COVID-19 UPDATE- Oregon Board of Pharmacy (OBOP) Information April 8, 2020

As circumstances and conditions continue to evolve, this document serves to compile information into a single source. The list of COVID-19 RESOURCES is available on last page of this document.

Safe Work Environment and Routine Pharmacy Services

Oregon Administrative Rule 855-041-1015 states that “Persons working in a pharmacy shall practice appropriate infection control.” It is the expectation of the Board of Pharmacy that pharmacy employers implement infection control practices in their pharmacies to protect workers and patients. During the declared Public Health Emergency (PHE) due to the Corona Virus (COVID-19) outbreak and per Executive Orders 20-10 and 20-12, pharmacists shall use professional judgment per individual circumstances and pharmacies should avoid offering routine services, such as vaccinations and blood pressure monitoring, that require person-to-person contact and are not required for the immediate health and safety of the individual.

- CDC’s Considerations for Pharmacies During COVID-19 Pandemic (4/3/2020)

Chloroquine/Hydroxychloroquine (CQ/HCQ) Emergency Temporary Rule UPDATED

On 4/2/2020, the Oregon Board of Pharmacy revised the adopted an emergency temporary rule (OAR 855-007-0085) which limits the dispensing of chloroquine and hydroxychloroquine (CQ/HCQ) as a measure to preserve supplies for treatment of malaria, inflammatory conditions, and patients with COVID-19 infection.

In response to the challenges related to testing availability and delayed resulting times faced by Oregon care providers, the revised language permits dispensing of CQ/HCQ to hospitalized/institutionalized individuals with either a positive test result for COVID-19 or pursuant to a clinical diagnosis of COVID-19 infection.

- Prescription Therapy for COVID-19 Patients Informational/FAQs – updated 4/2/2020

As this situation evolves, the Board continues to reassess temporary rule OAR 855-007-0085, to continue monitoring emerging evidence, availability of testing, and by working with state leadership, the Oregon Health Authority and the Oregon Medical Board to modify or rescind the rule as appropriate.

The Oregon Board of Pharmacy serves to promote and protect public health, safety and welfare by ensuring high standards in the practice of pharmacy and through effective regulation of the manufacture and distribution of drugs. 4/8/2020
Oregon Pharmacy Intern - School-Based Internship Ratio

During the PHE, an Oregon preceptor may monitor more than two interns completing non-direct patient care learning in school-based internships (SRIs). It is the responsibility of the preceptor to monitor only as many SRI interns they believe in their professional judgment is appropriate, and shall retain documentation of all interns monitored during this timeframe.

Oregon Pharmacy Drug Outlet – Annual Controlled Substance Inventory

Due to the potential of staff shortages during this PHE, the Board has received a number of inquiries related to the Annual Controlled Substance Inventory requirement [OARs 855-080-0070 & 855-019-0300(5)(d)].

If your pharmacy’s annual CS inventory comes due during the COVID-19 PHE and you are unable to complete the written inventory of all controlled substances annually within 365 days of the last written inventory, you must complete the inventory within 15 days of the end of the declared PHE. Retain documentation on site, for inspector review.

COVID-19 UPDATE- Oregon Board of Pharmacy (OBOP) Information, March 31, 2020

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Chloroquine/Hydroxychloroquine (CQ/HCQ) Dispensing Limitations

On 3/23/2020, the Oregon Medical Board and The Oregon Board of Pharmacy issued statements to licensees related to the inappropriate prescribing of chloroquine/hydroxychloroquine.

On 3/25/2020, the Oregon Board of Pharmacy adopted an emergency temporary rule (OAR 855-007-0085) prohibiting the dispensing of chloroquine and hydroxychloroquine for presumptive treatment or prevention of COVID-19 infection as a measure to preserve supplies for treatment of malaria, inflammatory conditions, and documented COVID-19 infection in hospitalized patients.

• Prescription Therapy for COVID-19 Patients Informational/FAQs – 3/27/2020

On 3/29/2020, the FDA issued an Emergency Use Authorization (EUA) to allow HCQ/CQ products donated to the Strategic National Stockpile (SNS) to be distributed and used for certain hospitalized patients with COVID-19. These drugs will be distributed from the SNS to states for doctors to prescribe to adolescent and adult patients hospitalized with COVID-19, as appropriate, when a clinical trial is not available or feasible.

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The EUA requires that fact sheets that provide important information about using chloroquine phosphate and hydroxychloroquine sulfate in treating COVID-19 be made available to health care providers and patients, including the known risks and drug interactions. The SNS will work with the Federal Emergency Management Agency (FEMA) to ship donated doses to states.

As this situation evolves, the Board continues to reassess temporary rule OAR 855-007-0085.

Related note: The FDA issued a letter to stakeholders, warning people to not use chloroquine phosphate intended for fish as treatment for COVID-19 in humans. Products marketed for veterinary use, “for research only,” or otherwise not for human consumption have not been evaluated for safety in humans. People should not take any form of chloroquine unless it has been prescribed by a licensed healthcare provider and is obtained through a legitimate source.

DEA Policies Updated

On 3/27/2020, the Drug Enforcement Agency (DEA) issued a policy entitled Exception to Regulations Emergency Oral CII Prescription in light of the current Coronavirus public health emergency (PHE).

This temporary policy impacts 21 CFR 1306.11(d), related to emergency schedule II prescribing, that states a pharmacist may dispense a schedule II controlled substance (CII, CS) upon receiving oral authorization of a prescribing individual practitioner, provided that certain requirements are fulfilled.

The DEA announced two temporary exemptions to the criteria of 1306.11(d) in order to enable greater flexibility on oral prescribing, during the PHE:

1. DEA grants practitioners 15 days within which to provide the follow-up paper prescription to the pharmacy (extending from 7 → 15 days)

2. DEA recognizes that during the PHE there may be times when providing the follow-up paper prescription to the pharmacy may prove very challenging or impossible. Therefore, in these instances, DEA permits the practitioner to send the follow-up prescription to the pharmacy via fax, or to take a photograph or scan of this follow-up prescription and send to the pharmacy in place of the paper prescription (Note: practitioner shall maintain the original paper rx in the patient file).

   a. It is the responsibility of the practitioner to ensure that the rx contains all requirements of 21 CFR 1306.05 and 1306.11(d), including the statement “Authorization for Emergency Dispensing”.

   b. Pharmacists continue to have a corresponding responsibility to ensure that any CS rx filled/dispensed was issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice, per 21 CFR 1306.04(a).

Note: DEA does not assign a numerical limit to the amount of CII CS to be prescribed. Rather, the quantity prescribed and duration of the emergency oral CII rx is to be determined by the practitioner’s “sound medical discretion”, and shall be limited to “the amount adequate to treat the patient during the emergency period.”

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4/8/2020
Prescription Refills – Options for Oregon Pharmacists to Issue Emergency Fills or Continuation of Therapy

As previously stated, the Division 007 rules are “in effect”, allowing pharmacists the ability to address individual patient needs to provide timely access to safe care, while actively working to minimize the burden on clinics for the routine refills needed. The OBOP appreciates every single effort made by each pharmacist, intern, and technician working steadfastly on the “frontlines” of this global coronavirus crisis.

The state of Oregon’s emergency situation is or will soon be entering the next wave of this pandemic – it is anticipated that our hospitals will potentially begin admitting a surge of patients, struggling with advanced stages of the COVID-19 infection. The following options are provided for Oregon pharmacists to issue emergency refills, continuation of therapy of patient’s maintenance medications, and respond to other patient needs.

As a reminder, Division 007 ([OAR 855-007-0090](https://www.oregon.gov/obop/index.cfm)) refill rules permit a pharmacist to dispense a refill of a prescription drug without a valid prescription provided that:

- In the pharmacist’s professional judgment, the drug is essential to the maintenance of the patient’s health or the continuation of therapy; and
- The pharmacist provides no more than a 30-day supply; and
- The pharmacist records all relevant information and indicates that it is an Emergency Prescription; and
- The pharmacist informs the patient or the patient’s agent that the drug is being provided without a prescriber’s authorization and that a prescriber authorization is required for any additional refill.

Note: The DEA has not suspended any regulations related to the scheduling of CS drugs, therefore a pharmacist may not dispense a refill of any CS medication without prescriber authorization.

Oregon licensed pharmacists and pharmacies should consider creating P&Ps and training staff to provide the pharmacy services and medication access permitted by [Division 020 – Pharmacist Prescriptive Authority](https://www.oregon.gov/obop/index.cfm), such as prescribing of:

- Any post-diagnostic drugs and devices listed in the [Formulary Compendium](https://www.oregon.gov/obop/index.cfm)
- Medications/patient care services listed in the [Protocol Compendium](https://www.oregon.gov/obop/index.cfm)
  - Continuation of Therapy
    - A pharmacist may prescribe any non-controlled medication to extend a patient’s prescription therapy to avoid interruption of treatment; and in such cases, a pharmacist shall only prescribe a drug quantity sufficient for the circumstances, not to exceed a 60 day supply, and no more than two extensions in a 12 month period per medication.
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Note: For patients seeking > 30 day supply of certain psychotherapeutic drugs, seek prescriber authorization, particularly in consideration of the potential risk for suicide (See American Psychiatric Association position statement)

- Suicide Prevention Lifeline call 1-800-273-8255 or chat online at www.suicidepreventionlifeline.org
- Oregon Health Authority – Crisis Lines

- Cough and cold symptom management
  - Pseudoephedrine products for patients 18 years of age and older, verified by positive identification, not to exceed 3.6 grams or a 60 count quantity per prescription, whichever is less, or a total of three prescriptions in a 12 month period. Pharmacist must review PDMP prior to issuing prescription and retain documentation of PDMP review
  - Benzonatate, for the treatment of cough, not to exceed a 7 day supply
  - Short-acting beta agonists, not to exceed 1 inhaler with or without a spacer, or 1 box of nebulizer ampules, per year
  - Intranasal corticosteroids
- Preventative care
  - Emergency Contraception, not including abortifacients
  - Male and female condoms

All prescribing pursuant to the Formulary and Protocol Compendia must adhere to regulations outlined in OAR 855-020-0110. Links to the Oregon Statewide Drug Therapy Management Protocols and additional information are provided on the Board’s webpage.

All pharmacists may additionally consider the use of Collaborative Drug Therapy Management practice agreements with available clinicians and Local Public Health Authorities, identifying a variety of ways that pharmacists can address local needs (of patients, health systems and various care facilities in communities throughout the state). Having proactive strategies in place, having anticipated unique needs is a critical element of preparedness.

Professional Volunteer Opportunities – SERV-OR

Health care workers in Oregon can support their community’s response to COVID-19 by registering with SERV-OR and their local Medical Reserve Corps. Visit https://serv-or.org/ to learn more and register.
COVID-19 UPDATE- Oregon Board of Pharmacy (OBOP) Information, March 23, 2020

On 3/23/2020, Governor Brown issued an Executive Order describing updated social distancing requirements – “Stay Home, Save Lives”. Based on this and ongoing reports in Oregon and via the media throughout this country this past weekend, the Oregon Board of Pharmacy strongly urges pharmacy drug outlets to deploy employee protection measures. Further, pharmacies shall provide appropriate guidance and ongoing direction to staff so they may continue to offer critical pharmacy services and access to patients.

New - Technician Supervision Regulations to be Amended

For the declared emergency timeframe only, on or after March 23, 2020 a pharmacy may consider remote processing functions, to include the option of pharmacy interns and pharmacy technicians to perform limited functions from a secure off-site, non-pharmacy location. A pharmacist may provide “remote monitoring” of a pharmacy intern or technician for the following remote processing functions only:

- Prescription order entry;
- Other data entry; and
- Insurance processing of prescriptions and medication orders

Pharmacy drug outlet shall download and complete the Board’s updated Remote Processing Checklist for use during COVID-19 Public Health Emergency. Checklist Policies & Procedures must be created, enforced and maintained on-site at the pharmacy drug outlet. As of 3/23/2020 and until further notice, any Oregon registered pharmacy participating in remote processing functions by ANY licensee must notify the Board. Send notification to pharmacy.board@oregon.gov (subject line: “Remote Processing Notification”). You are required to notify the Board, however do not submit checklist P&Ps.

Prescriptions for Chloroquine/Hydroxychloroquine to treat COVID-19

Across the nation, and in Oregon pharmacies are reporting an increase in the number of prescriptions being issued for this non-FDA approved purpose.

On 3/23/2020 the Oregon Medical Board (OMB) shared the following related statement about Inappropriate Hydroxychloroquine Prescribing:

The Board has received reports from pharmacies regarding physicians inappropriately prescribing hydroxychloroquine (Plaquenil). The Board does not approve of inappropriate or false prescribing, especially in times of crisis. Further, the Medical Board and the Board of Pharmacy provide the following reminders of some of the risks related to administering unproven therapies:

- Creating the risk of adverse effects and additional harm.
- Creating shortages of therapies for patients who have legitimate medical need for the drug’s intended purpose and use.

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4/8/2020
• Confounding the interpretation of efficacy (particularly when randomized controlled studies are necessary and are currently underway).
• Providing false hope to patients or a false sense of security.

Other Pharmacy Practice Considerations

• There are no Board of Pharmacy regulations that require a patient to sign for a medication upon pick-up. Please review and adjust pharmacy policy to comply with Governor’s latest executive order.
• To reiterate: Consider alternative methods to get prescriptions to patients – drive-thru, curbside delivery, home delivery, mailing
  o For patient counseling, a verbal offer or providing an offer to counsel in writing (i.e. a telephone number where a pharmacist may be reached) is required in accordance with OAR 855-019-0230.
• There are no pharmacy board regulations to prohibit e-prescribing of a Death with Dignity Act (DWDA) prescription. It is recommended that a DWDA e-prescription be transmitted to a pharmacy with a pharmacist who is aware of and has agreed to fill the DWDA prescription. For additional information, contact the Oregon Health Authority DWDA Program.

Licensing Clarification

Attention CPTs – Now is the time to renew your license! Certified Pharmacy Technician license renewal is active and available online. CPT licenses must be renewed by 6/30/2020. The process is an online process and our state’s current declared emergency does NOT present any barriers to renewal. (Recall that “Live CE” is not an Oregon Board of Pharmacy requirement.)

COVID-19 UPDATE- Oregon Board of Pharmacy (OBOP) Information, March 19, 2020

All items from OBOP’s prior notices remain current. As circumstances and conditions continue to evolve, this document serves to compile information into a single source. The list of COVID-19 RESOURCES is growing – available on last page of this document

Oregon Administrative Rule (OAR) Division 007 – Public Health Emergency is in effect for all Oregon pharmacies, as of 3/8/2020. In accordance with the nature of this COVID-19 pandemic, the focus remains on minimization of individuals in close contact with one another (“social distancing”). As this is a rapidly evolving situation, pharmacists and pharmacies should continue to care for their patients in a manner that assures access and safety. All state and federal pharmacy regulations remain in effect and Division 007 – Public Health Emergency rules apply only for the duration and scope of the declared public health emergency (PHE).

Pharmacist, Technician, Intern Licensing:

The Oregon Board of Pharmacy serves to promote and protect public health, safety and welfare by ensuring high standards in the practice of pharmacy and through effective regulation of the manufacture and distribution of drugs.
• **Inactive Pharmacist License Reactivation:** Per OAR 855-007-0050(4), the [Pharmacist License Reactivation Application](#) is available.
  
o Any pharmacist whose license has been inactive for **no more than two years** may reactivate their license **without** having to complete continuing education or MPJE. There is **no fee** and the license will revert back to lapsed status at the end of six months.

• **Due to test site closure:**
  
o NAPLEX or MPJE exam score expirations, pharmacist licensure transfer application dates and the internship requirements within the one-year period for reciprocity will be extended for 90 days after the ending date of the PHE issued on 3/8/2020. Extensions will be considered on a case by case basis, as requested. Please email pharmacy.licensing@oregon.gov, subject line “Extension Request”.

  o All Pharmacy Technician (PT) licenses with an expiration date of 6/30/2020: plan to extend to 12/31/2020. New licenses will be printed and mailed out to all PTs, prior to 6/30/2020. No action is required for this extension.

**Conservation of Personal Protective Equipment (PPE)/USP 797:**

Pharmacies and pharmacy personnel are expected to utilize and triage existing supplies in the most appropriate ways based on the needs of your specific location and circumstances, and in accordance with national recommendations. A pharmacy’s documented PPE Conservation Plan does **not** need to be approved by the OBOP.

If certification for PECs and SECs lapse due to vendor unavailability, the PIC should evaluate their setting, consider actions such as shortening BUDs, increased surface sampling and gloved fingertip sampling and take appropriate action. Consult national recommendations. Certification should be completed as soon as practical after end of the PHE.

**Controlled Substance Refills**

As of 3/19/2020, the DEA has not suspended any regulations. All controlled substance regulations remain in effect. Prescriber authorization is required for all controlled substance refills.

**Miscellaneous Pharmacy Practice Considerations**

- We appreciate but do not require notification of pharmacy policy changes, such as plans related to CPR expiration, certification lapses, hours of operation changes, resource allocation
- **Notification to OBOP** is required for:
  o Pharmacy closure
  o Request for extension of NABP, MPJE, reciprocity deadlines
- **Other issues and considerations:**
  o Implement and train staff on infection prevention practices in all pharmacy sites to maintain social distancing and disinfection routines to keep patients and staff safe
  o CPR certification for vaccine-certified pharmacists that lapse during the PHE should be completed as soon as practical after end of the PHE.

*The Oregon Board of Pharmacy serves to promote and protect public health, safety and welfare by ensuring high standards in the practice of pharmacy and through effective regulation of the manufacture and distribution of drugs.*
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COVID-19 UPDATE - Oregon Board of Pharmacy Information, March 16, 2020

- **Temporary Pharmacies** (OAR 855-007-0100): For the purpose of creating an alternative medication pick-up or dispensing location, the Oregon Board of Pharmacy has created an application for Temporary Pharmacy registration, for in-state pharmacy locations only. If applicable, pharmacies should download, complete and submit the completed application to pharmacy.board@oregon.gov
  - There is no fee for this application
  - Temporary Pharmacy must comply with all State and Federal pharmacy regulations, including those related to security, counseling, personnel (including requirement for pharmacist on site), recordkeeping, etc.

- **Emergency Licensure** (OAR 855-007-0050): An Oregon registered drug outlet may employ a pharmacist, intern or pharmacy technician who does not hold a license issued by the Board, provided that the individual provides evidence that they hold a comparable license issued by any other state or signatory to the Pacific Northwest Emergency Management Arrangement (PNEMA) or Emergency Management Assistance Compact (EMAC). The pharmacy shall retain on-site documentation of each such employee during the declared emergency and for 3 years.
  - Pacific Northwest Emergency Management Arrangement (PNEMA) means the compact between the states of Alaska, Idaho, Oregon and Washington, and the Province of British Columbia, and Yukon, to provide mutual assistance in an emergency or public health emergency.
  - Emergency Management Assistance Compact (EMAC) means the compact for mutual assistance that was ratified by Congress and signed by all states, and is codified in ORS 401.043.

- **Emergency Pharmacy Rules** (OAR 855-007-0090):
  - Does not apply to controlled substance medications
  - Pharmacist must retain all documentation on-site for each medication dispensed when pursuant to these emergency prescription rules

- **Temporary Compounding of Certain Alcohol-Based Hand Sanitizer**: The Oregon Board of Pharmacy permits this practice – guidance document from the FDA. 
  *Note: Permitted for OTC-sales and for patient-specific prescriptions*

All items from OBOP’s 3/13/2020 notice remain current, including:

- A pharmacy may deliver or mail medications to patients (permitted any time)
• Pharmacies and health-systems need to do what is necessary to treat patients and manage employee health. For the declared emergency timeframe only, if minimization of on-site personnel is needed, any Oregon licensed pharmacy may consider remote processing functions. If applicable, pharmacy shall download and complete Remote Processing Checklist
  o Checklist P&Ps must be created and followed, but DO NOT NEED TO BE APPROVED BY OBOP prior to use; maintain on-site at the pharmacy
  o This means formal waivers are NOT necessary for these functions during the declared emergency timeframe

• Technicians must be working in a pharmacy at the direction and control and under the supervision of a pharmacist – if staff minimization/reduction becomes critical, then it must be a pharmacist that physically functions at a pharmacy (not a technician working unsupervised)
  o This means that “remote supervision” of a pharmacy technician is not permitted by regulations.

Conditions and guidance are changing rapidly. Pharmacists should maintain up-to-date information on this evolving public health emergency to provide the public with factual and detailed information to help reduce the spread of this virus, particularly to vulnerable persons. The board will continue to provide updates as conditions evolve and trusts that you will take care of yourselves, your families, your patients, and your communities. We will get through this unprecedented situation together!

COVID-19 - Oregon Board of Pharmacy Information, March 13, 2020

Governor Kate Brown declared a 60-day state of emergency on March 8, 2020, to help the state prepare for the impacts of COVID-19 in Oregon and the US. At this time, COVID-19 is demonstrating sustained person-to-person community spread and on 3/12/2020, Governor Brown announced urgent strategies to slow the spread of the virus throughout the state. Federal and state health officials are emphasizing mitigation strategies to keep communities safe, focusing on older people and people with chronic diseases who are at higher risk of complications.

Oregon Pharmacy Impacts

Oregon Administrative Rule Division 007 – Public Health Emergency is in effect for all Oregon pharmacies, as of 3/8/2020. In accordance with the nature of this COVID-19 pandemic, the focus is minimization of individuals in close contact with one another (“social distancing”). As this is an evolving situation, pharmacists and pharmacies should continue to care for their patients in a manner that assures access and safety. All state and federal pharmacy regulations remain in effect.

• Division 007 addresses drug distribution and dispensing
• A pharmacy may deliver or mail medications to patients (permitted any time)
• The Oregon Board of Pharmacy (OBOP) is prepared to issue Temporary Pharmacy registrations, but only in the event of mass drug distribution needs

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- Pharmacies and health-systems need to do what is necessary to treat patients and manage employee health. For the declared emergency timeframe only, if minimization of on-site personnel is needed, pharmacy may consider remote processing functions. If applicable, pharmacy shall download and complete Remote Processing Checklist:
  - Checklist P&Ps must be created and followed, but DO NOT NEED TO BE APPROVED BY OBOP prior to use; maintain on-site at the pharmacy
  - This means formal waivers are NOT necessary for these function during the declared emergency timeframe
- Technicians must be working in a pharmacy at the direction and control and under the supervision of a pharmacist – if staff minimization/reduction becomes critical, then it must be a pharmacist that physically functions at a pharmacy (not a technician working unsupervised)
- If it becomes necessary, pharmacists have the authority to issue emergency refills of prescription drugs during the declared emergency and may assist in the storage and distribution of drugs from the Strategic National Stockpile.

Conditions and guidance are changing rapidly. Pharmacists should maintain up-to-date information on this evolving public health emergency to provide the public with factual and detailed information to help reduce the spread of this virus, particularly to vulnerable persons.

The board will continue to provide updates as conditions evolve and trusts that you will take care of yourselves, your families, your patients, and your communities. We will get through this unprecedented situation together!

COVID-19 resources:

- Oregon Health Authority
- World Health Organization
- FDA Letter to HCPS – regarding PPE conservation strategies
  - FDA FAQs – Shortages of Surgical Masks and Gowns
- New 4/3/2020: CDC’s Considerations for Pharmacies During COVID-19 Pandemic
- CDC Hospital Preparedness Assessment Tool
- CDC Strategies for Optimizing the Supply of N95 Respirators
- CDC Guidance for COVID-19 Preparedness
- FDA Guidance – Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products
  - USP – Compounding Alcohol-Based Hand Sanitizer during COVID-19 Pandemic
- FDA Guidance – Clinical Trials during COVID-19
- DEA COVID-19 Information Page (Note: As of 3/19/2020, the DEA has not suspended any regulations. All controlled substance federal and state regulations remain in effect.)
- APhA Pharmacists’ Guide to Coronavirus
- COVID-19: Downstream Implications for Sterile Compounding PPE guidance from Critical Point (Note: this webinar is shared for information purposes only and does not constitute an OBOP endorsement)
The Oregon Board of Pharmacy serves to promote and protect public health, safety and welfare by ensuring high standards in the practice of pharmacy and through effective regulation of the manufacture and distribution of drugs.

Joe Schnabel, Pharm.D, R.Ph.
Executive Director, Oregon Board of Pharmacy

• The Joint Commission COVID-19 Resource