimate prescription for appropriate diagnosis).

Question: If my pharmacy has a drug in stock that is nearing expiration or recently expired, and it is the only product I have available to dispense, can I use it?

Answer: FDA has published information relating to Expiration Dating Extension and also publishes a list of drugs and devices subject to Emergency Use Authorization.

- Review FDA's Search List of Extended Use Dates to Assist with Drug Shortages to see if the product has been issued extended expiry by FDA. It is updated daily with information obtained from manufacturers. To request extended expiry for a drug, send an email to DRUGSHORTAGES@fda.hhs.gov, including detailed information of product(s) for the extended expiration request (NDC number, lot numbers, expiration dates, at a minimum).
- If the drug product is not approved for extended expiration and is a drug relevant to the current pandemic (such as ventilator drugs), the pharmacy may reach out to their Local Homeland Security and Emergency Management Coordinator to request supply from state resources. If the state does not have resources available, the state will elevate the request to their federal resources.

Question: My hospital is unable to procure certain drugs needed for our hospitalized COVID-19 patients which aren't showing on the FDA drug shortage list. Can we obtain these drugs from an outsourcing facility?

Answer: Yes, under very specific conditions and parameters. FDA issued this Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Outsourcing Facilities During the COVID-19 Public Health Emergency which identifies specific drug products which will be allowed to be compounded by outsourcing facilities for hospitalized COVID-19 patients. Facilities compounding the identified drugs must adhere to the specific conditions identified in the Policy in order to be eligible for the FDA's enforcement discretion policy. The current list of drugs which may be compounded pursuant to the FDA's Temporary Policy can be found HERE.

Question: A compounding pharmacy called my hospital to offer compounded drug products that are in short supply without a patient-specific prescription. Can my hospital use this source of drug products?

Answer: Maybe, but use extreme caution. The FDA published a Temporary Policy which allows compounding pharmacies which are not registered as 503B outsourcing facilities to compound certain drug products for hospitals which are treating COVID-19 patients without first obtaining a patient-specific prescription, as would normally be required under the FD&C Act. Your pharmacy must exhaust all other sources of FDA-approved products before obtaining compounded products under this temporary policy (including checking FDA's searchable list of extended expiration dates; obtaining product from other Iowa-licensed dispensers, Iowa-licensed distributors, etc; and

obtaining compounded products from Iowa-licensed outsourcing facilities). The hospital must ensure the compounding pharmacy is licensed in Iowa and should ensure the compounding pharmacy has obtained notification from the Board that it does not object to the compounding pharmacy's provision of the compounded drug product(s). The Board would ask that hospitals which obtain drug product(s) in this manner notify the Board with any product issues or adverse events associated with the drug product(s) provided under this temporary policy. The current list of drugs which may be compounded pursuant to the FDA's Temporary Policy can be found HERE.

These conditions must be met in order to use this temporary policy:

- The hospital must be treating COVID-19 patients,
- The hospital is unable to obtain the drug product(s) from other sources, including outsourcing facilities
- The drug product(s) are limited to only those listed in the FDA temporary policy,
- The BUD is assigned according to the FDA temporary policy,
- The hospital provides relevant information to the pharmacy within 30 days, and
- The compounding pharmacy notifies the state regulatory authority for compounding (board of pharmacy, generally) both in the state in which the compounding pharmacy is located as well as the state in which the hospital is located and obtains notification that the regulatory authority does not object to the provision of the drug products.

COMPOUNDING

Question: Does the Board have any recommendations concerning the possibility of shortages of garb and personal protective equipment (PPE)?

Answer: The Board refers licensees to guidance issued by Critical Point, USP and/or FDA. The Board supports the use of PPE reuse and shortage guidance put forth by any of these organizations as it applies to your facility.

The Board strongly encourages compounding personnel to utilize the resources available at the Critical Point Peer Network where you can sign up for a Silver Subscription at no charge and access valuable information relating to compounding challenges resulting from the COVID-19 pandemic.

Additionally, USP issued an information resource that might be helpful: USP Response to Shortages of Garb and Personal Protective Equipment (PPE) for Sterile Compounding During COVID-19 Pandemic which may be downloaded HERE. The Board is aware that the recommendations are slightly different from those provided by Critical Point. The Board is supportive of licensees making professional judgments in their individual situation to determine the best course of action to ensure product quality, public safety, and employee protection.

On April 10, 2020, FDA issued a Temporary Policy Regarding NonStandard PPE Practices for Sterile Compounding by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency which provides that it does not intend to take

enforcement action regarding compliance with the insanitary conditions provision when drugs intended or expected to be sterile are compounded without standard PPE provided the compounder is compliant with the conditions identified in the temporary policy.

Question: Is it ok for my pharmacy to delay routine media-fill testing, gloved fingertip testing, and garbing technique observation in an effort to conserve garb?

Answer: Maybe. Since media-fill testing can reasonably be completed at the end of a compounding shift, this would not require additional, unnecessary use of garb and should not be delayed. If garbing is simply for the purpose of observing the garbing and aseptic technique of compounding personnel (unless for a newly trained compounder), the observer may consider remote observation (through a window, etc.) during normal compounding operations or, if that's not reasonable, testing could be delayed.

Question: Can my pharmacy compound prescription medications that are essentially copies of FDA-approved, commercially available products if they are on backorder or not available?

Answer: Yes. Board rule 657 IAC 20.12 currently authorizes a pharmacist to compound a drug that is otherwise commercially available when that product is not available due to a documented drug shortage or the drug is listed on the FDA Drug Shortages List.

Question: Can my pharmacy implement remote verification of compounding activities?

Answer: Yes, see "**REMOTE PROCESSING**" section for information about systems requirements to implement product or staging verification during compounding operations.

Question: Will the board or the FDA be enforcing the FDA's "one mile radius" limitation set in its draft Guidance for compounding within a health system?

Answer: The FDA recently announced a policy clarification that its draft guidance for hospital and health system compounding is still in draft and is planned to be revised. As the Guidance has only been issued for public comment, it has not been implemented and FDA will not be enforcing a one mile radius for hospitals and hospital systems. As such, the Board will also not be enforcing a one mile radius limitation.

Question: Will the board or FDA be enforcing the federal law which specifies a 5% limit on interstate distribution of compounded drug products?

Answer: FDA recently announced a policy clarification that it will not be enforcing the federal 5% distribution limitation until such time as the Memorandum of Understanding (MOU) can be finalized and states are allowed the opportunity to sign it. As such, the Board will also not be enforcing the 5% distribution limitation. On October 26, 2020, the FDA published the MOU which will be available for state consideration for one year prior to initiating enforcement provisions of the law. On August 9, 2021, FDA published that it has extended the deadline for states to consider entering into the MOU to October 27, 2022.

Question: What is the procedure for a pharmacy that wishes to provide compounded medications to a hospital without a patient-specific prescription under the FDA's Temporary Policy?

Answer: The FDA recently issued a 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 which authorizes 503A compounding pharmacies to distribute certain compounded drug products for use in hospitalized patients with COVID-19 without first obtaining a patient-specific prescription. The Temporary Policy identifies the specific drug products covered by the Policy as well as beyond-use-dating limitations for the compounded products, among other conditions. A pharmacy which intends to distribute non-patient specific compounded drug products pursuant to the FDA Temporary Policy must first notify the Board (via email to sue.mears@iowa.gov) and provide the following information:

- Pharmacy name and address,
- Iowa pharmacy license number, and
- Drug product(s) which the pharmacy intends to distribute.

Upon review of the notification and supporting documentation, Board staff will provide a response indicating if the Board does not intend to object to the pharmacy providing the drug product(s) to the hospital(s) without first obtaining a patient-specific prescription.

TELEHEALTH ENCOUNTERS / PRESCRIPTIONS ISSUED VIA TELEMEDICINE

Question: If an Iowa-located health system engages with prescribers located in another state to provide remote telehealth services to Iowa patients, is the prescriber required to obtain an Iowa CSA registration prior to issuing a controlled substance prescription?

Answer: Yes.