



Idaho State Board of Pharmacy

1199 W Shoreline Lane Ste 303 Boise, Idaho 83702-9103 <http://bop.idaho.gov>
P.O. Box 83720 Boise, Idaho 83720-0067 208.334.2356 208.334.3536 fax

MEMO:

Date: March 13, 2020; revised: 3/16, 3/17, 3/18, 3/19, 3/20, 3/21, 3/23, 3/25, 3/26, 3/27, 3/30, 3/31, 4/2, 4/5, 4/7, 4/8, 4/9, 4/10, 4/15, 4/30, 5/19, 5/22, 6/18/2020, 9/28/2020

To: All Licensees and Registrants

From: Nicki Chopski

Re: FAQ for COVID-19 Declaration of Emergency

NOTE: The newest posts are in green

1. If my staff becomes ill or has to be quarantined, is there a solution in place to get new temporary staff licensed quickly? And, what if it is an outlet that is affected?

For new instate licensure/registration, submission of an application online will be processed as quickly as possible. Licensing staff must be notified (Info@bop.idaho.gov) of the application and the urgency of the need. Licensure/ registration will be immediately granted for 30 days while paperwork is being processed. When the background check, if applicable, clears and other required elements have been verified, licensure will be extended to full length of term. PLEASE NOTE: If the background check does not clear and/or required elements of that application are not submitted, registration will expire after 30 days.

UPDATE: With the implementation of Governor Little's Rebound Idaho plan the state is now in phase four of re-opening. Therefore, new applications must be submitted with fingerprints and other required credentials to be considered complete. The agency is no longer granting immediate license/registration. Applications will be processed as occurred prior to the pandemic. Those who were granted immediate 30-day technician registrations are now expired. Any outstanding elements of the application must be completed immediately for the registration to be extended to the full length of the term. Posted 6/18/2020

UPDATE: For out-of-state pharmacists, technicians, interns and outlets (facilities) who hold other state licenses/registrations, Idaho is participating in the [Covid-19 NABP Passport](#) program. Pharmacists, pharmacy technicians and interns, and outlets (facilities) who want to practice in Idaho are to obtain an NABP Passport. There is no fee. The NABP Passport is a license verification process administered by the National Association of Boards of Pharmacy to assist in the pandemic response. Individuals can obtain an NABP Passport by logging into their NABP e-Profile at <https://dashboard.nabp.pharmacy/Login/Splash>, click 'customer', then 'my e-Profile', and then click on the tile labeled: "NABP Passport/COVID-19 Emergency". Please follow the "add a state" instructions on this page. Once complete, click submit.

Please note, your license information must be up to date including expiration date and license status. This information will be verified through this process.



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Once the NABP Passport for Idaho is approved, the individual is cleared to practice under the state emergency declaration. Licensees will also be notified on their e-Profile and via email.

UPDATE: NABP will no longer be accepting COVID-19 passport applications beginning October 1, 2020. Passports that were issued prior to October 1st will remain valid until December 31, 2020. Note that a few states have determined an earlier expiration date. NABP made this decision based on the feedback from member boards on current utilization of issued passports. If you wish to continue to practice in Idaho beyond 12/31/2020, please submit the appropriate application [online](#) .

Posted 3/13/2020;

Revised 3/25/2020, 3/27/2020, 4/15/2020, 9/28/2020

Please Note: The ISU College of Pharmacy has a number of students in need of both IPPE and APPE hours. Several sites are not precepting students during this time. All of the student pharmacists are already registered with the Board. It is possible that these talented students may be able to fulfill a staffing need at a pharmacy. Please contact Kevin Cleveland, Experiential Coordinator, at clevkevi@isu.edu if you might be able to use the help of a student during this pandemic.

Posted 3/18/2020

2. Can I close my pharmacy or change my hours?

During this emergency submit to Info@bop.idaho.gov with Emergency Pharmacy Operations in subject line.

It is strongly encouraged that pharmacy operations consider drive-through only or delivery only as an alternative to closure as patients need access to their medications. Stores that have multiple locations may have additional flexibility. There is no requirement in Idaho for pharmacies to have a walk-in counter. This decision can be made at the discretion of the supervising pharmacist.

Posted 3/13/2020; Revised 3/24/2020

3. Is there a limit to how much medication I can sell to a patient?

While the concern has been raised about patients requesting a year supply of their medication, we encourage pharmacists to use their professional judgement. Consideration should be given at a minimum to third party coverage, supply replenishment for the pharmacy for other patients, risk of misuse or danger of overuse and controlled substance limitations by both state and federal law.

Posted 3/13/2020

UPDATE: This morning the Board conducted an emergency meeting and promulgated additional language to the existing temporary rule 704. The rule is effective immediately. District Health Departments have verified patients can receive a copy of their test results through their provider.

Rule 704. Medication Limitations.

01. No prescription for chloroquine or hydroxychloroquine may be dispensed unless all of the following apply:



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- a. *The prescription bears a written diagnosis from the prescriber consistent with the evidence for its use;*
- b. *The prescription is limited to no more than a fourteen (14) day supply; and*
- c. *No refills may be permitted unless a new prescription is furnished.*
- d. *The provisions of subsections b and c do not apply if the patient was previously established on the medication prior to the effective date of this rule.*

02. No prescription for oral azithromycin may be dispensed unless all of the following apply:

- a. *The prescription bears a written diagnosis from the prescriber consistent with the evidence for its use;*
- b. *The prescription is limited to no more than a five (5) day supply; and*
- c. *No refills may be permitted*
- d. *The provisions of subsections b and c do not apply if the patient was previously established on the medication prior to the effective date of this rule.*

(3/26/2020)

Originally Posted 3/19/2020; 3/26/2020

Update: At the 6/11/2020 meeting of the Board, Rule 704 was rescinded – effective immediately.

Posted 6/18/2020

4. Will Idaho accept the recommendations to compounders as it relates to PPE supply concerns?

Yes, the recommendations set forth by Critical Point related to limited re-use of PPE in light of the COVID-19 supply concerns have been reviewed and will be accepted. Please be sure to communicate your facility's intentions with all the staff so that protection can be achieved consistently to all staff as well as to the patients that are in your care.

There is a webinar available at no cost and can be accessed via Critical Point's Peer Network portal. Individuals may register for an account by visiting <https://peernetwork.criticalpoint.info/posts/webinars/covid-19-downstream-implications-for-sterile-compounding>.

Correction to Webinar Recommendations

Critical Point recommended that masks for reuse be stored in new plastic "sandwich" bags after use, but were informed by several participants that the CDC recommendations for the use of masks or respirators during a pandemic suggests that masks for reuse should be stored in paper bags that are clean and breathable to reduce the potential for microbial growth.

Visit <https://www.cdc.gov/niosh/topics/hcwcontrols/recommendedguidanceextuse.html> for more information.

It is acceptable to purchase brown paper lunch bags in bulk providing they are new and unused, but these bags may not be reused. Store unused bags in a plastic bag or bin. Subsequently, Critical Point is officially amending its mask and respirator reuse storage instructions as follows:

- Label masks or respirators on the outside
- Doff masks without touching the inside



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- Place the doffed mask for reuse into a new paper bag
- Place the user's initial on the outside of the paper bag so each user can find his or her mask again
- Store all the bags with masks in a bin on the dirty side of the anteroom
- When the respirator is sought for reuse, remove it from the bag and don it without touching the inside of the mask or respirator
- **Discard** the bag that it had been stored in
- A new bag must be used each time it is stored

Posted 3/16/2020

Update: The FDA's Intergovernmental Affairs (IGA) team would like to bring your attention that today the Agency issued a [guidance](#) for immediate implementation for pharmacy compounders that experience shortages of the personal protective equipment (PPE) they typically use to compound human drugs that are intended or expected to be sterile. PPE shortages have the potential to significantly impact the quality, purity and availability of drugs that are compounded for patients, including those in critical need. The guidance discusses how pharmacies may be able to preserve PPE if supplies are limited.

Further, as a temporary measure to address the public health emergency posed by COVID-19, the agency is providing limited regulatory flexibility for compounders that cannot obtain sufficient supplies of PPE for sterile compounding, provided they adopt risk mitigation strategies as described in the guidance. FDA adopted this policy to help assure patient access to needed medicines and to reduce the risks of compounding when standard PPE are not available.

Posted 4/10/2020

Update: The FDA's Intergovernmental Affairs (IGA) team would like to bring your attention that the Agency issued an update to its [guidance](#) for pharmacy compounders that experience shortages, due to the COVID-19 public health emergency, of the personal protective equipment (PPE) they typically use to compound human drugs that are intended or expected to be sterile. In the update, FDA has clarified that drugs can be compounded under the policy in a segregated compounding area that is not in a cleanroom, when the following beyond-use dates are utilized: up to 12-hours for product stored at room temperature, and up to 24 hours for products stored refrigerated. These beyond use dates aim to reduce the risk of contamination.

FDA adopted this policy to help assure patient access to needed medicines and to reduce the risks of compounding when standard PPE are not available. FDA wants to ensure that health care professionals are aware of this guidance and the potential for greater contamination risk when compounded drugs are prepared without standard PPE or within segregated compounding areas. FDA encourages health care professionals who purchase compounded drugs to engage with compounders to balance these risks and the need for compounded products for patient care.

Posted 5/19/2020



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5. Does Idaho permit the temporary compounding of alcohol base hand sanitizer during this emergency?

Yes, please refer to the FDA's Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency Immediately in Effect Guidance for Industry

<https://www.fda.gov/media/136118/download>

Posted 3/16/2020

6. Will the Board of Pharmacy permit remote data entry of prescriptions as a work from home solution?

Yes, so long as the cybersecurity and patient confidentiality is maintained and the essential steps of the dispensing process are also maintained. Current law is these functions can be location agnostic.

Posted 3/17/2020

7. We are registered as a non-resident Central Drug Outlet. If we implement work-from-home operations, is notification to the Board required?

No, it would not be necessary to notify the Idaho Board of Pharmacy if work is transitioned to work-from-home during the state of emergency.

Posted 3/17/2020

8. We have a facility wanting to refill all the controlled substances for their hospice patients early just in case we have a run on medications due to the spread of COVID-19. What is the Board of Pharmacy's stance on this issue?

In general, controlled substances are not primary to the treatment of COVID-19. The board will waive the early refill for controlled substances for the hospice patients of a facility. As a best practice keep the filled medications secured in the pharmacy for future delivery. This allows for the reversal and return to stock of any medication that ends up not being needed. It also keeps the controlled substances secure until they are needed at the facility yet assuring the facility that the supply will be there when it's time for their next fill.

PLEASE CONTACT THE BOARD FOR OTHER SITUATIONS INVOLVING CONTROLLED SUBSTANCES THAT DO NOT FIT WITHIN THIS SCENARIO.

Posted 3/17/2020

9. MEDICAID INFORMATION RELEASE MA20-06

Prescription Drugs

Idaho Medicaid will work with participants and providers to make sure participants have adequate drug supplies. Many maintenance drugs used for common chronic conditions such as



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asthma, diabetes and hypertension are available and payable as a 3-month supply on request at the pharmacy. A list of these drugs is available at [here](#).

Early refills can be requested by calling the Idaho Medicaid call center line at 208-364-1829. In an emergency, a pharmacy may also be able to dispense a 72-hour supply of most medications. Participants are encouraged to also check with their pharmacy as several are currently offering free delivery of medications. Posted 3/17/2020

10. IF manufactured supplies are exhausted locally, can we compound otc products like children's acetaminophen and ibuprofen?

Yes, current rules permit:

Pharmacists to compound commercially available products in times of shortage.

Pharmacists can compound anticipatory quantities.

Pharmacists can write scripts for any otc products for patients.

The Board is waiving the statutory restriction prohibiting pharmacists to prescribe compounded products. This waiver is exclusively related to COVID response-related shortages and is not a general waiver request. Posted 3/18/2020

11. Is there a temporary suspension on requirements like initial (or renewal) gloved fingertip testing and media fill testing in sterile compounding?

The Idaho rules don't speak to initial gloved fingertip testing nor initial media fill testing. To the extent that a person may be due for these annual evaluations this month as part of the annual requirement, Idaho will show enforcement discretion for the duration of the state of emergency. Today the Idaho Board of Pharmacy received this communication from USP:

Dear Valued Stakeholder,

In light of the rapidly evolving COVID-19 pandemic, the demand for garbing and personal protective equipment (PPE) and alcohol-based hand sanitizer is expected to outpace available supply. During this pandemic, USP supports State Boards and other regulators using **risk-based enforcement discretion** related to the implementation of USP compounding standards and the compounding of alcohol-based hand sanitizers for consumer use.

The USP Compounding Expert Committee developed the following informational resources that may be of assistance during this public health emergency:

- [USP Response to Shortages of Garb and Personal Protective Equipment \(PPE\) for Sterile Compounding During COVID-19 Pandemic](#)
- [Compounding Alcohol-Based Hand Sanitizer During COVID-19 Pandemic](#)



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Any additional questions should be directed to the USP Healthcare Quality and Safety staff at CompoundingSL@usp.org.

Sincerely,

Healthcare Quality & Safety Team

While Idaho can't speak for any given accreditation standard or pharmacy policy, perhaps this could be useful in showing those entities ("other regulators") the approach USP has taken today.

Posted 3/19/2020

12. There have been several questions that have been raised such as;

Can we remove/waive proof of delivery requirements for pharmacists (e.g., collect patient signature upon delivery or mailing of a prescription during emergency period)?

Can co-pays be waived for essential, life-sustaining medications (e.g. insulin, among others) are implemented based on specific days supply (i.e. 14-day or 30-day supply).

Given instances of drug shortages/rationing, can formularies be loosened to allow an alternative or can copay waivers be implemented regardless of a specific days supply amount, and pharmacies be reimbursed for the cost of dispensing?

Can PBM restrictions on mail delivery by retail pharmacies be waived?

These topics fall outside of the purview of the Board of Pharmacy. They have been passed on to the state associations and other state agencies for evaluation and possible pursuit through those channels.

Posted 3/19/2020

UPDATE: In response to our request and others to address these issues the Department of Insurance issued [Bulletin No. 20-02](#) to their website. It authorizes health insurance carriers to waive:

- Policy limitations on the number of pharmaceutical refills and early refills;
- Restrictions that would disallow coverage of a 90-day refill at a retail (as opposed to mail-order) setting, unless doing so would be inconsistent with an applicable prescription safety limits of the Social Security Act; and
- Requirements for in-person pharmacy signature logs as well as the associated signature audits by insurers or pharmacy benefit managers.

Health insurance carriers are encouraged to work with their pharmacy benefit managers to implement this guidance.

Posted 4/8/2020

13. Can the BOP make a statement that hydroxychloroquine goes to patients with ongoing therapy first?



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UPDATE: This morning the Board conducted a special meeting and promulgated additional language to the existing temporary rule 704. The rule is effective immediately. District Health Departments have verified patients can receive a copy of their test results through their provider.

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- (3/26/2020)***

Update: At the 6/11/2020 meeting of the Board, Rule 704 was rescinded – effective immediately. **Originally Posted 3/19/2020; 3/26/2020, 6/18/2020**

14. May pharmacies fill if insurance does not approve and ask only for the patient's usual copay as payment? Is insurance or this allowance something Idaho has governance over? Does it have to be decided by the corporations if one is involved or may Idaho overrule?

This topic falls outside of the purview of the Board of Pharmacy. This has been passed on to the state associations and other state agencies for evaluation and possible pursuit through those channels.

Posted 3/19/2020

15. Could you clarify if positive identification for controlled substances and signatures for counsel are needed during crisis.

Counseling signatures are not required. Counseling is required. That said, it can be accomplished via technology.

Update: As gathering identification could be a vector of transmission, the Board is not requiring positive ID. It remains a best practice.

Posted 3/19/2020; 4/6/2020

16. APhA's Pharmacist's Guide to Coronavirus



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<https://www.pharmacist.com/coronavirus>

Posted 3/19/2020

17. DEA's COVID-19 Information Page

This page contains important guidance concerning COVID-19 and the national drug supply, electronic prescribing of controlled substances, telemedicine, medicated assisted treatment, and other important federal and state information. This site will be **updated frequently** as new information and guidance is issued. Please check back frequently for further information.

<https://www.deadiversion.usdoj.gov/coronavirus.html>

Update: Effective March 23, 2020, the DEA Call Center has temporarily suspended phone operations due to COVID-19 health epidemic. Assistance will only be available through DEA.Registration.Help@usdoj.gov. We will respond to your emails as quickly as possible.

Posted 3/20/2020, 3/23/2020; 3/26/2020

18. We are seeking permission for pharmacists who may have their CPR certifications expiring soon to extend current CPR certifications until December 31, 2020 to allow pharmacists to continue providing immunizations.

Idaho rules do not specifically speak to immunizations or CPR certification, but the Board certainly recognizes that it is standard of care to hold a CPR certification if involved with immunization administration. Therefore, yes, we will recognize the extension of CPR certification beyond the expiration date through the end of the year for both pharmacists and technicians involved in immunizing.

Posted 3/20/2020

19. I've heard WA is allowing pharmacies to accept a fax for a CII that has a wet signature. Is Idaho permitting this?

Idaho is not permitting the acceptance of a fax for a CII beyond the language in 21 CFR 1306.11. The link to the DEA COVID-19 information page is found above in #17 and does not reflect this allowance. A review of the Washington Quality Assurance Commission website does not have this allowance in plain view and is also not found in other information available at this time.

We have escalated this as an ask at the federal level and will update if new information becomes available.

Update: DEA Policy: [Exception to Regulations Emergency Oral CII Prescription](#)

The Controlled Substances Act, 21 U.S.C. 801 et seq., provides that a pharmacist may not dispense a schedule II controlled substance without a written prescription with the exception of an oral prescription in emergency situations. According to 21 CFR 1306.11(d), to issue an emergency oral prescription, the quantity prescribed and dispense is to be limited to the amount adequate for treatment of the patient during the emergency period; prescription shall be



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immediately reduced to writing by pharmacist and contain all information required in 1306.05, except for prescribing practitioner's signature; if pharmacist does not know the individual prescribing practitioner, the pharmacist must make a reasonable effort to determine that the oral authorization came from a registered individual practitioner; and within 7 days after authorizing an emergency oral prescription, the individual prescribing practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to the exception stated above, **DEA announces two temporary exceptions: (1) practitioners have 15 days to deliver the follow-up paper prescription to the dispensing pharmacy; and (2) practitioners are allowed to send the follow-up prescription via facsimile, photograph, or scan to the pharmacy in place of the paper prescription.** The practitioner must ensure that for whichever method they use, the prescription contains all required information stated in 1306.05 and 1306.11(d), including a statement that prescription is "Authorized for Emergency Dispensing." Practitioners who choose to send this specific type of prescription to the pharmacy via facsimile, photograph, or scan must maintain the original paper prescription in the patient file. There is no numerical limit to the amount of schedule II controlled substance to be prescribed.

Posted 3/21/2020, 3/30/2020

20. Will the Board authorize pharmacies to temporarily operate in an area not designated by permit?

At this time, we will handle these requests on a case-by-case basis. Currently within the state of Idaho, this level of action is not necessary. Governor Little has directed all essential functions to continue to be open in the State which includes pharmacies. Contact the Board of Pharmacy through info@bop.idaho.gov if you have a specific request for us to address at this time. Include the details of the case and the timeline in which the temporary operational area will open and we'll review quickly.

Posted 3/21/2020

UPDATE: The Idaho Board of Pharmacy will match the guidance that has come out from DEA. By utilizing the same process it should make for an easy copy and paste. Simply send the same information to us that you submit to DEA. The same is holds true for wholesalers.

*If a hospital or community pharmacy needs to set up an alternate site, they should follow these procedures and provide information on the following:

Email: info@bop.idaho.gov with the subject line: TEMPORARY DRUG OUTLET REGISTRATION REQUEST and include the following information

1. Email should include details of the business category, i.e. pharmacy, hospital/clinic and state license information
2. Add address of temporary location
3. Add security details of where CS will be stored
4. Add name/DEA of supplier so that we can contact them in case they need controlled substances ASAP

Update Posted 4/2/2020



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21. Will the Board authorize pharmacists and pharmacy staff to conduct routine pharmacy tasks remotely as necessary (i.e., prescription data entry and script verification), including outside state efforts to ensure business continuity?

This is already permitted under current rules.

Posted 3/21/2020

22. Will the Board waive pharmacy technician ratios?

Idaho has no tech ratio under current rules.

Posted 3/21/2020

23. Will the Board authorize pharmacists to conduct therapeutic interchange and substitution without authorization of a prescriber when and if product shortages arise?

Idaho has therapeutic interchange and substitution language under the current rules in place that addresses this.

Posted 3/21/2020

24. Will the Board authorize additional expanded authority for pharmacy staff, including but not limited to:

- **Allow pharmacy technicians to transfer prescriptions, excluding controlled substances?** Already permitted under current rules as it's not expressly prohibited.
- **Allow pharmacy technicians to accept and document the refusal of patient counseling?** Already permitted under current rules as it's not expressly prohibited.
- **Allow pharmacy technicians to compound?** Already permitted under current rules as it's not expressly prohibited

Posted 3/21/2020

25. Will the Board of Pharmacy allow these specific requests for infusion pharmacies:

- **Extension of clean room certification deadlines?**

Clean room certifications that expire during the state of emergency will be extended for 90 days beyond the end of the declaration.

- **Permission for alternative strategies for compounding (outside of USP 797 guidance) may be required due to efforts to conserve sterile isopropyl alcohol as well as the above-mentioned clean room garb?**



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Idaho has not formally adopted <USP 797> and the Idaho rules do not speak specifically to sterile isopropyl alcohol. Therefore, there is some latitude to alternatives strategies for compounding so long as they are within the standard of care. Posted 3/21/2020

26. We have associates that are not licensed that we would like to assist with running the cash register and assist with delivering prescriptions to curbside for curbside prescription pickup for patients. I did see that there was an expedited process for obtaining licensure, but wondered if it would be required to have a license for those associates to assist with running the cash register and assisting with curbside pickup.

Rule 300.03 already permits for this.

300. DRUG OUTLETS: MINIMUM FACILITY STANDARDS.

A resident drug outlet that dispenses prescription drugs to patients in Idaho must meet the following minimum requirements:

03. Authorized Access to the Restricted Drug Storage Area. Access to the restricted drug storage area must be limited to authorized personnel. (7-1-18)

27. FDA Guidance for hydroxychloroquine- The FDA's Intergovernmental Affairs (IGA) team would like to bring your attention to the following announcement concerning hydroxychloroquine.

The FDA added hydroxychloroquine sulfate to [category 1](#) under the [Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act](#). The FDA does not intend to object to [registered outsourcing facilities](#) using hydroxychloroquine (or chloroquine phosphate, which was already on category 1), to compound human drugs provided the drugs meet other conditions and requirements in the FD&C Act. Compounding is generally a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. The FDA is placing hydroxychloroquine sulfate on category 1 after it reviewed the nomination and determined there was sufficient information for the agency to evaluate the substance for outsourcing facilities to use in compounding. When FDA categorized hydroxychloroquine sulfate it did not change its approach, but we prioritized this substance due to the COVID-19 pandemic. There are currently no FDA approved therapeutics or drugs to treat, cure or prevent COVID-19; however, there are FDA-approved treatments that may help ease the symptoms of COVID-19. Additionally, state-licensed pharmacies and federal facilities that compound drugs under section 503A of the FD&C Act may compound drugs using hydroxychloroquine sulfate or chloroquine phosphate bulk drug substances because they are components of an FDA-approved drug, provide other requirements in the Act are met.

In addition, there is a significant surge in demand of chloroquine/hydroxychloroquine and FDA is doing everything possible to work with manufacturers to increase production. We are working with manufacturers to assess their supplies and are actively evaluating market demand for patients dependent on it for treatment of malaria, lupus and rheumatoid arthritis. But please know this is a fluctuating and dynamic situation we are actively engaged on.



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Currently the manufacturers still have supply and are increasing production and we are working on that with them -now it's a matter of continuing to meet demand and also making sure there is not a shortage for rheumatologic patients.

Please know that FDA will continue to do all we can to work with the firms to increase supplies to meet the ongoing demand and prevent shortages.

FDA encourages State Pharmacy Boards to consider policies to protect supply for patients who have existing prescriptions for these drugs that are non-COVID-19 related for conditions such as Lupus, Arthritis, Sjogren's Syndrome, and other autoimmune disorders.

For general FDA-related inquiries, please feel free to contact FDA's IGA staff at IGA@fda.hhs.gov.

Posted 3/26/2020

28. Can we request a delay in the 2020 annual controlled substance inventory if the date of inventory falls within the timeframe of the state declaration of emergency?

The due date of the inventory will be extended to within 120 days from the end of the IDAHO COVID -19 Emergency Declaration. This waiver is for the state of Idaho only as it is outside the agency's jurisdiction to waive the federal requirement for inventory.

Posted 3/27/2020

29. Does the rule regarding azithromycin also apply to veterinary prescriptions?

The rule is applicable to all prescriptions regardless of the prescriber's practice. Veterinary prescriptions should be for animal use only. There have been reports of veterinarians attempting to obtain these medications for themselves which would not be in accordance with Idaho law.

Posted 3/31/2020

30. What guidance is available for disinfecting procedures for a pharmacy with suspected/confirmed COVID-19?

Today we posted on the website under Hot Topics the CDC's [Environmental Cleaning and Disinfection Recommendations](#) - Interim Recommendations for US Community Facilities with Suspected/Confirmed Coronavirus Disease 2019.

Posted 3/31/2020

31. Is there any guidance pharmacy employers/employees can use to make decisions about working/quarantine?

Today we posted a [COVID-19 Decision Tree](#) that may be useful in decision making. This is a general guideline from Eastern Idaho Public Health and has no way to contemplate the specific circumstances of individual pharmacy scenarios.

Posted 3/31/2020



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32. We received communication from the Idaho Board of Medicine yesterday about waiving renewals. Will you all be doing anything similar?

Since renewal for individuals are by their birth month, we have not suspended renewals. Renewals will be open during this emergency to allow those that can renew the option to do so. However, we have suspended the expiration of those with currently active registrations until resolution of the Idaho State of Emergency. Posted 4/2/2020

UPDATE: With the implementation of Governor Little's Rebound Idaho plan the state is carefully re-opening in phases. Therefore, those with licenses or registrations that expired in March and April are expected to renew as are all others with expirations in subsequent months. Starting today courtesy reminder notices are being emailed. Extension of enforcement discretion will end in 60 days. Posted 5/22/2020, 6/18/2020

33. Governor Brad Little announced the suspension of an additional 18 regulations today. Were any pharmacy regulations?

Yes, a portion of 54-1704(5) was included. See changes below.

The prescribing of:

(b) Agents for active immunization when prescribed for susceptible persons ~~six (6) years of age or older~~ for the protection from communicable disease;

(g) Drugs, drug categories, or devices that are prescribed in accordance with the product's federal food and drug administration-approved labeling and that are limited to conditions that:

(i) Do not require a new diagnosis;

(ii) Are minor and generally self-limiting;

(iii) Have a test that is used to guide diagnosis or clinical decision-making and are waived under the federal clinical laboratory improvement amendments of 1988; or

(iv) In the professional judgment of the pharmacist, threaten the health or safety of the patient should the prescription not be immediately dispensed. In such cases, only sufficient quantity may be provided until the patient is able to be seen by another provider.

The board shall not adopt any rules authorizing a pharmacist to prescribe a controlled drug; ~~compounded drug or biological product~~ Posted 4/2/2020

34. Is there any CDC Guidance specifically for pharmacies and staff yet?

UPDATE: Summary of Recent Changes - Below are changes to the guidance as of April 14, 2020:



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Everyone entering the pharmacy should wear a face covering, regardless of symptoms. Cloth face coverings should not be placed on young children under age 2, anyone who has trouble breathing, or is unconscious, incapacitated or otherwise unable to remove the mask without assistance.

Pharmacists and pharmacy technicians should always wear a facemask while they are in the pharmacy for source control.

Postpone and reschedule delivery of some routine clinical preventive services, such as adult immunizations, which require face to face encounters.

Special considerations for clinics that are co-located in pharmacies.

Click [here](#) for the full updated guidance for pharmacies from CDC

Posted 4/5/2020, 4/15/2020

35. Has FDA provided any guidance on other compounding topics not already covered in this FAQ?

FDA's Intergovernmental Affairs (IGA) team wanted to share with you the following from the Center for Drug Evaluation's Compounding Team.

We have received many emails from stakeholders about a few of our policies and we wanted to provide clarification:

- Our guidance for [hospital and health systems](#), which includes the "one mile radius" provision, is still in draft and we are planning to issue a revision. This draft guidance document was issued for public comment and has not been implemented.
- Although federal law specifies a 5 percent limit on interstate distribution of compounded drug products for pharmacy compounders, we do not intend to enforce the 5 percent limit until after we have finalized a [Memorandum of Understanding](#) (MOU) and given states an opportunity to sign it. The MOU is currently in draft form.
- We do not consider drugs that are on FDA's [shortage list](#) or that have been discontinued and are no longer marketed as "commercially available" under the ["essentially a copy" provision](#) for pharmacy compounders.
- We also do not consider a compounded drug produced by an outsourcing facility as ["essentially a copy"](#) if it is identical or nearly identical to an FDA-approved drug that is on FDA's [drug shortage list](#). The agency also does not intend to take action under this provision if the facility fills orders for a compounded drug that is essentially a copy of an approved drug that has been discontinued and is no longer marketed.

Additionally, hospital pharmacies operating under section 503A of the Federal Food, Drug, and Cosmetic Act have asked whether they may have flexibility with beyond use dates when they compound drug



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products using FDA-approved drug products as a starting material to treat patients in critical need during the COVID-19 pandemic.

Use of FDA-approved drugs that include instructions for “in-use” time:

For a single intravenous drug that is labeled with a limited “in-use” date, the agency cannot provide information on extending the in-use time unless the hospital pharmacy provides the following information:

1. the name of the FDA-approved drug
2. the labeled length of time the drug can be used once the container is breached
3. the labeled name of the distributor or manufacturer, or both if provided
4. the NDC number

A clear and legible photograph of the container label would be helpful but is not necessary.

The agency will evaluate submissions as quickly as possible and provide available information to the hospital pharmacy, as appropriate.

Use of FDA-approved drugs that do **not** include instructions for “in-use” time:

If the FDA-approved drug label for an intravenous drug does not have a limitation on the “in-use time,” state law generally includes standards for beyond use dating for hospital pharmacies that compound drugs using an FDA-approved drug that has no in-use statement on the drug label. State regulatory authorities may have the discretion to adjust the beyond use dates based upon patients’ needs during this public health crisis, which is informed by the currently available scientific information.

Many states recognize USP Chapter <797>, which provides default beyond use dates that are based on the level of risk when compounding the drug:

- Low risk: 48 hours Room temp/14 days refrigerated/45 days frozen
- Medium risk: 30 hours room temp/9 days refrigerated/45 days frozen
- High risk: 24 hours room temp/3 days refrigerated/45 days frozen

FDA generally has not taken regulatory action with respect to beyond-use dating when drug products are not made under insanitary conditions and are labeled consistent with the standards for beyond-use dating provided by states.

See [human drug compounding](#) and [drug shortages](#) for more information. Please email compounding@fda.hhs.gov with questions.

Posted 4/8/2020

36. Yesterday HHS released a [statement](#) authorizing pharmacists to order and administer COVID-19 Tests. Does the Board still have information on obtaining a CLIA waiver for a pharmacy?

Yes, the [How-To for Idaho pharmacies](#) to get a CLIA waiver has been re-posted to the board’s website.



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Here is an update from [CMS](#) that might be useful if you haven't already obtained a CLIA waiver.

This is an additional document from CMS on [How to Obtain a Certificate of Waiver](#).

Posted 4/9/2020

37. Our pharmacy has not traditionally mailed a large number of prescriptions to patients; however, we are now offering to mail prescriptions to patients in an effort to minimize risk of COVID-19 exposure. Many patients are requesting that their prescriptions be mailed across state lines. Our pharmacists have been advised not to mail prescriptions across state lines. Some pharmacists question this guidance and have begun reaching out to the Board. In an effort to prevent multiple pharmacists calling to ask the same question, we would like to ask the following questions:

1. Can a retail pharmacy in another state mail prescriptions into Idaho without holding an out-of-state permit during the COVID pandemic? An out of state pharmacy would need to be registered with Idaho as a mail service drug outlet to ship into Idaho. However, during the Idaho State Declared COVID emergency, if the facility follows the direction in FAQ #1 above then they would be able to ship into Idaho without an Idaho registration. An out of state pharmacy acting as a central fill pharmacy for in state pharmacies would also have to be registered with Idaho as a mail service drug outlet and would follow FAQ #1.

2. Can a retail pharmacy in another state mail prescriptions into Idaho without holding an out-of-state permit as a general practice under normal circumstances, after the COVID pandemic? A pharmacy from another state would need to be registered with Idaho as a mail service drug outlet to ship into Idaho. An out of state pharmacy acting as a central fill pharmacy for Idaho pharmacies would also have to be registered as a mail service drug outlet.

3. Does the Board have a position on whether a pharmacy should mail out of the state if the receiving state does not require an out-of-state permit? If an Idaho pharmacy is mailing out, this board would not have a position on that practice. It would be up to the receiving state.

38. Has FDA provided any flexibility relating to the Drug Supply Chain Security Act?

Yes, the FDA issued [guidance](#) today. "The statutory provisions described in the guidance facilitate the distribution of prescription drug products needed to respond to COVID-19, such as drugs to treat symptoms of COVID-19. Under these statutory provisions, DSCSA requirements related to certain product tracing and product identification activities, and wholesale distribution, do not apply during the COVID-19 public health emergency in the circumstances described. The flexibility described aims to balance the need for effective distribution of products under emergency conditions and the need to protect consumers from exposure to products that may be counterfeit, stolen or otherwise harmful."

Updated 4/30/2020



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39. Has the federal government published any information on potential reimbursement for COVID-19 testing?

While reimbursement does not fall within the Board's purview, this information was recently posted and may be helpful to pharmacies contemplating COVID-19 testing.

CMS Allows Pharmacies to Temporarily Enroll as Clinical Diagnostic Laboratories to Provide COVID-19 Testing

Centers for Medicare & Medicaid Services (CMS) has released a [document](#) detailing a process that allows pharmacies to temporarily enroll as independent clinical diagnostic laboratories. This process will allow those facilities to seek Medicare reimbursement for coronavirus disease 2019 (COVID-19) tests, making it easier for them to provide that service during the pandemic.

Posted 5/19/2020

40. If not covered above a waiver may be needed.

a.) How do I submit a waiver?

During this emergency submit to Info@bop.idaho.gov with **WAIVER** in subject line.

b.) What other information should I submit with my waiver request?

Please submit additional information that explains how you will alternatively protect the safety, health and welfare of the public during the waiver period.

c.) When can I expect a response?

The Declaration of Emergency has granted board staff with delegated authority to review waiver requests and make determinations. A written response will be returned within 24 hours of receipt of the request.

All allowances and waivers will be in effect for the period of the declaration of emergency only

Posted 3/13/2020

Appendix: Relevant Rules

IDAPA 27.01.01.102. WAIVERS OR VARIANCES.

01. Criteria. The board may grant or deny, in whole or in part, a waiver of, or variance from, specified

rules if the granting of the waiver or variance is consistent with the Board's mandate to promote, preserve and protect public health, safety and welfare. (7-1-18)

02. Emergency Waiver. In the event of an emergency declared by the President of the United States,



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the Governor of the State of Idaho, or by any other person with legal authority to declare an emergency, the Board

may waive any requirement of these rules for the duration of the emergency. (7-1-18)

IDAPA 27.01.01.402. FILLING PRESCRIPTION DRUG ORDERS: PRACTICE LIMITATIONS.

03. Refill Authorization. A prescription drug order may be refilled when permitted by state and federal law and **only** as specifically authorized by the prescriber. **except that a A** pharmacist may **also** refill a prescription for a non-controlled drug when the prescriber is not available for authorization. **In such cases, a pharmacist may dispense a refill up to the quantity on the most recent fill or a thirty (30) day supply, whichever is less.** (4-11-19)

As part of the *Temporary Suspension of Rules for Duration of the Emergency* Rule 402 now reads:

402. Filling Prescription Drug Orders: Practice Limitations

03. Refill Authorization. A prescription drug order may be refilled when permitted by state and federal law and as specifically authorized by the prescriber. A pharmacist may also refill a prescription for a non-controlled drug when the prescriber is not available for authorization. (3/19/2020)

Please note the thirty day supply limitation has been removed.

Posted 3/23/2020