MEMO:


To: All Licensees and Registrants

From: Nicki Chopski

Re: FAQ for COVID-19 Declaration of Emergency

NOTE: The newest posts are added to the bottom of the list

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: For pharmacists and technicians who hold other state licenses/registrations, Idaho is participating in the Covid-19 NABP Passport program. Pharmacists and pharmacy technicians 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.

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

For interns, and those who hold other state licenses/registrations, and are currently licensed/registered and in good standing with the home state, the facility can send outlet information, name of licensee/registrant with a copy of the home state license/registration to info@bop.idaho.gov. This permits work/operations without ID licensure for the period of the declared emergency.

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:
   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)
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 CriticalPoint’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

CriticalPoint 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.


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, CriticalPoint 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
• 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
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 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 https://healthandwelfare.idaho.gov/LinkClick.aspx?fileticket=GHGhmE6Ry_Q%3d&tabid=119 &portalid=0&mid=1111.

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

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.

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.

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

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.
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   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

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 fall 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. 
Controlled substances - Rule 409 applies only to prescriptions that are picked up. As written, 
many patients are already excluded. The rule is focused on those prescriptions that raise 
concerns. Posted 3/19/2020

16. APhA’s Pharmacist’s Guide to Coronavirus 
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.


**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.


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.

Posted 3/21/2020

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
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.  
Post 3/21/2020

22. Will the Board waive pharmacy technician ratios?

Idaho has no tech ratio under current rules.  
Post 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.  
Post 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  
Post 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?**
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.
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.

28. Idaho Personal Protective Equipment (PPE) Drive on Saturday, March 28th from noon to 4 p.m. at Albertson’s Stadium on BSU’s campus (east lot).

29. 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.

30. 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

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, 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. 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