Oregon
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COVID-19 UPDATES

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.

Table of Contents:

COVID-19 UPDATE – Oregon Board of Pharmacy (OBOP) Information April 22, 2023

COVID-19 Updates from the Food and Drug Administration (FDA)

- **Emergency Use Authorization (EUA) Terminated for monovalent mRNA COVID-19 vaccines (Moderna and Pfizer)**
  On 4/18/2023, the FDA terminated Emergency Authorization (EUA) for monovalent mRNA COVID-19 vaccines. The Emergency Use Authorization (EUA) for Novavax and Johnson & Johnson vaccines is not affected by this change.

Updates from the Oregon Health Authority (OHA)

- **Updated: OHA COVID-19 Vaccine Protocol**
  On 4/19/2023 following FDA regulatory action, the CDC acted to simplify its COVID-19 vaccine recommendations and allow more flexibility for people at higher risk who want the option of added protection from additional bivalent COVID-19 vaccine doses. The CDC also updated its guidance to no longer recommend the use of the original (monovalent) COVID-19 mRNA vaccines. On 4/21/2023, the OHA Public Health Division Immunization Program updated the COVID-19 Vaccine Pharmacy Protocol for Immunization. The major changes to the protocol since include:
  - Removal of the monovalent mRNA vaccines.
  - Authorization of current bivalent vaccines to be used for all doses administered to individuals ≥6 months of age.
  - Authorization of an additional bivalent vaccine dose for adults ≥65 years of age ≥4 months after their previous bivalent dose. This dose is optional but may be administered at the recipient's request.

- Authorization of an additional bivalent vaccine dose for certain immunocompromised persons 1 or 2 months after their previous bivalent dose, depending on age. Additional doses may be administered at their provider's discretion.

Persons ≥6 years of age are up-to-date if they have received a single dose of bivalent COVID-19 vaccine, regardless of any previous COVID-19 vaccination history. Persons who are unable or choose not to receive a bivalent mRNA vaccine, are up-to-date if they have received the recommended number of Novavax doses.

Board of Pharmacy Statement on Services Provided Under DHHS Guidance

On March 17, 2020, the U.S. Department of Health & Human Services (DHHS) issued a Declaration Under the Public Readiness and Emergency Preparedness Act (PREP Act) for Medical Countermeasures Against COVID-19 to provide liability immunity for activities related to medical countermeasures against COVID-19. There have been 10 amendments as well as various General Counsel advisory opinions and DHHS guidance documents concerning the PREP Act. For a PREP Act emergency determination, the Secretary must specify an end date; in this case, it is currently October 1, 2024, in most cases (although there are some exceptions). On April 14, 2023 DHHS noticed an intent to extend certain provisions of the act to December 31, 2024. Advisory Opinion 20–02 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, (May 19, 2020), set forth the PREP Act's legal framework for identifying a ''qualified person'' (which include pharmacists, pharmacy technicians, and pharmacy interns) and preemption of state law that is different from, or is in conflict with, that designation.

The Oregon Board of Pharmacy has determined that it will not take disciplinary action against licensees and registrants who act in accordance with DHHS guidance considering DHHS's position that state law is preempted. The Board does not take a position on whether DHHS's position on the preemption of state law is valid. If a complaint is received by the board relating to activities covered under DHHS guidance, the board will expect the licensee and registrant to provide documentation of full compliance with provisions of the PREP Act and DHHS Guidance. Failure to do so may result in disciplinary action.

COVID-19 UPDATE – Oregon Board of Pharmacy (OBOP) Information March 14, 2023

Updates from the Oregon Health Authority (OHA)

- **Oregon will lift mask requirement for health care settings on April 3, 2023.**
  Workers, patients and visitors in health care settings will no longer be required to wear masks starting April 3, 2023.

  OHA is rescinding provisions in Oregon Administrative Rule (OAR) 333-019-1011 that require workers in health care settings – including pharmacies – to wear masks. The requirement has been in effect since August 2021.

  In addition, Executive Order 22-24 expired on March 6, 2023. The emergency gave hospitals needed flexibility to respond to a surge in respiratory infections, including COVID-19, RSV and influenza.

  OHA's decision to end statewide health care mask requirements aligns with decisions in other states, including Washington.

End of the Federal COVID-19 National Emergency and COVID-19 PHE on May 11, 2023

On Jan. 30, 2023, the Biden Administration announced its intent to end the national emergency and public health emergency declarations on May 11, 2023, related to the COVID-19 pandemic. These emergency declarations have been in place since early 2020, and gave the federal government flexibility to waive or modify certain requirements in a range of areas, including in the Medicare, Medicaid, and CHIP programs, and in private health insurance, as well as to allow for the authorization of medical countermeasures and to provide liability immunity to providers who administer services, among other things.

- **FDA's EUAs for COVID-19 products (including tests, vaccines, and treatments)**
  A separate emergency declaration pursuant to Section 564 of the Federal Food, Drug, and Cosmetic (FD&C) Act was issued by the Secretary of HHS in February 2020. Based on this determination, on March 27, 2020, the Secretary declared that circumstances existed to justify emergency use authorization (EUA) of medical countermeasures for COVID-19. An EUA is a mechanism to facilitate availability and use of medical countermeasures that are determined to be safe and effective but have not yet been formally approved. An emergency declaration issued pursuant to Section 564 of the FD&C Act remains in effect until terminated by the HHS Secretary. **The timing to conclude the EUA is to be determined; it will not conclude on May 11, 2023, with the other declarations.**

- **PREP Act Liability Immunity**
  A declaration under the Public Readiness and Emergency Preparedness (PREP) Act (pursuant to Section 319F-3 of the Public Health Service Act) was issued by the Secretary of HHS in March 2020. This declaration provides liability immunity for activities related to COVID-19 medical countermeasures. Since then, 10 amendments to the declaration have been issued to extend liability protections related to COVID-19 countermeasures. For a PREP Act emergency determination, the Secretary must specify an end date; in this case, it has been set as October 1, 2024, in most cases (although there are some exceptions).

- **FDA Notice Concerning COVID-19-related Guidance Documents**
  On March 10, 2023, FDA issued a notice in the Federal Register addressing the agency's COVID-19-related guidance documents, including which of those guidance documents will no longer be in effect after the expiration of the COVID-19 public health emergency (PHE) declared under the Public Health Service (PHS) Act, and which of those guidance documents the FDA is revising to temporarily continue in effect. Below is a summary list of guidance's that apply to pharmacies. Please note this list is abbreviated and registrants/licensees should refer to the Federal Register notice for a complete list.
  - **Table 1—22 Guidance Documents That Will No Longer Be in Effect Upon Expiration of the COVID-19 PHE Declaration**
    - Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Outsourcing Facilities During the COVID-19 Public Health Emergency.
    - Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency Guidance for Industry.
    - Temporary Policy Regarding Non-Standard PPE Practices for Sterile Compounding by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency.

- Temporary Policy on Prescription Drug Marketing Act Requirements for Distribution of Drug Samples During the COVID-19 Public Health Emergency.

- **Table 2— 22 Guidance Documents the FDA Is Revising To Continue in Effect for 180 Days After the COVID-19 PHE Declaration Expires.** The FDA indicates that these guidances can be discontinued in connection with expiration of the COVID-19 PHE declaration but an additional wind-down period is appropriate to allow for an orderly transition.
  - Policy for Certain REMS Requirements During the COVID-19 Public Health Emergency Guidance for Industry and Health Care Professionals.
- **Table 3—24 Guidance Documents FDA Is Revising To Continue in Effect for 180 Days After the PHE Declaration Expires, During Which Time FDA Plans to Further Revise the Guidances**
  - Emergency Use Authorization for Vaccines to Prevent COVID-19.
  - Development and Licensure of Vaccines to Prevent COVID-19.
  - COVID-19: Developing Drugs and Biological Products for Treatment or Prevention.
  - Enforcement Policy for Face Masks and Barrier Face Coverings During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency.
- **Table 4—4 Other COVID-19-Related Guidance Documents** will remain in effect after expiration of the COVID-19 PHE declaration.
  - Product-Specific Guidances for Chloroquine and Hydroxychloroquine.
  - Policy for Coronavirus Disease-2019 Tests (Revised).

- **OAR 855-007 Public Health Emergency Rules**

  Most rules in OAR 855-007 will no longer be in effect when the Federal COVID-19 PHE ends on May 11, 2023 per OAR 855-007-0010(1).

COVID-19 UPDATE – Oregon Board of Pharmacy (OBOP) Information October 31, 2022

COVID-19 Updates from the Food and Drug Administration (FDA)

- **Emergency Use Authorization (EUA) Update for Novavax COVID-19 Monovalent Use as a Booster Vaccine**

  On 10/19/2022, the U.S. Food and Drug Administration:
  Issued an updated the EUA for Novavax COVID-19 monovalent vaccine to be administered as a booster dose (instead of a bivalent mRNA booster dose) at least 6 months after a primary series for individuals age 18 and older:
  - For whom an FDA-authorized mRNA bivalent COVID-19 booster vaccine is not accessible or clinically appropriate, or
  - Who elect to receive the Novavax COVID-19 vaccine because they would otherwise not receive a booster dose of a COVID-19 vaccine.

  Novavax is not authorized in individuals who have already received a prior booster dose. The booster is the same monovalent Novavax vaccine product and dose (0.5 mL) that is authorized for the primary series. Note that the primary series of Novavax is authorized for ages 12+, but the booster is limited to ages 18+. People ages 18 years and older who have never received a prior booster and who receive a monovalent Novavax booster are considered up to date.
  - Novavax COVID-19 Vaccine EUA Letter of Authorization
  - Novavax COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers
  - Novavax COVID-19 EUA Fact Sheet for Recipients and Caregivers

- **Emergency Use Authorization (EUA) Updates for Pfizer and Moderna COVID-19 Bivalent Booster in Children**

  On 10/12/2022, the U.S. Food and Drug Administration:
  - Amended the EUAs for Pfizer and Moderna COVID-19 vaccines to authorize a bivalent booster dose in people aged ≥6 years (for Moderna) and ≥5 years (for Pfizer). These bivalent boosters may be provided as:
    - A single booster dose to individuals 5 years (Pfizer) or 6 years (Moderna) through 11 years of age at least 2 months after completion of primary vaccination with any authorized or approved monovalent COVID-19 vaccine; or
    - A single booster dose to individuals 5 years (Pfizer) or 6 years (Moderna) through 11 years of age at least 2 months after receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine.
  - De-authorized the use of monovalent Pfizer Orange Cap as a booster dose.
  - The original, monovalent Moderna COVID-19 Vaccine and Pfizer-BioNTech COVID-19 Vaccine continue to be authorized for primary series administration in individuals six months of age and older. Bivalent vaccines are not authorized for primary series doses.
  - Updated EUA Documents:
    - Pfizer-BioNTech 5-11 years old COVID-19 Bivalent Vaccine EUA Fact Sheet for Healthcare Providers
    - Pfizer-BioNTech 5-11 years old COVID-19 Bivalent Vaccine EUA Fact Sheet for Recipients and Caregivers
    - Moderna 6+ years old COVID-19 Bivalent Vaccine EUA Fact Sheet for Healthcare Providers
    - Moderna 6+ years old COVID-19 Bivalent Vaccine EUA Fact Sheet for Recipients and Caregivers
  - Visual product charts from the FDA:
    - Moderna
    - Pfizer
  - CDC resources related to this recommendation:
    - COVID-19 Vaccines for Children and Teens | CDC
    - Resources to Promote the COVID-19 Vaccine for Children & Teens | CDC
    - Clinical Guidance for COVID-19 Vaccination | CDC
    - COVID-19 Vaccination Schedule At-a-Glance (for non-immunocompromised people)

Updates from the Oregon Health Authority (OHA)

- **Updated: OHA COVID-19 Vaccine Protocol**

  On 10/13/2022 and 10/20/2022, the OHA Public Health Division Immunization Program updated the COVID-19 Vaccine Pharmacy Protocol for Immunization. The major changes to the protocol since 10/13/2022 include:
  - Authorization to provide Pfizer and Moderna COVID-19 bivalent booster vaccines to people aged ≥6 years (for Moderna) and ≥5 years (for Pfizer) if it has been at least 2 months since completion of a COVID-19 primary vaccine series or receipt of a monovalent booster dose, regardless of the number of booster doses previously received.
  - De-authorization of Pfizer-BioNTech and Moderna monovalent vaccines for use as a booster dose.

- Authorization to provide Novavax COVID-19 monovalent vaccine as a booster dose in limited circumstances.

COVID-19 UPDATE – Oregon Board of Pharmacy (OBOP) Information September 2, 2022

COVID-19 Updates from the Food and Drug Administration (FDA)

- **Emergency Use Authorizations (EUA) for Pfizer and Moderna COVID-19 Monovalent Primary Series Vaccine and Bivalent Booster Vaccine**

  On 8/31/2022, the U.S. Food and Drug Administration:
  - Issued updated EUAs for monovalent Pfizer and Moderna Covid-19 Primary Series vaccines. The monovalent COVID-19 vaccines cannot be used as a booster dose in patients ≥12 years of age.
    - Pfizer-BioNTech Fact Sheets (English) and FAQs
    - Moderna COVID-19 Vaccine Fact Sheets (English) and FAQs
  - Issued new EUAs for new, bivalent Pfizer and Moderna Covid-19 Booster vaccines. All persons ≥12 years of age are eligible for a bivalent booster dose if it has been at least 2 months since completion of a COVID-19 primary vaccine series or receipt of a monovalent booster dose, regardless of the number of booster doses previously received.

Updates from the Oregon Health Authority (OHA)

- **Updated: OHA COVID-19 Vaccine Protocol**

  On 8/25/2022 and 9/2/2022, the OHA Public Health Division Immunization Program updated the COVID-19 Vaccine Pharmacy Protocol for Immunization. The major changes to the protocol since 8/25/2022 include:
  - Novavax COVID-19 Vaccine, Adjuvanted, is authorized as a 2-dose primary series for children 12-17.
  - Pfizer-BioNTech and Moderna monovalent vaccines are no longer authorized for use as a booster dose in patients ≥12 years of age.
  - Pfizer-BioNTech and Moderna bivalent vaccines are authorized for a booster dose in all persons ≥12 years of age if it has been at least 2 months since completion of a COVID-19 primary vaccine series or receipt of a monovalent booster dose, regardless of the number of booster doses previously received.

COVID-19 UPDATE – Oregon Board of Pharmacy (OBOP) Information August 1, 2022

COVID-19 Updates from the Food and Drug Administration (FDA)

- **Emergency Use Authorization (EUA) issued for Novavax Covid-19 Vaccine**

  On 7/13/2022, the U.S. Food and Drug Administration issued an emergency use authorization (EUA) for Novavax vaccine for the prevention of coronavirus disease 2019 (COVID-19) for individuals 18 years of age and older.
  - Novavax COVID-19 Vaccine EUA Letter of Authorization
  - Novavax COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers

- Novavax COVID-19 EUA Fact Sheet for Recipients and Caregivers

Updates from the Oregon Health Authority (OHA)

- **Updated: OHA COVID-19 Vaccine Protocol**
  On 7/22/2022, the OHA Public Health Division Immunization Program updated the COVID-19 Vaccine Pharmacy Protocol and on 7/26/2022 the COVID-19 Vaccine Pharmacy Protocol for Immunization was further updated due to some errors and omissions on the 7/22/2022 version. The major changes to the protocol since 6/28/2022 include:
    - Novavax COVID-19 Vaccine, Adjuvanted, is authorized as a 2-dose primary series for adults ≥ 18 years of age.
      - No dilution is needed. Each vial contains 10 doses of 0.5mL
      - The dosing schedule is two 5mcg/0.5mL doses administered IM at least 21 days apart.
        - Persons who receive the Novavax series are not currently eligible for additional doses or for booster doses.
        - Novavax vaccine is not authorized for use as a booster dose in persons who received a primary series of another COVID-19 vaccine
      - Store unopened vials between 2° to 8°C (36° to 46°F). Once vial stopper has been punctured, hold the vial between 2° to 25°C (36° to 77°F) for use within 6 hours. Discard the vial 6 hours after the first puncture.

- **Updated: Paxlovid (nirmatrelvir/ritonavir tablets) EUA:**
  On 7/6/2022, the U.S. Food and Drug Administration update the Paxlovid Emergency Use Authorization (EUA) to allow for pharmacist prescribing for individual patients under the following conditions:
    - Sufficient information is available, such as through access to health records less than 12 months old or consultation with a health care provider in an established provider-patient relationship with the individual patient, to assess renal and hepatic function; and
    - Sufficient information is available, such as through access to health records, patient reporting of medical history, or consultation with a health care provider in an established provider-patient relationship with the individual patient, to obtain a comprehensive list of medications (prescribed and non-prescribed) that the patient is taking to assess for potential drug interaction.

  The state-licensed pharmacist should refer an individual patient for clinical evaluation with a physician, advanced practice registered nurse, or physician assistant licensed or authorized under state law to prescribe drugs, if any of the following apply:
    - Sufficient information is not available to assess renal and hepatic function.
    - Sufficient information is not available to assess for a potential drug interaction.
    - Modification of other medications is needed due to a potential drug interaction
    - PAXLOVID is not an appropriate therapeutic option based on the authorized Fact Sheet for Healthcare Providers or due to potential drug interactions for which recommended monitoring would not be feasible.

  With this recent change in the Paxlovid EUA, Oregon-licensed pharmacists now have liability immunity and scope of authority to prescribe Paxlovid under the 9th amendment of the Department of Health and Human Services Public Readiness and Emergency Preparedness (PREP) Act. Pharmacy interns and technicians cannot prescribe Paxlovid under the PREP Act because the Paxlovid EUA only authorizes pharmacists to prescribe Paxlovid. Pharmacists must adhere to the EUA and the PREP Act when

prescribing Paxlovid, including all documentation and patient follow-up required under the EUA and PREP Act.

If you have any questions, please reach out to oha.therapeutics@dhsoha.state.or.us.

COVID-19 UPDATE – Oregon Board of Pharmacy (OBOP) Information June 30, 2022

Updates from the Oregon Health Authority (OHA)

- **Updated: OHA COVID-19 Vaccine Protocol**
  On 6/28/2022, the OHA Public Health Division Immunization Program updated the COVID-19 Vaccine Pharmacy Protocol and on 6/29/2022 the COVID-19 Vaccine Pharmacy Protocol for Immunization was further updated due to some significant errors and omissions on the 6/28/2022 version. The major changes to the protocol since 6/21/2022 include:
    - Children 6-11 years of age may be vaccinated with the currently available adult booster, 50mcg/0.5mL formulation of Moderna vaccine with the dark blue cap and a label with a purple border. For this presentation, the cartons and vial labels state "BOOSTER DOSES ONLY"; however, this presentation may be used to provide primary series doses to individuals 6 years-11 years of age.
        - No dilution is needed. Each vial contains 5 doses of 0.5mL
        - The dosing schedule is two 50mcg/0.5mL doses administered IM 28 days apart. Immunocompromised patients should receive a 3rd dose at least 28 days after the 2nd dose. The Moderna COVID-19 Vaccine is not authorized to provide booster doses to individuals 6 -11 years of age.
        - There is a different EUA Caregiver Fact Sheet specific to the formulation(s) authorized for 6-11 years of age that must be given to the patient or caregiver.
        - There is a different EUA HCP Fact Sheet specific to the formulation(s) approved for 6-11 year years of age with detailed information on the storage & handling, age indications, preparation and dosage.
        - Moderna will be producing a new 50mcg/0.5mL presentation of Moderna vaccine with the dark blue cap and a label with a teal border specifically labeled for 6-11 years old, but this presentation is not available yet. The Fact Sheets above also include information on this presentation and will be applicable when it becomes available.
    - Children 12-17 years of age may be vaccinated with the currently available adult 100mcg formulation of Moderna vaccine with a red cap and a label with a light blue border. For this formulation:
        - No dilution is needed. There are two vial sizes available. The 5.5mL vials contain 10-11 doses of 0.5mL and the 7.5mL vial contain 13-15 doses of 0.5mL.
        - The dosing schedule is two 100mcg/0.5mL doses administered IM 28 days apart. Immunocompromised patients should receive a 3rd dose at least 28 days after the 2nd dose. The Moderna COVID-19 Vaccine is not authorized to provide booster doses to individuals 12-17 years of age.

        - The EUA Caregiver Fact Sheet specific to the Moderna COVID-19 vaccine with a red cap and a label with a light blue border formulation has been updated and must be given to the patient or caregiver.
        - The EUA HCP Fact Sheet specific to Moderna COVID-19 vaccine with a red cap and a label with a light blue border formulation has been updated with detailed information on the storage & handling, age indications, preparation and dosage.
    - An updated EUA Caregiver Fact Sheet has been issued for the Pfizer COVID Vaccine (maroon cap) 6 months – 4 years of age.
        - EUA Caregiver Fact Sheet

Please see the 3/30/2022 update to this communication regarding the Pharmacists authorization to administer vaccines to persons ≥ 3 Years of age.

COVID-19 UPDATE – Oregon Board of Pharmacy (OBOP) Information June 21, 2022

Updates from the Oregon Health Authority (OHA)

- **Updated: OHA COVID-19 Vaccine Protocol**
  On 6/19/2022, the OHA Public Health Division Immunization Program updated the COVID-19 Vaccine Pharmacy Protocol for Immunization to include:
    - Children 3-4 years (<5 years) of age may be vaccinated with a new pediatric, 3mcg formulation of Pfizer vaccine. For the Pfizer pediatric (maroon cap) formulation:
        - The vials will have maroon caps and borders to differentiate the vials from the pediatric formulation (orange caps and border) and the adolescent/adult formulation (purple or gray caps and borders).
        - Each vial will need 2.2 mL of diluent (sterile 0.9% Sodium Chloride Injection, USP) and once mixed will contain 10 doses of 0.2mL.
        - The dosing schedule is two 3mcg/0.2mL doses administered IM 21 days apart and a 3rd dose administered at least 56 days after the 2nd dose.
        - There is a different EUA Caregiver Fact Sheet specific to the pediatric (maroon cap) formulation that must be given to the patient or caregiver.
        - There is a different EUA HCP Fact Sheet with detailed information on the storage & handling, age indications, preparation and dosage.
    - Children 3-5 years (<6 years) of age may be vaccinated with a new pediatric, 25mcg formulation of Moderna vaccine. For the Moderna pediatric formulation:
        - The vials will have blue caps and magenta borders to differentiate the vials from the adolescent/adult formulation that utilizes red caps and blue borders.
        - No dilution is needed. Each vial contains 10 doses of 0.25mL
        - The dosing schedule is two 25mcg/0.25mL doses administered IM 28 days apart. Immunocompromised patients should receive a 3rd dose at least 28 days after the 2nd dose.

- There is a different EUA Caregiver Fact Sheet specific to the pediatric (blue cap/magenta borders on label) formulation that must be given to the patient or caregiver.
- There is a different EUA HCP Fact Sheet with detailed information on the storage & handling, age indications, preparation and dosage.

Please see the 3/30/2022 update to this communication regarding the Pharmacists authorization to administer vaccines to persons ≥ 3 Years of age.

COVID-19 UPDATE – Oregon Board of Pharmacy (OBOP) Information May 20, 2022

Oregon Board of Pharmacy Office Reopened

After two years of our office being closed by the State of Oregon to minimize the spread of COVID-19, we are pleased to announce that the Portland State Office Building where the Oregon Board of Pharmacy office is located has reopened to the public on Tuesday, May 3.

Over the past 26 months, we have found a way to serve you, our licensees and registrants, by being available by virtual means; however, we know nothing takes the place of being able to meet and work as a group in person. Resuming face-to-face interactions will once again bring back that sense of camaraderie we feel when we gather physically in one place.

The next board meeting will be held June 8-10, 2022 and the meeting will be open to the public. The meeting will be noticed next week.

Updates from the Oregon Health Authority (OHA)

- **Updated: OHA COVID-19 Vaccine Protocol**
  On 5/20/2022, the OHA Public Health Division Immunization Program updated the COVID-19 Vaccine Pharmacy Protocol for Immunization to include:
  - Children 5-11 years of age who completed a Pfizer-BioNTech COVID-19 vaccine series are recommended to receive a booster dose of Pfizer vaccine ≥5 months after their last dose. An updated EUA specific to children age 5-11 is now available.
  - Children 5-11 years of age who are immunocompromised (and who have received a third primary series dose a Pfizer-BioNTech COVID-19 vaccine) should get a booster dose of a Pfizer-BioNTech COVID-19 vaccine ≥3 months after receiving the third dose in their primary vaccine series.
  - Strengthened language discouraging use of the Janssen vaccine, based on amendment of the EUA by the FDA.

- **Oral Antiviral for Treatment of COVID-19**
  Two oral antiviral medications are available for treatment of COVID-19 under emergency use authorization. The federal government has released the Test to Treat Locator to make it easier to find Test to Treat (T2T) sites and where providers can send prescriptions to.

- **Lageviro (Molnupiravir)**

  FDA authorized Lageviro (Molnupiravir) in December 2021 for the treatment of mild-to-moderate COVID-19 in adults with positive results of direct SARS-CoV-2 viral testing who are also at high risk for progression to severe COVID-19, including hospitalization or death.

  Dosage: 800 mg (four 200 mg capsules) taken orally every 12 hours for 5 days, with or without food.

  FDA Tools for Lageviro (Molnupiravir):
  - Fact Sheet for Health Care Providers
  - Fact Sheet for Patients and Caregivers
  - Prescriber Patient Eligibility Screening Checklist

- **Paxlovid (nirmatrelvir/ritonavir tablets):**

  FDA authorized Paxlovid (nirmatrelvir and ritonavir) in December 2021 for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing who are also at high risk for progression to severe COVID-19, including hospitalization or death.

  Dosage: 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet), with all three tablets taken together twice daily for 5 days.

  Dose reduction for moderate renal impairment (eGFR ≥30 to <60 mL/min): 150 mg nirmatrelvir (one 150 mg tablet) with 100 mg ritonavir (one 100 mg tablet), with both tablets taken together twice daily for 5 days.

  Prescriptions should specify the numeric dose of each active ingredient within PAXLOVID

  FDA Tools for Paxlovid:
  - Fact Sheet for Health Care Providers
  - Fact Sheet for Patients, Parents and Caregivers
  - Eligibility Screening Checklist Tool – includes an alphabetized list of other drugs with potentially significant drug interactions.

  Paxlovid Renal Impairment Packaging:
  On April 14, 2022, the U.S. Food and Drug Administration (FDA) revised the Emergency Use Authorization (EUA) for the COVID-19 oral antiviral therapeutic Paxlovid to authorize an additional dose pack presentation with appropriate dosing for patients with moderate renal impairment within the scope of the EUA. As a result, Paxlovid is now available in two package presentations.

  In the event that the Paxlovid 150 mg/100 mg dose pack is unavailable: The Pharmacist should refer to the provided instructions entitled "Important Paxlovid™ EUA Dispensing Information for Patients with Moderate Renal Impairment" for dispensing of Paxlovid to patients with moderate renal impairment and patients should be informed that their daily blister card has been altered to ensure they receive the correct dose.

COVID-19 UPDATE – Oregon Board of Pharmacy (OBOP) Information April 1, 2022

The Oregon Public Health Emergency Declaration Has Ended

With the end of the Governor's COVID-19 related state of emergency on April 1, 2022, (See Executive Order No. 20-03) and the possible termination on April 15, 2022, of the federal public health emergency (PHE) declared under section 319 of the federal Public Health Services Act, pharmacies, pharmacists, pharmacy technicians, and pharmacy interns have had questions about whether these events mean changes for pharmacy practice, scope of practice and legal protections under state law and the federal Public Readiness and Emergency Preparedness (PREP) Act.

PREP Act

The PREP Act declaration and PREP Act amendments are not tied to the federal PHE referenced above. PREP Act protections for all qualified persons identified in the declaration and all amendments that have been issued, extend through October 1, 2024. See Tenth Amendment to Declaration under the PREP Act, effective January 7, 2022. Therefore, to the extent the PREP Act has expanded the scope of practice for pharmacists, pharmacy technicians and pharmacy interns, those PREP Act provisions remain in place.

Board of Pharmacy Statement on Immunization Services Under DHHS Guidance

Issued: November 30, 2020

On October 20, 2020, U.S. Department of Health & Human Services (DHHS) issued the third amendment to a declaration under the Public Readiness and Emergency Preparedness Act (or PREP Act). This declaration provides liability protection and authorizes both qualified pharmacy technicians and State-authorized pharmacy interns acting under the supervision of a qualified pharmacist to administer FDA-authorized or FDA-licensed COVID-19 vaccines to persons ages three or older and to administer FDA-authorized or FDA-licensed ACIP-recommended vaccines to persons ages three through 18 according to ACIP's standard immunization schedule. The DHHS guidance lists requirements that qualified pharmacy technicians and State-authorized pharmacy interns must satisfy.

The declaration states that the authorization preempts any state and local law that prohibits or effectively prohibits those who satisfy requirements as set forth in the declaration from administering COVID-19 or routine childhood vaccines. The Oregon Board of Pharmacy will not take disciplinary action against persons who act in accordance with this DHHS guidance considering DHHS's position that state law is preempted. The Board does not take a position on whether DHHS's position on the preemption of state law is valid. If a complaint is received relating to activities covered under DHHS guidance, the Board will expect the licensee to provide documentation of full compliance. Failure to do so may result in disciplinary action.

Board of Pharmacy Rules

- **Temporary Rule Adopted: 91-day extension period to emergency licensure after a declared emergency ends**

  On 3/29/2022, the board adopted a temporary rule amendment adding a 91-day extension period to emergency licensure in OAR 855-007-0050(2) after a declared emergency ends. The amendment will allow a drug outlet to 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 Pacific Northwest Emergency Management Arrangement

(PNEMA) or Emergency Management Assistance Compact (EMAC) for an additional 91 days after the declared emergency ends. This rule will expire in 180 days unless repealed earlier.

- **Temporary Rule Adopted: Addition of emergency registration designation for Remote Processing/Central Fill services during a declared emergency and for 91 days after it ends**
  On 3/30/2022 the board adopted a temporary rule, OAR 855-007-0055 permitting an Oregon-registered drug outlet to perform Central Fill and/or Remote Processing prior to approval by the Board during a declared emergency and for 91-days after the PHE ends. The outlet must complete the Central Fill Drug Outlet and/or Remote Processing Drug Outlet Designation Application, have policies and procedures for these services, and retain the application and policies and procedures on-site for one year. This rule will expire in 180 days unless repealed earlier.

COVID-19 UPDATE – Oregon Board of Pharmacy (OBOP) Information March 30, 2022

End of the Oregon Public Health Emergency (PHE) on 4/1/2022 and Federal PHE on 4/15/2022.
On 02/24/2022, Governor Kate Brown announced that she will be lifting Oregon's COVID-19 emergency declaration, effective April 1. The federal emergency declaration (COVID-19) was last renewed by U.S. Department of Health and Human Services (HHS) Secretary Xavier Becerra effective 1/14/2022 and through 4/15/2022, unless renewed by Secretary Becerra. Pharmacy licensees should be aware of the following changes that will impact the practice of pharmacy with the end of the public health emergency:

- **Rules**
  - **Temporary Rule Adopted: 91-day extension period to emergency licensure after a declared emergency ends**
    On 3/29/2022, the board adopted a temporary rule amendment adding a 91-day extension period to emergency licensure in OAR 855-007-0050(2) after a declared emergency ends. The amendment will allow a drug outlet to 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 Pacific Northwest Emergency Management Arrangement (PNEMA) or Emergency Management Assistance Compact (EMAC) for an additional 91 days after the declared emergency ends. This rule will expire in 180 days unless repealed earlier.
  - **Temporary Rule Adopted: Addition of emergency registration designation for Remote Processing/Central Fill services during a declared emergency and for 91 days after it ends**
    On 3/30/2022 the board adopted a temporary rule, OAR 855-007-0055 permitting an Oregon-registered drug outlet to perform Central Fill and/or Remote Processing prior to approval by the Board during a declared emergency and for 91-days after the PHE ends. The outlet must complete the Central Fill Drug Outlet and/or Remote Processing Drug Outlet Designation Application, have policies and procedures for these services, and retain the application and policies and procedures on-site for one year. This rule will expire in 180 days unless repealed earlier.

- **Licensure**
  - **Requirement for Licensure**

    91 days after the state or federal COVID-19 PHE ends (whichever comes later), Pharmacists, Interns, and pharmacy technicians (PT and COPT) must hold a license with the Oregon Board of Pharmacy to continue practicing or assisting in the practice of pharmacy (OAR 855-007-0050). Pharmacies that have employed Pharmacists, Interns, or pharmacy technicians (PT or COPT) during the PHE who are not licensed by the Oregon Board of Pharmacy, but hold a comparable license issued by any other state or signatory to PNEMA or EMAC must retain on-site documentation of each such employee during the declared emergency and for 3 years.

- **Immunizations**
  - **Order Authorizing Pharmacists to Administer Vaccines to Persons ≥ 3 Years of Age**

    On March 29, 2022, Public Health Director Rachael Banks amended her existing order to authorize pharmacists to administer Covid-19 and influenza vaccines down to children age 3. In the next few months, the U.S. Federal Food and Drug Administration (FDA) will likely authorize under an Emergency Use Authorization, the administration of at least one COVID-19 vaccine for additional children under the age of 5, and the Centers for Disease Control and Prevention (CDC) will recommend such a vaccination for these younger children.
    Director Banks, based on authority provided under ORS 433.444, during the current outbreak and epidemic of COVID-19, authorizing the following:

    1. Pharmacists licensed under ORS chapter 689, may administer COVID-19 vaccines to eligible persons who are three years of age or older, as authorized by the FDA and the CDC.
    2. Pharmacists licensed under ORS chapter 689, may administer any FDA approved and CDC recommended influenza vaccine to persons who are three years of age or older.

    This order remains in effect until January 1, 2023, unless terminated earlier or extended. Read the entire amended order here.

    NOTE: While the order allows COVID-19 vaccine to age 3 and older, no authorization currently exists to vaccinate children age 3-4 with COVID-19 vaccine.

    Information regarding the Oregon Board of Pharmacy Statement on Immunization Services Under DHHS Guidance & PREP Act 3rd Amendment allowing qualified pharmacy technicians and State-authorized pharmacy interns acting under the supervision of a qualified pharmacist to administer vaccines to persons ages three or older was included in the 12/4/2020 OBOP COVID Communication Update.

  - **Updated: OHA COVID-19 Vaccine Protocol**

    On 3/29/2022, the OHA Public Health Division Immunization Program updated the COVID-19 Vaccine Pharmacy Protocol for Immunization to include:

    - Adults ≥50 years of age and for certain immunocompromised patients 12–49 years of age: A 2nd booster dose may be administered ≥4 months after the previous booster dose.
      - Children 12–17 years of age need to receive the Pfizer vaccine, but patients ≥18 years of age may select either Pfizer or Moderna vaccine.

- Adults that received a primary Janssen dose followed by a booster dose of Janssen vaccine to receive a second booster dose of a mRNA vaccine ≥4 months after the previous booster dose.

- **Telework/Remote Processing/Central Fill**
  - **Telework:**
    - Pharmacists, Interns and Certified Oregon Pharmacy Technicians may only engage in telework according to OAR 855-041-3200 to 855-041-3250.
    - Pharmacy Technicians are not permitted to engage in telework according to OAR 855-041-3235(2).
  - **Remote Processing/Central Fill:**
    - 91 days after the state or federal COVID-19 PHE ends (whichever comes later), Oregon registered pharmacies must have obtained a remote processing and/or central fill registration designation with the Oregon Board of Pharmacy to continue providing these services. Outlets may not continue utilizing central fill or remote processing beyond the PHE + 91 days unless the Central Fill Drug Outlet and/or Remote Processing Drug Outlet Designation Application has been received, reviewed and approved by the board.
    - Central Fill rules can be found in OAR 855-041-3005 to 855-041-3045.
    - Remote Processing rules can be found in OAR 855-041-3100 to 855-041-3130.

COVID-19 UPDATE – Oregon Board of Pharmacy (OBOP) Information March 2, 2022

End of the Oregon Public Health Emergency (PHE)- 4/1/2022

On 2/24/2022, Governor Kate Brown announced that she will be lifting Oregon's COVID-19 emergency declaration, effective 4/1/2022. The federal emergency declaration (COVID-19) was last renewed by U.S. Department of Health and Human Services (HHS) Secretary Xavier Becerra effective 1/14/2022 and through 4/15/2022, unless renewed by Secretary Becerra. The board will be sending additional information in the coming weeks regarding Oregon PHE allowances that will no longer be in effect as of 4/1/2022.

Updates from the Oregon Health Authority (OHA)

- **Updated: OHA COVID-19 Vaccine Protocol**

  On 2/24/2022, the OHA Public Health Division Immunization Program updated the COVID-19 Vaccine Pharmacy Protocol for Immunization to include:
  - For healthy patients 12-64 years of age and especially for males ages 12-39 years of age, an 8-week interval may be optimal to balance disease protection and vaccine risk.*
  - Adults ≥65 years of age, patients who are immunocompromised, and others that need rapid protection should continue to be vaccinated using the minimum interval.

  *The CDC recently updated its Interim Clinical Considerations for Use of COVID-19 Vaccines to lengthen the recommended interval between doses 1 and 2 of an mRNA COVID vaccine series. For healthy persons aged 12-64 years of age, particularly for men ages 12-39 years of age, the second dose should be given 8 weeks after dose 1. CDC believes this additional month may reduce the risk of adverse

events like myocarditis as well as producing peak antibody responses. An interval longer than 8 weeks has not been shown to provide additional benefit. Adults 65 years of age and older, people with moderate to severe immunocompromise, and people who need rapid protection due to increased community transmission or the risk of severe disease should continue to receive dose 2 using the minimum spacing of 21-days or 28-days, depending on the product used.

- **Updated: Masking Requirements**
  On 2/28/2022, OHA announced that it will lift the indoor mask requirements for the general public at 11:59pm on 3/11/2022. OHA has no current plans to lift mask requirements in health care settings (which includes pharmacies) as outlined in OAR 333-019-1011. OAR 333-019-1011 also includes that patients, residents and clients must wear a face covering when entering, exiting, or in a health care setting. Additional resources are available at:

  - OHA Mask webpage
  - OHA Mask FAQ (translations in process) – updated 2/25/2022
  - OHA Health Care Setting (includes pharmacies) Masking Requirements FAQ – updated 2/15/2022
  - Mask Required Sign for Health Care Setting – updated 2/15/2022

- **Pharmacies Encouraged to Accommodate CDC COVID-19 Vaccine Provider Site Visits**
  On October 18, 2021, the CDC updated the COVID-19 Vaccination Program Provider Agreement to require that COVID-vaccinators participate in quality assurance site visits. The provider agreement states, "*CDC and/or state/local public health staff are required to conduct certain provider oversight activities in each jurisdiction. COVID-19 vaccination providers and depot locations that store or redistribute COVID-19 vaccine must accommodate these staff and participate in COVID-19 quality assurance site visits and other educational opportunities associated with COVID-19 vaccination program requirements*."

  Site visits will be performed by the Oregon Rural Practice-based Research Network (ORPRN) on behalf of the CDC.

- **Updated: Shingles and Pneumococcal Vaccine Protocols**
  On 02/11/2022, the OHA Public Health Division Immunization Program updated the Shingles Pharmacy Protocol for Immunization to include:
    - Recommendation for zoster vaccine in immunocompromised adults ≥19 years of age.

  On 2/28/2022, the OHA Public Health Division Immunization Program updated the Pneumococcal Pharmacy Protocol for Immunization to include:
    - For adults ≥65 years of age PCV20 (Prevnar 20™) or PCV15 (VAXNEUVANCE™) should be administered followed by PPSV23 (Pneumovax ®23). This replaces all pervious recommendations for routine PPSV23 for adults ≥65 years of age.
    - Adults 19–64 years of age with certain underlying conditions should receive a dose of PCV20, or PCV15 followed by PPSV23.
    - Adults previously vaccinated with PCV13 do not need to be revaccinated with either PCV20 or PCV15.

COVID-19 UPDATE – Oregon Board of Pharmacy (OBOP) Information February 16, 2022

Safe Pharmacy Practice Conditions

- **Board of Pharmacy Statement**

  On 2/11/2022, the Oregon Board of Pharmacy issued a statement concerning providing safe pharmacy practice conditions during the COVID-19 pandemic.

- **Licensee Survey**

  The Board of Pharmacy requests licensee feedback on current pharmacy practice conditions. As noted in the statement linked above, the board has received several reports regarding workplace issues and has become concerned about the possibility of conditions that may potentially have a negative impact on patient safety. The board is very interested in hearing from all licensees on this issue. A brief survey (~6 minutes) was developed by the board and the board's Safe Pharmacy Practice Conditions Workgroup. No identifying information will be collected (e.g. IP address) or available to the board through the survey. The survey information will be accumulated and analyzed by the board and the Safe Pharmacy Practice Conditions Workgroup for future policy discussion and input on proposed rules. Please complete the survey linked here by 3/2/2022.

Temporary Rules Adopted

- **Pharmacy Technician (PT) and Certified Oregon Pharmacy Technician (COPT)**

  On 2/11/2022, the board adopted temporary rule amendments to assist in alleviating the shortage of licensed personnel remove barriers to licensure of PTs and COPTs by clarifying licensure qualifications, the elements of a complete application and the requirements for renewal/reinstatement. The rules also allow a PT to renew or reinstate their license. As a result, the PT licensee must pay the workforce data collection fee and complete biennial CPE requirements. Later this week, these rules will also be noticed as permanent rules for public rulemaking comment.

- **Permanent Pharmacy Closures**

  On 2/11/2022, the board adopted a temporary rule regarding Permanent Pharmacy Closures. During the COVID-19 pandemic, there has been an increase in permanent pharmacy closures. Registrants need clear direction on orderly disposition of prescription and non-prescription drugs, devices, related supplies, and pharmacy records when a pharmacy permanently closes. Patients and healthcare providers need to be able to access medications prior to a permanent closure and locate prescription records after a pharmacy closure. The proposed rule provides a list of items that must be completed prior to, on the date of or within 24 hours and within 30 calendar days of the permanent pharmacy closure. These rules will be noticed for public rulemaking comment after the April board meeting.

COVID-19 Updates from the Oregon Health Authority (OHA)

- **Updated: OHA COVID-19 Vaccine Protocol**

  On 2/15/2022, the OHA Public Health Division Immunization Program updated the COVID-19 Vaccine Pharmacy Protocol for Immunization to include:

  - For patients who are immunocompromised only, the interval between the final dose in an mRNA primary series and the recommended booster dose has been shortened from 5 months to 3 months.
  - For patients who are immunocompromised and received Janssen vaccine only, an additional dose of mRNA vaccine has been added to the primary series. Patients are recommended to receive an additional dose of an mRNA vaccine at least 28 days after dose one. This additional primary dose

should be followed by a booster dose of any vaccine at least 2 months after the second primary dose.

- CDC has removed a deferral period for vaccination in patients who recently received passive antibody products. These patients may be vaccinated immediately, except that prophylaxis with tixagevimab/cilgavimab (EVUSHELD™) should be deferred for at least 2 weeks after vaccination.

- **Postponed: Authorization of Pfizer COVID-19 Vaccine for 6 Months to 4 Years**
  On 2/11/2022, the FDA announced they have postponed the scheduled advisory committee meeting to discuss the request for authorization of the Pfizer COVID-19 vaccine for children ages 6 months through 4 years to allow more time to evaluate additional data, including the ongoing evaluation of a third dose. Please see FDA's press release.
- **Updated: Masking Requirements**
  On 2/7/2022, OHA announced that it will lift the indoor mask requirements for the general public no later than March 31, 2022. OHA has no current plans to lift mask requirements in health care settings (which includes pharmacies) as outlined in OAR 333-019-1011. OAR 333-019-1011 also includes that patients, residents and clients must wear a face covering when entering, exiting, or in a health care setting. Additional resources are available at:

  - OHA Mask webpage
  - OHA Mask FAQ (translations in process)

Clarification Regarding Interns: Ending Operational Allowances Granted Early in the Pandemic/Public Health Emergency
On 9/24/2021, the board communicated that some PHE operational allowances would cease to be effective 12/31/2021, which included the delay of lapsed CPR certification renewal for vaccine-certified pharmacists. It was the intention of the board to include vaccine-certified interns to this allowance sunset. While interns were not included in this allowance, it is expected that all immunizing pharmacists and interns must have an active CPR certification to administer vaccines per OAR 855-019-0270.

COVID-19 UPDATE – Oregon Board of Pharmacy (OBOP) Information January 28, 2022

Revised EUA for REGEN-COV®
On 1/24/2022, the U.S. Food and Drug Administration (FDA) amended the Emergency Use Authorization (**EUA**) for Regeneron's REGEN-COV® (casirivimab and imdevimab) to exclude its use in geographic regions where, based on available information including variant susceptibility and regional variant frequency, infection or exposure is likely due to a variant such as Omicron (B.1.1.529) that is not susceptible to the treatment. With this EUA revision, REGEN-COV® is not currently authorized for use in any U.S. states, territories or jurisdictions, since Omicron is currently the dominant variant across the United States. The FDA stated that if, in the future, patients in certain geographic regions are likely to be infected or exposed to a variant that is susceptible to REGEN-COV®, then the limitation on use may be revised in these areas. Per OAR 855-020-0300(2)(c) A pharmacist may prescribe, via statewide drug therapy management protocol and according to rules outlined in this Division, an FDA-approved drug and device listed in the following compendium: Conditions – COVID-19 Monoclonal Antibody Protocol (v. 12/2021). Per the protocol, pharmacists must review the revised Fact Sheet for Healthcare Providers and must adhere to the EUA when prescribing/administering REGEN-COV®. At this time, adhering to the EUA means not prescribing/administering REGEN-COV®.

COVID-19 Updates from the Oregon Health Authority (OHA)

- **Updated OHA COVID-19 Vaccine Protocol**
  On 1/19/2022, the OHA Public Health Division Immunization Program updated the COVID-19 Vaccine Pharmacy Protocol for Immunization to include:
  - Removal of minor consent language not applicable to pharmacists (Previously appendix D). Please see the COVID communication from 6/4/2021 for further information regarding minor consent.

Reminder: Immunocompromised Patients and COVID Vaccine 4th Doses

Pharmacists are reminded that immunocompromised persons who received their three-dose primary series are eligible for a booster dose (3 primary doses + 1 booster = 4th dose) if it has been 5 months since completion of their primary series.

- From the Protocol: Immunocompromised patients receiving an mRNA vaccine should receive a three-dose primary series of the same vaccine brand. A different brand of vaccine may be used if the same brand is unknown or unavailable.

- People ≥12 years of age who completed a Pfizer vaccine series are recommended to receive a booster dose of Pfizer vaccine ≥5 months after their last dose.
- People ≥18 years of age who completed a Moderna mRNA vaccine series should receive a booster dose ≥5 months after their last dose.

Please be advised that the ALERT system may be causing some confusion as the system marks a patient's third dose as a "booster" as ALERT is unable to differentiate between immunosuppressed and immunocompetent patients. ALERT may also indicate that a patient's COVID vaccine series is "complete" after the third dose.

COVID-19 UPDATE – Oregon Board of Pharmacy (OBOP) Information January 7, 2022

COVID-19 Updates from the Oregon Health Authority (OHA)

- **Updated OHA COVID-19 Vaccine Protocol**
  On 1/7/2022, the OHA Public Health Division Immunization Program updated the COVID-19 Vaccine Pharmacy Protocol for Immunization to include:

  - People who received the Moderna COVID-19 vaccine as their primary series are recommended to get a booster after 5 months instead of 6 months.

COVID-19 UPDATE – Oregon Board of Pharmacy (OBOP) Information January 6, 2022

COVID-19 Updates from the Oregon Health Authority (OHA)

- **Updated OHA COVID-19 Vaccine Protocol**
  On 1/6/2022, the OHA Public Health Division Immunization Program updated the COVID-19 Vaccine Pharmacy Protocol for Immunization to include:

  - People aged 12-17 years should receive a booster shot 5 months after their initial Pfizer-BioNTech vaccination series. At this time, only the Pfizer-BioNTech COVID-19 vaccine is authorized and recommended for adolescents aged 12-17 years old.

- People who received the Pfizer-BioNTech COVID-19 vaccine as their primary series are recommended to get a booster after 5 months instead of 6 months.

- Children aged 5-11 years who are moderately or severely immunocompromised should receive an additional primary dose of the Pfizer-BioNTech COVID-19 vaccine 28 days after their second shot.

Assistant Secretary for Preparedness and Response (ASPR) Pauses Shipping of Bamlanivimab and Etesevimab Together, Etesevimab Alone, and REGEN-COV

On 12/23/2021, it was announced that circulating SARS-CoV-2 viral variants, including Omicron, may be associated with resistance to monoclonal antibodies. Health care providers should review the Antiviral Resistance information in the Healthcare Provider Fact Sheet for each authorized therapeutic for details regarding specific variants and resistance. The Centers for Disease Control and Prevention (CDC) publishes information about circulating variants in the United States by region. The frequency of the Omicron variant is increasing throughout the U.S. and health care providers should refer to these frequency data as they choose a therapeutic option for their patients.

FDA updated the Health Care Provider Fact Sheets for bamlanivimab and etesevimab administered together, REGEN-COV, and sotrovimab with specific information regarding expected activity against the Omicron variant (B.1.1.529/BA.1). These data show that it is unlikely that bamlanivimab and etesevimab administered together or REGEN-COV will retain activity against this variant. Based on similar cell culture data currently available, sotrovimab appears to retain activity against the Omicron variant.

ISMP Special Alert: Dispensing Information on EUA of Paxlovid (nirmatrelvir and ritonavir)

Emergency use of Paxlovid is indicated for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death. Special dosing considerations are required for patients with moderate renal impairment, which require dispensing pharmacists to remove tablets from the blister cards and apply a manufacturer-provided pre-printed sticker with instructions.

COVID-19 UPDATE – Oregon Board of Pharmacy (OBOP) Information December 23, 2021

Public Health Emergency Declaration Extensions

Oregon's public health emergency declaration (EO 21-36) was extended effective 12/21/2021 and through 6/30/2022, unless extended by Governor Brown. The extension is to support ongoing COVID-I9 vaccination, response and recovery efforts. The federal emergency declaration (COVID-19) was last renewed by U.S. Department of Health and Human Services (HHS) Secretary Xavier Becerra effective 10/18/2021 and through 01/19/2022, unless renewed by Secretary Becerra.

COVID-19 UPDATE – Oregon Board of Pharmacy (OBOP) Information December 20, 2021

Public Health Emergency Declarations

While there is a declaration of emergency as outlined in OAR 855-007-0010, OAR 855-007-0050 applies. Oregon's emergency (EO 21-15) currently ends 12/31/2021 unless extended by the Governor. The federal

emergency (COVID-19) currently ends 1/13/2022 (90 days from date of signature) unless extended by the President.
Per 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 must 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, and is codified in ORS 402.250 and Public Law 105-381.
- 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 402.105 and Public Law 104-321.

COVID-19 Updates from the Oregon Health Authority (OHA)

- **Updated OHA COVID-19 Vaccine Protocol**

  On 12/16/2021, the OHA Public Health Division Immunization Program updated the COVID-19 Vaccine Pharmacy Protocol for Immunization to include:

  - A preferential recommendation for the use of Pfizer and Moderna mRNA vaccines over the Janssen Ad26 vaccine for people aged ≥18 years.

  This recommendation occurred after both the CDC and the Western States Scientific Safety Review Workgroup endorsed the updated recommendations made by the Advisory Committee on Immunization Practices (ACIP) for the prevention of COVID-19, expressing a clinical preference for individuals to receive an mRNA COVID-19 vaccine over Johnson & Johnson's COVID-19 vaccine for those 16 and over, given their greater effectiveness and stronger safety profile. ACIP's unanimous recommendation followed a robust discussion of the latest evidence on vaccine effectiveness, vaccine safety and rare adverse events, and consideration of the U.S. vaccine supply.
  On December 14, 2021, the FDA announced revisions to the Janssen COVID-19 Vaccine Fact Sheet for Heath Care Providers Administering Vaccine (Vaccination Providers) and the Fact Sheet for Recipients and Caregivers. The fact sheets will now include a Contraindication to the administration of the Janssen COVID-19 Vaccine to individuals with a history of thrombosis with thrombocytopenia following the Janssen COVID-19 Vaccine or any other adenovirus-vectored COVID-19 vaccine, and to update the information about the risk of thrombosis with thrombocytopenia syndrome or TTS following vaccination.

- **Pfizer COVID-19 Vaccine Transition to New Formulation (Gray Cap) for ages 12+.**

  Pfizer has announced changes to their COVID-19 vaccine for ages 12+. The transition from the original Pfizer (purple cap) to the new Pfizer (gray cap) will start in late December or early January. The changes include the storage, handling, and minimum order quantity of the vaccine.
  The new Pfizer COVID-19 vaccine (gray cap) doses will:

  - Have a different shipping quantity: 300 dose increments (five cartons of 10 6-dose vials)
  - Arrive in a shipping container like pediatric Pfizer (10 kg of dry ice) that cannot be used for storage or reused; providers must return the data logger
  - Be stored like pediatric Pfizer: until the expiration date in ultracold temperatures, up to 10 weeks in fridge (2 to 8C) but no standard freezer storage is allowed

- Require no diluent; the same volume of vaccine is used: 0.3mL
- In terms of eligible population, be interchangeable with the purple cap, and can be substituted for one another within an individual's series.

Pharmacies are encouraged to print this chart comparing Pfizer COVID-19 vaccine products.

COVID-19 UPDATE – Oregon Board of Pharmacy (OBOP) Information December 10, 2021

OTC COVID-19 Antigen Self-Test Approved and Added to Protocol Compendia

On 12/3/2021, the Public Health and Pharmacy Formulary Advisory Committee (PHPFAC) approved a protocol for the pharmacist prescribing of OTC COVID-19 Antigen Self-Tests. On 12/10/2021, a temporary rule was filed that adds the COVID-19 Antigen Self-Test to the Protocol Compendia based on the PHPFAC's recommendation. Per OAR 855-020-0300(2)(d) A pharmacist may prescribe, via statewide drug therapy management protocol and according to rules outlined in this Division, an FDA-approved drug and device listed in the following compendium: Conditions - COVID-19 Antigen Self-Test Protocol (v. 12/2021).

During the COVID-19 pandemic, patients need access to affordable COVID-19 antigen self-tests. Some insurance carriers (including Oregon Medicaid) will cover all COVID-19 testing products authorized by Emergency Use Authorization. By allowing pharmacists to order/prescribe COVID-19 antigen self-tests, insurance can be billed on the patient's behalf increasing access to self-tests and pharmacists can counsel patients on their proper use.

All prescribing pursuant to the Formulary and Protocol Compendia must adhere to regulations outlined in OAR 855-020-0110 and OAR 855-020-0120.
Oregon Health Authority Fax to Pharmacies (11/19/2021): Fee-for-service coverage of COVID-19 home testing policy update

Temporary Pharmacy Closures OAR 855-041-1092

On 12/10/2021, temporary rule OAR 855-041-1092 Pharmacy Closures was adopted. This rule supersedes Board Recommendations when a Pharmacy Temporarily Closes issued 11/19/2021.

(1) Temporary Closing. Unless subject to an exemption in OAR 855-041-1092(3), when a pharmacy is temporarily closed to the public the pharmacy must:

(a) Post notification of closure on each building entrance and each pharmacy entrance as soon as the need to deviate from the posted hours is known by the pharmacy, but no later than 2 hours after the temporary closure begins. The posting must include:

(A) Estimated period of time the pharmacy will be closed; and

(B) Options for prescription pick-up (e.g. another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions).

(b) Post notification of closure on each telephone greeting and pharmacy operated internet (e.g. website, social media, mobile applications) as soon as possible. The posting must include:

(A) Estimated period of time the pharmacy will be closed; and

(B) Options for prescription pick-up (e.g. another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions).

(c) If the pharmacy is temporarily closed greater than 2 consecutive business days, notify the board office as soon as possible but no later than 72 hours after the temporary closure begins with the date and time the closure began, anticipated date and time of re-opening, and the reason for the temporary closure.

(2) Federal and state holidays are exempt from the requirements of (1).

(3) Emergency closing. If pharmacy is closed suddenly due to fire, destruction, natural disaster, death, property seizure, eviction, bankruptcy, or other emergency circumstances and the pharmacist-in-charge cannot provide notification as required in (1), the pharmacist-in-charge must comply with the provisions of (1) as far in advance or as soon after the closing as allowed by the circumstances.

COVID-19 Updates from the Oregon Health Authority (OHA)

- **Updated OHA COVID-19 Vaccine Protocol**
  On 12/9/2021, the OHA Public Health Division Immunization Program updated the COVID-19 Vaccine Pharmacy Protocol for Immunization to include:
  - People aged 16-17 years who completed an initial Pfizer series are eligible for a Pfizer booster doses ≥6 months after their last dose.
  - People aged ≥18 years may receive booster doses of any brand of vaccine, regardless of the vaccine received for the initial dose(s) of the series.
    - People aged ≥18 years who received an initial mRNA vaccine series (Pfizer or Moderna) are eligible for a booster dose ≥6 months after their previous dose.
    - People aged ≥18 years who received an initial Johnson & Johnson vaccine are eligible for a booster dose ≥2 months after their previous dose.

- **OHA Supplemental Programs for Pharmacies related to COVID-19**
  - Supplemental Compensation- Pharmacies engaged in equity measures can apply for an additional $35 per COVID-19 vaccine dose administered.
  - Supplemental Staffing- Independent pharmacies can request temporary staffing to increase community access to COVID-19 services.

NAN Alert on Age-Related COVID-19 Vaccine Mix-Ups

The National Alert Network (NAN) has issued an alert about Age-Related COVID-19 Vaccine Mix-Ups. Since the US Food and Drug Administration (FDA) authorized the emergency use of a specific formulation (10 mcg/0.2 mL) of the Pfizer-BioNTech coronavirus disease 2019 (COVID-19) vaccine for children ages 5 through 11 years, reports of mix-ups with the Pfizer-BioNTech COVID-19 vaccine formulation intended for individuals 12 years and older (30 mcg/0.3 mL) have been pouring in. Most of the mix-ups occurred in outpatient or ambulatory care settings such as public health clinics, community pharmacies, physician practices, and outpatient clinics. Based on reports sent to the ISMP National Vaccine Errors Reporting Program (ISMP VERP) involving hundreds of children, and the fact that adverse event reporting programs do not receive all the actual cases, it is likely that thousands have been impacted. Some children ages 12 and older received the formulation intended for children 5 to 11 years, resulting in underdoses. Other

children ages 5 to 11 years received the formulation intended for individuals 12 years and older, resulting in overdoses. Some errors are due to vial or syringe mix-ups. In other errors, healthcare providers incorrectly thought it was acceptable if only 10 mcg of the formulation intended for individuals 12 years or older was administered to children 5 to 11 years, either as 0.1 mL (10 mcg) or by diluting the 10 mcg dose in a syringe to 0.2 mL. For more detailed information on these errors, please read the alert.

COVID-19 UPDATE – Oregon Board of Pharmacy (OBOP) Information November 22, 2021

Updated OHA COVID-19 Vaccine Protocol

On 11/19/2021, the OHA Public Health Division Immunization Program updated the COVID-19 Vaccine Pharmacy Protocol for Immunization to include:

- People aged ≥18 years who completed an mRNA vaccine series are eligible for booster doses ≥6 months after their last dose.
- People aged ≥18 years who received the Johnson & Johnson vaccine are eligible for a booster dose ≥2 months after their previous dose.
- Booster doses may be any brand of vaccine, regardless of the vaccine received for the initial dose(s) of the series.
- Moderna's presentation has changed to 10-dose vials.

COVID-19 UPDATE – Oregon Board of Pharmacy (OBOP) Information November 19, 2021

Accurate Hours of Pharmacy Operation OAR 855-041-1015(3)

On 11/19/2021, temporary rule OAR 855-041-1015(3) was adopted.
(3) A Pharmacy must conspicuously display accurate hours of operation at each pharmacy entrance, on each telephone greeting, and pharmacy-operated internet (e.g. website, social media, mobile applications).

Board Recommendations when a Pharmacy Temporarily Closes

The board is aware of an increase in temporary pharmacy closures. If a pharmacy is temporarily closed to the public, the pharmacy should:

- Post updated hours as required in OAR 855-041-1015(3) as soon as the need to deviate from the posted hours is known by the pharmacy.
- Provide notice of alternative options for prescription pick-up.
- Provide the date and time the pharmacy will reopen to the public.
- Configure systems to provide notification to providers and patients of the temporary closure and prevent receipt of new prescriptions or refill requests.
- Notify the board office as soon as possible but no later than 72 hours after the temporary closure begins.

COVID-19 UPDATE – Oregon Board of Pharmacy (OBOP) Information November 3, 2021

Order Authorizing Pharmacists to Administer Vaccines to Persons ≥ 3 Years of Age

Per ORS 689.645(1) In accordance with rules adopted by the State Board of Pharmacy under ORS 689.205, a pharmacist may:
(a) Administer vaccines:
(A) To persons who are seven years of age or older; or

(B) If authorized by the Governor under ORS 433.441 or the Public Health Director under ORS 433.443 or 433.444, to a person three years of age or older.

On 10/22/2021, Oregon Public Health Director, Rachel Banks, issued an order based on the authority provided to her under ORS 433.444. The order states that "during the current outbreak and epidemic of COVID-19, I am authorizing the following:

1. Pharmacists licensed under ORS chapter 689, may administer COVID-19 vaccines to eligible persons who are three years of age or older, as authorized by the FDA and the CDC.
2. Pharmacists licensed under ORS chapter 689, may administer any FDA approved and CDC recommended influenza vaccine to persons who are three years of age or older."

This order will remain in effect during the current COVID-19 declaration of emergency under EO 21-15, unless terminated earlier or extended. Updated influenza vaccine and COVID vaccine protocols were issued by OHA (see below). NOTE: While the order allows COVID vaccine to age 3 and older, no authorization exists to vaccinate children age 3-4 at this time.
Information regarding the Oregon Board of Pharmacy Statement on Immunization Services Under DHHS Guidance & PREP Act 3rd Amendment allowing qualified pharmacy technicians and State-authorized pharmacy interns acting under the supervision of a qualified pharmacist to administer vaccines to persons ages three or older was included in the 12/4/2020 OBOP COVID Communication Update.

Updated OHA Vaccine Protocols:

- **Influenza Vaccine for People ≥ 3 Years of Age**
  On 10/25/2021, the OHA Public Health Division Immunization Program updated the Influenza Vaccine (IIV and LAIV) Pharmacy Protocols for Immunization for to include:
  - People ≥ 3 years of age

- **COVID Vaccine for People ≥ 5 Years of Age**
  On 11/2/2021, the OHA Public Health Division Immunization Program updated the COVID-19 Vaccine Pharmacy Protocol for Immunization to include:
  - Children 5–11 years of age may be vaccinated with a new pediatric, 10mcg formulation of Pfizer vaccine. For the Pfizer pediatric formulation:
    - The vials will have orange caps and borders to differentiate the vials from the adolescent/adult formulation that utilizes purple or gray caps and borders.
    - Each vial will need 1.3 mL of diluent (sterile 0.9% Sodium Chloride Injection, USP) and once mixed will contain 10 doses
    - The dosing schedule is two 10mcg/0.2mL doses administered IM 21 days apart
    - Please pay very careful attention to the vaccine storage and handling section of the protocol– the pediatric product cannot be stored at regular freezer temperatures. There are also significant differences in the conditions for storing reconstituted vaccine.
    - There is a different EUA Fact Sheet specific to the pediatric formulation that must be given to the patient or caregiver.
  - The updated COVID vaccine protocol also includes that Moderna vials have a limit of 20 needle punctures of the vial stopper. If using a 14- dose vial for booster doses, 20 doses is

the maximum number that can be withdrawn from a single vial. Any remaining doses in the vial after the 20th puncture should be discarded.

COVID-19 UPDATE – Oregon Board of Pharmacy (OBOP) Information October 22, 2021

Updated OHA COVID-19 Vaccine Protocol: Booster Dose for J&J and Moderna COVID Vaccines

On 10/22/2021, the OHA Public Health Division Immunization Program updated the COVID-19 Vaccine Pharmacy Protocol for Immunization to include:

- Booster doses:
  - The following groups of people who completed a two-dose series of Moderna or Pfizer COVID vaccine ≥ 6 months ago are eligible for a booster dose:
    - All persons ≥65 years of age,
    - Residents ≥18 years of age living in long-term care settings,
    - People ≥18 years of age with underlying medical conditions, or
    - People ≥18 years of age who live or work in high-risk settings.
  - The following group of people who completed one-dose series of J&J COVID vaccine ≥ 2 months ago are eligible for a booster dose:
    - People ≥18 years of age
  - Booster doses may be any brand of vaccine, regardless of the vaccine received for the initial dose(s) of the series.
  - Note: Booster doses of Pfizer (30mcg/0.3mL) and J&J (5×10^{10} viral particles/0.5mL) are the same dose/volume as the original doses; booster doses of Moderna doses (50mcg/0.25mL) are a different dose/volume than the original doses (100mcg/0.5mL).
- 3rd doses: Immunocompromised persons receiving a 3rd dose should receive the same vaccine brand as their first two doses, as in that case the 3rd dose is not considered a booster dose.

COVID-19 UPDATE – Oregon Board of Pharmacy (OBOP) Information October 18, 2021

Compliance with the Oregon Health Authority's COVID-19 Requirements

On 10/18/2021, temporary rule OAR 855-007-0088 was adopted. It obligates OBOP licensees and registrants to comply with the Oregon Health Authority's COVID-19 Requirements during declared emergencies including, but not limited to:

- OAR 333-019-1010 COVID-19 Vaccination Requirement for Healthcare Providers and Healthcare Staff in Healthcare Settings
- OAR 333-019-1011 Masking Requirements to Control COVID-19 in Health Care Settings
- OAR 333-019-1025 Masking Requirements for Indoor and Outdoor Spaces

Additional information regarding these rules was included in the 9/1/2021 OBOP COVID Communication Update.

Updated OHA Immunization Protocols: Adverse Events and Other Vaccines

On 8/10/2021, OBOP notified licensees via the COVID Communication Update that the currently posted immunization protocols expiring on July 31, 2021 had been extended through September 30, 2021 by OHA. During September 2021, OHA published updated protocols for Guidelines for Managing Adverse Events and

other routine vaccines including Hepatitis A, MMR, Shingrix, and Varicella. Per the updated Guidelines for Managing Adverse Events protocol, pharmacies are required to stock either 1 MDV or 2 SDV of diphenhydramine 50 mg/mL injectable IM as diphenhydramine IM is now required when following the protocol for urticaria.

NAN Alert on Mix-Ups Between the Influenza Vaccine and COVID-19 Vaccines

The National Alert Network (NAN) has issued an alert about Mix-Ups Between the Influenza Vaccine and COVID-19 Vaccines. Since the 2021-22 influenza (flu) vaccine became available last month, the Institute for Safe Medication Practices (ISMP) has received 16 cases of accidental influenza and coronavirus disease 2019 (COVID-19) vaccine mix-ups. All reports were sent by consumers or healthcare practitioners via one of the ISMP medication error reporting programs. Most of the mix-ups occurred in patients who consented to a flu vaccine but received one of the COVID-19 vaccines instead. In three cases, patients received the flu vaccine instead of the intended COVID-19 vaccine. All the events occurred in community/ambulatory care pharmacies.

Given that flu season is already a busy time for vaccinations on top of staffing and workload challenges, many pharmacies are facing unprecedented workload pressures. Since many of the errors were reported by consumers, details about the contributing factors were not provided in many cases. Please use safe, standardized processes to avoid vaccine mix-ups in your practice.

COVID-19 UPDATE – Oregon Board of Pharmacy (OBOP) Information September 24, 2021

Updated OHA COVID-19 Vaccine Protocol: Booster Dose for Pfizer COVID mRNA Vaccine

On 9/24/2021, the OHA Public Health Division Immunization Program updated the COVID-19 Vaccine Pharmacy Protocol for Immunization to include:

- Added recommendations for booster doses for all persons ≥ 65 years of age and for patients ≥ 18 years of age with underlying conditions or who work in high-risk occupations.
    - The following groups of people who completed a two-dose series of Pfizer mRNA vaccine ≥ 6 months ago are eligible for a booster dose:
        - People ≥ 65 years of age; or
        - People ≥ 18 years of age with a self-attested underlying medical condition; or
        - People ≥ 18 years of age who self-report working in a high-risk occupation.
    - Booster doses are not currently recommended for persons who received Moderna or Johnson and Johnson COVID vaccines.

Ending Operational Allowances Granted Early in the Pandemic/Public Health Emergency

In board communications regarding the PHE between March 2020 and May 2020, pharmacies were provided with some operational allowances that would sunset at the end of the PHE; however, due to the lingering nature of the pandemic the board is notifying licensees and registrants that the following allowances will cease effective 12/31/2021:

- Delay of the pharmacy's annual CS inventory
- Delay of lapsed CPR certification renewal for vaccine-certified pharmacists
- Delay of lapsed PECs and SECs certification renewal
- Temporary/mobile pharmacy registrations

US Department of Health and Human Services (DHHS) PREP Act 9th Amendment

On 9/10/2021 the U.S. Department of Health and Human Services (DHHS) issued an Ninth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act (PREP Act) for Medical Countermeasures Against COVID–19 and Republication of the Declaration. This amendment:

- Provides liability immunity to and expands the scope of authority for licensed pharmacists to order and administer select COVID 19 therapeutics to populations authorized by the FDA and for pharmacy technicians and pharmacy interns to administer COVID 19 therapeutics to populations authorized by the FDA when certain criteria are met

Under the PREP Act and the Declaration, a qualified person is a covered person. Subject to certain limitations, a covered person is immune from suit and liability under federal and state law with respect to all claims for loss resulting from the administration or use of a covered countermeasure if a declaration under the PREP Act has been issued with respect to such countermeasure.

On 11/30/2020, the Oregon Board of Pharmacy issued a statement that it will not take disciplinary action against persons who act in accordance with DHHS guidance considering DHHS's position that state law is preempted. The Board does not take a position on whether DHHS's position on the preemption of state law is valid. If a complaint is received relating to activities covered under DHHS guidance, the Board will expect the licensee to provide documentation of full compliance. Failure to do so may result in disciplinary action.

Oregon Safe + Strong

As a nation we have found ourselves in and out of crisis response for more than a year and a half. For health care providers on the front line, this is even more true. To put it mildly, this has been exhausting, both physically and emotionally. It is helpful to discuss what is happening in a supportive and safe environment. Validation of your experiences and acknowledgement of your emotional and physical reactions is helpful. There are people in your area who are here to help. If you've been affected by the ongoing pandemic, there are resources and support for you and those you love. Connect with counselors, support groups and local county resources to get the help you need.

If you are concerned about the changes you are experiencing, reach out to your employers Employee Assistance Program or a local behavioral health counselor. In addition, no matter where you are in Oregon, the Safe + Strong Helpline is available by calling 800-923-HELP (4357). Safe + Strong support is confidential. Confidential means your conversation is private. No file is created in your name. Safe + Strong also maintains a website with many resources including: COVID-19 vaccine, COVID-19 safety, mental and emotional health, community resources and community partners. Pharmacists, if you are concerned about your own mental health and/or substance use, the Professional Recovery Network of Oregon (PRN) is a collaborative, volunteer program linking licensed professionals struggling with substance use or mental health disorders to critical recovery information and resources.

As the pandemic continues: Be patient with yourself, take extra self-care measures and reach out for help when you need it!

COVID-19 UPDATE – Oregon Board of Pharmacy (OBOP) Information September 1, 2021

COVID-19 Monoclonal Antibody Protocol Approved and Added to Protocol Compendia

On 8/31/2021, the Public Health and Pharmacy Formulary Advisory Committee (PHPFAC) approved a protocol for the pharmacist prescribing and subcutaneous administration of COVID monoclonal antibodies (mAb) with REGEN-COV™. On 9/1/2021, a temporary rule was filed that adds the COVID-19 Monoclonal Antibody protocol to Protocol Compendia based on the PHPFAC's 8/31/2021 recommendation. Per OAR 855-020-0300(2)(c) A pharmacist may prescribe, via statewide drug therapy management protocol and according to rules outlined in this Division, an FDA-approved drug and device listed in the following compendium: Conditions - COVID-19 Monoclonal Antibody Protocol (v. 08/2021).

COVID mAb treatments have the potential to save lives, keep COVID-19 patients out of the hospital and relieve the current burden on Oregon's health care system. REGEN-COV™ is free of charge to the patient and the requesting treatment sites, as the United States government is paying for the product. While monoclonal antibody treatments are available for direct ordering through HHS, OHA can be contacted with questions: ORESF8.LogisticsChiefs@dhsoha.state.or.us

Per an Emergency Use Authorization (EUA), REGEN-COV™ is authorized for the:

- Treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death
- Post-exposure prophylaxis of COVID-19 in adult and pediatric individuals (12 years of age and older weighing at least 40 kg) who are at high risk for progression to severe COVID-19, including hospitalization or death, and are:
    - not fully vaccinated or who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination (for example, individuals with immunocompromising conditions including those taking immunosuppressive medications) and
        - have been exposed to an individual infected with SARS-CoV-2 consistent with close contact criteria per Centers for Disease Control and Prevention (CDC) or
        - who are at high risk of exposure to an individual infected with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting (for example, nursing homes, prisons)

Oregon licensed pharmacists and pharmacies should consider creating policies & procedures and train Pharmacists to provide COVID mAbs as permitted by Division 020 – Pharmacist Prescriptive Authority. All prescribing pursuant to the Formulary and Protocol Compendia must adhere to regulations outlined in OAR 855-020-0110 and OAR 855-020-0120.

COVID-19 Updates from the Oregon Health Authority (OHA)

- **Amended Rule Requires Workers in Healthcare Settings to be Fully Vaccinated**

  To prevent and slow the spread of COVID-19, all Oregon healthcare providers and healthcare staff must be fully vaccinated against COVID-19 or request an exemption by **October 18, 2021**.
  OAR 333-019-1010 is amended effective 8/25/2021. The amended rule states:
  (3) After October 18, 2021:
  (a) A health care provider or healthcare staff person may not work, learn, study, assist, observe, or volunteer in a healthcare setting unless they are fully vaccinated or have provided documentation of a medical or religious exception.

(b) An employer of healthcare providers or healthcare staff, a contractor, or a responsible party may not employ, contract with, or accept the volunteer services of healthcare providers or healthcare staff persons who are working, learning, studying, assisting, observing or volunteering at a healthcare setting unless the healthcare providers or healthcare staff persons are fully vaccinated against COVID-19 or have a documented medical or religious exception.
(4) On or before October 18, 2021, healthcare providers and healthcare staff must provide their employer, contractor or responsible party with either:
(a) Proof of vaccination showing they are fully vaccinated; or
(b) Documentation of a medical or religious exception.
As a reminder, OAR 333-019-1010 applies to any individuals, paid and unpaid working, learning, studying, assisting, observing, or volunteering in a health care setting providing direct patient or resident care or who have the potential for direct or indirect exposure to patients, residents, or infectious materials, and includes but is not limited to **any individual licensed by a health regulatory board** as defined in ORS 676.160 *(which includes Pharmacists, Interns, Certified Oregon Pharmacy Technicians, and Pharmacy Technicians)*, unlicensed caregivers, and any clerical, dietary, environmental services, laundry, security, engineering, and facilities management, administrative, billing, student, and volunteer personnel. Healthcare settings covered by this rule include **pharmacies**.

Details on medical or religious exceptions are outlined in the rules. Employers of healthcare providers or healthcare staff, contractors and responsible parties who violate any provision of this rule are subject to civil penalties of $500 per day per violation.
The new regulations are administered and enforced by the Oregon Health Authority (OHA). For additional details on the vaccination requirements and exemptions, please review the full text of the OHA rule, OAR 333-019-1010, OHA's Letter to Interested Parties and Healthcare Provider and Healthcare Staff Vaccine Rule FAQs. Questions may be directed to the Oregon Health Authority at COVID.19@dhsoha.state.or.us.

- **Oregon Healthcare Workforce COVID-19 Vaccine Uptake Dashboard**
  OHA tracks healthcare workforce COVID-19 vaccine uptake utilizing the Health Care Workforce Reporting Program (HWRP). Healthcare workers from the HWRP are included in this analysis if they self-report practicing at an Oregon location. There are two license types represented in the data for the Board of Pharmacy: Pharmacist at 79% and Pharmacy Technician at 69% vaccinated. The Healthcare Workforce COVID-19 Vaccine Uptake dashboard is updated monthly around the first week of the month.
- **COVID Vaccine FAQs- Answers from OHA**
  Q1: Can the FDA approved Pfizer-BioNTech Comirnaty product be used interchangeably with the EUA approved Pfizer-BioNTech product?
  A1: The FDA-approved Pfizer-BioNTech product COMIRNATY (COVID-19 Vaccine, mRNA) and the FDA-authorized Pfizer-BioNTech COVID-19 Vaccine under EUA have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series without presenting any safety or effectiveness concerns. Therefore, providers can use doses distributed under the EUA to administer the vaccination series for those seeking the approved vaccine. The Fact Sheet for Recipients provides additional information about both the approved and authorized vaccine. Providers should continue to use the vaccines on their shelves.
  Q2: How do we respond and act when parents quite obviously misrepresent the age of a child. (i.e. it is known that the birth year given is incorrect based on previous data obtained about the family and patient such that the child is clearly 10 or 11, but parents state they are 12.)

A2: Pharmacy staff is permitted to refuse to provide service based on verifiable age information that does not align with the approved EUA and FDA approved indications. Providing the service to a patient in this case would violate the provider agreement that providers sign with FDA/CDC to be able to administer these products pre-purchased by the federal government.

Q3: How should the pharmacy handle a physician order for off label use of FDA approved vaccine, specifically age indications?

A3: Pharmacy staff is permitted to refuse to provide service for off-label prescribing that does not align with the approved EUA and FDA approved indications. Providing the service to a patient in this case would violate the provider agreement that providers sign with FDA/CDC to be able to administer these products pre-purchased by the federal government.

- **All Healthcare Providers Must Collect and Share REALD Information with OHA by 10/1/2021 for Healthcare Visits Related to COVID-19**

  In 2020, the Oregon legislature passed House Bill 4212 (pg. 15-16) that requires health care providers to collect REALD information at health care visits related to COVID-19, and share this information with the Oregon Health Authority (OHA). Per House Bill 4212 a health care provider includes an individual licensed or certified by the State Board of Pharmacy. There are 3 implementation phases:
  - 10/1/2020- Hospitals except for licensed psychiatric hospitals, health care providers within a health system and health care providers working in a federally qualified health center.
  - 3/1/2021- Health care facilities, health care providers working in or with individuals in a congregate setting
  - 10/1/2021- All health care providers must collect and report REALD data in accordance with the REALD standards

  OHA offers two implementation guides to assist healthcare providers with implementation:
  - HB 4212 Implementation Guide
    This guide provides information to help health systems and providers meet the data collection and reporting requirements of HB 4212. Topics include:
    - Quick links: Resources, statutes and Oregon Administrative Rules
    - HB 4212 requirements: Affected providers, implementation timeline, compliance and enforcement, data collection, data reporting, patient privacy protections
    - Data collection and reporting: How to collect and submit data
    - Alignment with federal race and ethnicity reporting standards

  - REALD Implementation Guide
    This comprehensive guide to REALD provides in-depth information to facilitate implementation of the REALD data collection standards. This guide also includes information to support analysis and reporting of REALD data. Topics include:
    - REALD and what it means for Oregon
    - Understanding the REALD categories and questions
    - OHA's REALD Implementation Policy and work plan
    - Data collection: Key points and concepts
    - Data quality, analyses and reporting
    - Data collection resources
    - REALD and communities (community engagement)
    - Community engagement resources
    - References for researchers
    - Reliability and validity of the ACS disability questions

COVID-19 UPDATE – Oregon Board of Pharmacy (OBOP) Information August 24, 2021

COVID-19 Updates from the Oregon Health Authority (OHA)

- **New Rule Clarifies that Pharmacies and their Patients Must Comply with Mask Mandates**
  On 8/20/2021, the OHA Public Health Division temporarily adopted OAR 333-019-1011 which helps to prevent and slow the spread of COVID-19 by requiring health care personnel in health care settings and patients, residents, clients, and visitors in most healthcare settings to wear a mask or face covering. The rule is intended to apply to any settings not covered by Oregon Occupational Health and Safety Division (Oregon OSHA) rule, OAR 437-001-0744, or when more restrictive than Oregon OSHA requirements. To the extent any requirement in this rule conflicts with the statewide indoor masking rule in OAR 333-019-1025 and is more restrictive, this rule applies. This temporary rule is effective August 20, 2021, through February 15, 2022.

  As a reminder, OAR 333-019-1011 applies to **patients**, residents, clients and **visitors** in most healthcare settings. Healthcare settings covered by this rule include **pharmacies**. In addition the rule applies to any individuals, paid and unpaid working, learning, studying, assisting, observing, or volunteering in a health care setting providing direct patient or resident care or who have the potential for direct or indirect exposure to patients, residents, or infectious materials, and includes but is not limited to any individual licensed by a health regulatory board as defined in ORS 676.160 *(which includes Pharmacists, Interns, Certified Oregon Pharmacy Technicians, and Pharmacy Technicians)*, unlicensed caregivers, and any clerical, dietary, environmental services, laundry, security, engineering, and facilities management, administrative, billing, student, and volunteer personnel.

  People responsible for health care settings and health care personnel must adopt and follow policies requiring that health care personnel wear masks or face coverings while in a health care setting unless they are alone and in a closed room. People responsible for health care settings and health care personnel must also adopt and follow policies requiring that patients, clients, and visitors wear masks or face coverings, with limited exceptions.
  A person responsible for a health care setting or health care personnel who violates the rule may be subject to civil penalties of $500 per day per violation.
- **Recent COVID-19 Vaccine Updates**
  - **COMIRNATY®**
    On 8/23/2021, the U.S. Food and Drug Administration approved the first COVID-19 vaccine. The vaccine has been known as the Pfizer-BioNTech COVID-19 Vaccine, and will now be marketed as COMIRNATY® (koe-mir'-na-tee), for the prevention of COVID-19 disease in individuals 16 years of age and older. The vaccine also continues to be available under emergency use authorization (EUA), including for individuals 12 through 15 years of age and for the administration of a third dose in certain immunocompromised individuals. There is not an anticipated update to the OHA Pharmacy Immunization Protocols due to this approval.

- **Interchangeability of FDA authorized and FDA approved COVID-19 Products**

  The FDA-approved Pfizer-BioNTech product COMIRNATY® (COVID-19 Vaccine, mRNA) and the FDA-authorized Pfizer-BioNTech COVID-19 Vaccine under EUA have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series without presenting any safety or effectiveness concerns. Therefore, providers can use doses distributed under the EUA to administer the vaccination series for those seeking the approved vaccine. The Fact Sheet for Recipients and Caregivers provides additional information about both the approved and authorized vaccine. Providers should continue to use the vaccines on their shelves.

- **CDC COVID-19 Vaccination Program Provider Agreements and Off-Label Use of the Vaccine**

  Providers of COVID-19 vaccine via a CDC agreement are responsible for adhering to all requirements outlined in the agreement. Specifically, providers are reminded that they must administer COVID-19 vaccines in accordance with all program requirements and recommendations of CDC, the Advisory Committee on Immunization Practices (ACIP), and the U.S Food and Drug Administration (FDA). This applies to both EUA and FDA-approved COVID-19 vaccines. Accordingly, use of these products outside of those that have been approved and authorized by FDA (often referred to as "off-label use") is not recommended as it would violate the provider agreement and could expose providers to the following risks:
  - Administration of the product off label may not be covered under the PREP Act or the PREP Act declaration; therefore, providers may not have immunity from claims.
  - Individuals who receive an off-label dose may not be eligible for compensation under the Countermeasures Injury Compensation Program after a possible adverse event.
  - CDC has defined the scope of the CDC COVID-19 Vaccination Program in terms of how the USG-provided vaccines may be used in the program. Providers giving off-label doses would be in violation of the CDC Program provider agreement potentially impacting their ability to remain a provider in the CDC program.
  - Administration fees may not be reimbursable by payers.

- **COVID-19 Booster Shots for all Americans Receiving mRNA vaccines**

  On 8/18/2021, public health and medical experts from the U.S. Department of Health and Human Services (HHS) released a media statement related to COVID-19 booster shots for the mRNA vaccines. "Based on our latest assessment, the current protection against severe disease, hospitalization, and death could diminish in the months ahead, especially among those who are at higher risk or were vaccinated during the earlier phases of the vaccination rollout," read the statement. "For that reason, we conclude that a booster shot will be needed to maximize vaccine-induced protection and prolong its durability."

  The current administration is prepared to offer COVID-19 booster shots for all Americans starting the week of Sept. 20 and eight months after an individual's second dose of an mRNA vaccine series. (HHS expects more data on the need for a potential Johnson & Johnson booster shot in the coming weeks.)

  Before any booster shots are distributed, the U.S. Food and Drug Administration (FDA) must first review the safety and effectiveness of administering booster doses of the Pfizer and Moderna vaccines. The Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) will then review the FDA's evaluation. When the FDA and ACIP complete their reviews, the Western States Scientific Safety Review Workgroup will assess the

recommendation. Once the workgroup finishes its analysis, OHA will establish further guidance for booster shots in Oregon and update the Pharmacy Immunization Protocols to reflect these updates.

COVID Monoclonal Antibodies

There will be a Special Meeting of the Public Health and Pharmacy Formulary Advisory Committee to consider a protocol for the administration of casirivimab and imdevimab (REGEN-COV™) for treatment and prevention of COVID-19 by pharmacists on Thursday 8/26/2021 6-8pm. Please view the special meeting notice for additional detail. Licensees can learn more about this therapy via an OHA webinar on COVID Monoclonal Antibodies being held on Thursday 8/26/2021 12-1 pm. You can register here for the webinar.

US Department of Health and Human Services (DHHS) PREP Act 8th Amendment

On 8/4/2021 the U.S. Department of Health and Human Services (DHHS) issued an Eighth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act (PREP Act) for Medical Countermeasures Against COVID–19 and Republication of the Declaration. This amendment:

- Clarifies that qualified pharmacy technicians and interns are Qualified Persons covered by the Declaration.
- Expands the authorization for qualified pharmacy technicians and interns to administer seasonal influenza vaccines under the supervision of a pharmacist to persons aged 19 and older consistent with ACIP recommendations.

Under the PREP Act and the Declaration, a qualified person is a covered person. Subject to certain limitations, a covered person is immune from suit and liability under federal and state law with respect to all claims for loss resulting from the administration or use of a covered countermeasure if a declaration under the PREP Act has been issued with respect to such countermeasure.

On 11/30/2020, the Oregon Board of Pharmacy issued a statement that it will not take disciplinary action against persons who act in accordance with DHHS guidance considering DHHS's position that state law is preempted. The Board does not take a position on whether DHHS's position on the preemption of state law is valid. If a complaint is received relating to activities covered under DHHS guidance, the Board will expect the licensee to provide documentation of full compliance. Failure to do so may result in disciplinary action.

COVID-19 UPDATE – Oregon Board of Pharmacy (OBOP) Information August 17, 2021

COVID-19 Updates from the Oregon Health Authority (OHA)

- **Updated OHA COVID-19 Vaccine Protocol: 3rd Dose mRNA Vaccines for Moderate to Severely Immunocompromised Individuals**

  On 8/16/2021, the OHA Public Health Division Immunization Program updated the COVID-19 Vaccine Pharmacy Protocol for Immunization to include:

  - Moderate to severely immunocompromised persons should be offered a third dose of either Pfizer or Moderna COVID-19 vaccine, depending on the brand received previously. There is currently no indication for additional doses of Johnson and Johnson vaccine.
  - Conditions causing moderate to severe immunodeficiency include:
    - Active treatment for solid tumor and hematologic malignancies
    - Receipt of solid-organ transplant and taking immunosuppressive therapy

- Receipt of CAR -T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge, Wiskott-Aldrich syndromes)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids (i.e., ≥20 mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, TNF blockers, and other biologic agents that are immunosuppressive or immunomodulatory.

In addition, the updated protocol requires all administered COVID-19 doses to be reported to ALERT IIS within 72 hours of administration.

- **Reinstatement of Statewide Masking Mandate**

  On 8/13/2021, the OHA Public Health Division temporarily adopted OAR 333-019-1025 requiring masks to be worn in indoor spaces in Oregon. This temporary rule is effective August 13, 2021, through February 8, 2022.

  The temporary rule is in response to the significant increase in COVID-19 cases and the significant decrease in hospital bed capacity in Oregon as a result of spread of the Delta variant.

  COVID-19 undergoes frequent mutations as it replicates, which over time has resulted in variants that are more transmissible, cause more severe disease, or have other features of public health concern such as decreased vaccination effectiveness. At the time of this rule adoption, the Delta variant made up the vast majority of sequenced specimens in Oregon. The Delta variant is approximately two to three times more infectious than early wild-type COVID-19 variants. There is emerging evidence that people infected with the Delta variant have similar viral loads regardless of vaccination status suggesting that even vaccine breakthrough cases may effectively transmit this variant.

  COVID-19 infection is transmitted predominately by inhalation of respiratory droplets generated when people cough, sneeze, sing, talk, or breathe. Studies show that masks and face coverings block the release of respiratory droplets into the environment and can reduce the wearer's exposure to droplets. COVID-19 viral particles spread between people more readily indoors than outdoors. In the interest of public health, individuals are required to wear a mask or face covering when in indoor spaces defined as follows:

  > "Indoor spaces" mean anywhere indoors, including but not limited to public and private workplaces, businesses, indoor areas open to the public, building lobbies, common or shared spaces, classrooms, elevators, bathrooms, transportation services and other indoor spaces where people gather for any purpose. An indoor space does not include a private residence, or a private automobile used for personal use that is not used for ride sharing.

  If you have any questions, please send an email to COVID.19@dhsoha.state.or.us.

COVID-19 UPDATE – Oregon Board of Pharmacy (OBOP) Information August 10, 2021

COVID-19 Updates from the Oregon Health Authority (OHA)

- **New Rule Requires Workers in Health Care Settings to be Fully Vaccinated or Tested Weekly**

  OAR 333-019-1010 helps to prevent and slow the spread of COVID-19 by requiring health care personnel and healthcare staff who work in healthcare settings to either be fully vaccinated against COVID-19 or be tested for COVID-19 on at least a weekly basis.

Healthcare personnel includes individuals, paid and unpaid working, learning, studying, assisting, observing, or volunteering in a healthcare setting who are providing direct patient or resident care or who have the potential for direct or indirect exposure to patients, residents, or infectious materials. This includes but is not limited to **any individual licensed by a health regulatory board** as defined in ORS 676.160 *(which includes Pharmacists, Interns, Certified Oregon Pharmacy Technicians, and Pharmacy Technicians)*, unlicensed caregivers, and any clerical, dietary, environmental services, laundry, security, engineering, and facilities management, administrative, billing, student, and volunteer personnel.

Healthcare settings covered by this rule include any place where health care, including physical or behavioral health care is delivered, including, but not limited to any health care facility or agency licensed under ORS chapter 441 or 443, such as hospitals, ambulatory surgical centers, birthing centers, special inpatient care facilities, long-term acute care facilities, inpatient rehabilitation facilities, inpatient hospice facilities, nursing facilities, assisted living facilities, adult foster homes, residential facilities, residential behavioral health facilities, **pharmacies**, hospice, vehicles or temporary sites where health care is delivered (e.g., mobile clinics, ambulances), and outpatient facilities, such as dialysis centers, health care provider offices, behavioral health care offices, urgent care centers, counseling offices, offices that provide complementary and alternative medicine such as acupuncture, homeopathy, naturopathy, chiropractic and osteopathic medicine, and other specialty centers.

An employer of healthcare providers or healthcare staff, contractors or responsible parties must have and follow a policy for:
(a) Requesting and obtaining proof of vaccination from every healthcare provider and healthcare staff person.
(b) Requiring COVID-19 testing on at least a weekly basis for any healthcare provider or healthcare staff person who is unvaccinated or has an unknown vaccination status.
(c) Maintaining documentation of weekly COVID-19 test results for any healthcare provider or healthcare staff person who is unvaccinated or has an unknown vaccination status.

Full compliance with the rule is required no later than September 30, 2021.

- **Off-label Use of COVID-19 Vaccine is Not Allowed**

  IMPORTANT REMINDER: The COVID-19 vaccine provider agreement does NOT allow for off-label use of the vaccine, including additional doses such as a second dose after a Johnson & Johnson or a third dose after a Pfizer or Moderna series.

  Oregon Health Authority continues to endorse CDC and ACIP recommendations for COVID-19 vaccine dosing. Under current conditions, CDC and ACIP do not recommend administering booster doses of the COVID-19 vaccines. Administering a booster to an individual is outside the scope of the FDA emergency use authorization (EUA). Providers writing prescriptions for additional doses of vaccine should note that this practice is outside of the EUA and not recommended. Boosters recommended by a physician beyond the EUA scope should be discussed directly with the manufacturer and FDA. Vaccines given according to the currently recommended schedule continue to be highly effective in reducing the risk of serious illness from COVID-19. Observational data confirm that currently available vaccines are effective against new variants, including the Delta variant.

- **Expired Pharmacy Immunization Protocols Online**
  Many of the currently posted immunization and pharmacy protocols expired on July 31, 2021. The Oregon Health Authority (OHA) is in the process of reviewing these expired protocols for updates and putting the most commonly used protocols into an updated format. The OHA anticipates having this complete by September 15th. Until that time, with the approval of the Immunization Program's medical director, Dr. Paul Cieslak, the OHA is extending the expiration date to September 30, 2021. The OHA does not anticipate that the needed updates to these protocols are significant or that following the currently published protocols as written will cause any issues. If you have any questions, please contact Amanda Timmons at amanda.j.timmons@dhsoha.state.or.us.

Ivermectin Prescriptions for Treating or Preventing COVID-19

The US Food and Drug Administration has not approved ivermectin for use in treating or preventing COVID-19 in humans and it has not been proven to be safe or effective for this indication. Pharmacists receiving prescriptions for ivermectin for the treatment or prevention COVID-19 should use their professional judgment in determining whether to fill them. If you have concerns related to the prescribing practices of a practitioner, it may be appropriate to reach out to their licensing board.

The following rules may apply:
OAR 855-019-0200 General Responsibilities of a Pharmacist
ORS 689.025 states that "the practice of pharmacy in the State of Oregon is declared a health care professional practice affecting the public health, safety and welfare". Pharmacy practice is a dynamic patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and consultative purposes. A pharmacist licensed to practice pharmacy by the Board has the duty to use that degree of care, skill, diligence and professional judgment that is exercised by an ordinarily careful pharmacist in the same or similar circumstances.

OAR 855-019-0210 Duties of the Pharmacist Receiving a Prescription
(2) A pharmacist receiving a prescription is responsible for:
(a) Using professional judgment in dispensing only pursuant to a valid prescription. A pharmacist shall not dispense a prescription if the pharmacist, in their professional judgment, believes that the prescription was issued without a valid patient-practitioner relationship. In this rule, the term practitioner shall include a clinical associate of the practitioner or any other practitioner acting in the practitioner's absence. The prescription must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of their professional practice and not result solely from a questionnaire or an internet-based relationship;

COVID-19 UPDATE – Oregon Board of Pharmacy (OBOP) Information June 25, 2021

Executive Order Rescinding All Remaining COVID-19 Restrictions; Continuing State Efforts to Support Ongoing COVID-19 Vaccination, Response and Recovery Efforts.

In a press conference held on 6/25/2021, Governor Brown signed a recovery-focused Executive Order 21-15 that will lift all remaining COVID-19 health and safety restrictions issued under Oregon's emergency statutes when Oregon achieves a 70% first dose adult vaccination rate or on Wednesday, June 30, whichever occurs sooner. With restrictions lifted, the state will shift to a focus on helping Oregonians and communities recover from the impacts and the economic toll of the pandemic.

With the repeal of the set of executive orders (20-66, 20-22, 21-06, 20-28, 20-19) that placed COVID-19 related restrictions on Oregonians, the recovery order extends the emergency declaration for the ongoing COVID-19 pandemic. The governor's remaining emergency authority will be limited in focus to COVID-19 recovery efforts. Under the new recovery order, masks will no longer be required statewide, but they will still be required in some places under federal guidance, including airports, public transportation and health care settings.

For pharmacies, the recovery order will maintain all of the COVID-19 emergency rules that are currently in place for pharmacies (remote work, temporary pharmacies, out of state licensees, PREP Act, etc.) and it is anticipated that there will not be a change from previous OHA interpretations pertaining to pharmacies and health care settings (see COVID communication update from 6/4/2021).

Please view the governor's press release for additional information.

COVID-19 UPDATE – Oregon Board of Pharmacy (OBOP) Information June 4, 2021

COVID-19 Updates from the Oregon Health Authority (OHA)

- **Updated OHA Guidance Documents**
  As a reminder, per OAR 855-007-0086 during a declared emergency, unprofessional conduct includes failing to comply with Oregon Health Authority (OHA) guidance implementing an Executive Order. Pharmacies are responsible for keeping up to date with the most recent guidance. The updates below are provided for pharmacy convenience.
    - On May 18, 2021 the Oregon Health Authority issued a new Statewide Reopening Guidance – Masks, Face Coverings, Face Shields
        - Under the updated guidance, people who are fully vaccinated will no longer be required to wear a mask indoors, in most public settings where vaccination status is checked. In public settings where vaccination status is not checked, masks will still be required. Businesses remain free to establish their own, more restrictive policies regarding mask usage.
        - If a business or employer chooses to no longer require masks and physical distancing, the business or employer must require visitors to show proof of vaccination and review the proof of vaccination. In that case, a business would need to have a policy for checking the vaccination status of customers and employees if they are not wearing masks. Fully vaccinated individuals would need to provide proof they are vaccinated if they want to remove face coverings and not observe physical distancing guidelines.
        - Fully vaccinated individuals are required to continue wearing a mask and observe physical distancing on public transportation and in schools, healthcare settings, homeless shelters, youth and adult correctional facilities and long-term care facilities.

- Statewide, masks, face coverings or face shields are required to be worn by all individuals at all times unless the individual is fully vaccinated, UNLESS the individual is in:
  - any setting where the owner or operator continues to require masks, face coverings or face shields in accordance with the Statewide Mask, Face Coverings, Face Shields Guidance
  - *health care settings*

- On May 20, 2021, the Oregon Health Authority issued revised
  - Statewide Reopening Guidance – Retail Stores (includes pharmacies)
  - Statewide Reopening Guidance – General Guidance for Employers

- On May 25, 2021, the Oregon Health Authority issued a revised Minor Consent Statement
  - Pharmacists are not on the list of providers who can treat minors 15 and older without parental consent under Oregon law (ORS 109.640) and so most pharmacies will require parental or guardian consent, which can be verbal or written.
  - Some pharmacists may operate at the direction of a provider listed under ORS 109.640, and in this case the pharmacist is prohibited from requiring parental or guardian consent for a minor 15 or older who is consenting to a COVID-19 vaccination.

- **OHA Interpretation of *Health Care Setting* as it Relates to Pharmacies**

  The board has received questions from licensees requesting clarification of the updated mask guidance. We understand that OHA interprets *health care settings* as they relate to pharmacies as indicated below:

  Q*: Does a health care setting include a pharmacy department in a retail store?
  A*: The pharmacy "area" is a health care setting but the entire retail store is not considered a health care setting. If there is a pharmacy inside a retail store, the following areas related to the pharmacy are considered a health care setting:
  - Any area where pharmacy staff are engaged in the pharmacy activities, including but not limited to preparing prescriptions, interacting with patients, administering vaccines.
  - Any area where patients are waiting to interact with pharmacy staff, including but not limited to waiting in a line or in a designated waiting area for the pharmacy.
  - Any area where a patient is interacting with pharmacy staff, including but not limited to dropping off /picking up a prescription or consulting with the pharmacist.

  As an example, if there is a pharmacy within a retail store, the retail store after checking for proof of vaccination, could allow an individual to enter the retail store without a mask, face covering or face shield. If that fully-vaccinated individual goes to the pharmacy to pick up a prescription, the individual would have to put their mask, face covering or face shield back on when waiting in line or in a waiting area, and when interacting with pharmacy personnel.

  Q*: Is a "closed door" pharmacy, such as a mail order pharmacy or a pharmacy in an office setting that does not directly serve or interact with the public or patients a health care setting?

A*:

- If a pharmacy is in a stand-alone building or office setting/suite within a building where the public or patients are not directly served nor interacted with, it would not be considered a health care setting.
- If a pharmacy is in a part of a health care facility or medical office that is a health care setting where the public or patients are not directly served nor interacted with in the pharmacy "area" *and* it is physically separated from areas where patients are allowed or health care is delivered, with walls from floor to ceiling and a door that remains closed when not being used, that space would not be considered a health care setting.
- If fully vaccinated individuals are permitted to be in these non-health care setting areas without a mask, face covering or face shield, they must still wear a mask, face covering or face shield within any area that is a health care setting.

COVID-19 UPDATE – Oregon Board of Pharmacy (OBOP) Information May 13, 2021

COVID-19 Updates from the Oregon Health Authority (OHA)

- **Updated OHA COVID-19 Vaccine Protocol**
  On 5/12/2021, the OHA Public Health Division Immunization Program updated the COVID-19 Vaccine Pharmacy Protocol for Immunization to:
  - Expand the age indication for Pfizer vaccine to children 12-15 years of age in addition to persons 16 years of age and older.
  - Removed the 14-day interval between COVID vaccine and other vaccines.
  - Added Polysorbate-80 has moved from contraindication to precaution for Pfizer and Moderna vaccines. It continues to be a contraindication for the Johnson & Johnson vaccine.

- **Updated OHA Guidance Documents**
  As a reminder, per OAR 855-007-0086 during a declared emergency, unprofessional conduct includes failing to comply with Oregon Health Authority (OHA) guidance implementing an Executive Order. Pharmacies are responsible for keeping up to date with the most recent guidance. The updates below are provided for pharmacy convenience.
  - On May 11, 2011 the Oregon Health Authority issued revised Statewide Reopening Guidance – Masks, Face Coverings, Face Shields
    - On April 27, 2021 the Oregon Health Authority issued revised Statewide Reopening Guidance – General Guidance for Employers

COVID-19 UPDATE – Oregon Board of Pharmacy (OBOP) Information April 26, 2021

Resuming Use of Johnson & Johnson (J&J) COVID-19 Vaccine

Vaccine providers in Oregon may now resume the use of the Johnson & Johnson COVID-19 vaccine so long as they ensure that recipients or their caregivers receive the new warning information regarding thrombosis and thrombopenia. This information must be provided in the individual's primary language or in a manner that the individual can understand, considering English language proficiency and Americans with Disabilities Act accessibility needs. Updated fact sheets including this warning have been approved by the FDA, including the Fact Sheet for Healthcare Providers administering vaccine and the Fact Sheet for Recipients and Caregivers.

Updates Regarding OBOP COVID-19 Temporary Rules

On 3/24/2021, a temporary rule was filed that removes the limit of the number of epinephrine devices that may be dispensed to an entity. Per OAR 855-041-2320(3)(b) A pharmacist may dispense epinephrine to an entity when:
(A) The epinephrine is acquired by a valid prescription presented to the pharmacy;
(B) The prescription identifies the entity as the patient for the purpose of prescribing and labeling the prescription.

COVID-19 Updates from the Oregon Health Authority (OHA)

- **OHA Epinephrine Standing Order for Entities**
  The OHA is working with Federal Long-Term Care pharmacy partners to provide a standing order for epinephrine for use in immunization events at assisted living facilities. The board has adopted a temporary rule (*see above*) to remove the quantity limit of epinephrine that can be dispensed to an entity to allow an appropriate amount epinephrine to be available in these settings.
- **Updated OHA COVID-19 Vaccine Protocol**
  On 4/6/2021, the OHA Public Health Division Immunization Program updated the COVID-19 Vaccine Pharmacy Protocol for Immunization to:
  - Include guidance that when ALERT IIS is unavailable, the Pharmacist should use available documentation and patient statement
  - Update to storage and handling for Pfizer vaccine
  - Add Johnson & Johnson COVID-19 vaccine

- **Updated OHA Guidance Documents**
  As a reminder, per OAR 855-007-0086 during a declared emergency, unprofessional conduct includes failing to comply with Oregon Health Authority (OHA) guidance implementing an Executive Order. Pharmacies are responsible for keeping up to date with the most recent guidance. The updates below are provided for pharmacy convenience.
    - On March 12, 2021 the Oregon Health Authority issued revised Statewide Reopening Guidance – Masks, Face Coverings, Face Shields
    - On April 23, 2021 the Oregon Health Authority issued revised Sector Guidance – Retail Stores.

Phone Scam

The board has become aware that licensees are receiving scam phone calls from individuals impersonating Oregon Board of Pharmacy staff members. Licensees should be cautious of giving confidential or payment information over the phone without verifying that the source is legitimate as board staff will never ask for or accept payment for any fees by phone. Scammers, claiming to be Oregon State Board of Pharmacy staff members, are calling pharmacists and saying that their facility or individual license is under investigation. Scammers may also state that they are working with Food and Drug Administration (FDA) or Drug Enforcement Administration (DEA) on a case, and further claim that the licensee is under investigation for suspicious activity or drug trafficking. In either case, the scammers claim that licensees will face disciplinary action, a revoked license, or arrest if they do not immediately pay a fine over the phone. Additionally, many scammers are "spoofing" the phone number used to call the pharmacist. Spoofing involves disguising the caller's true phone number and making it appear that the phone number is from a legitimate source. Scammers may even give a fake name and a

fraudulent inspector identification number as "proof" of identity. If the call sounds suspicious, hang up and call the board directly at 971-673-0001 or contact the board at pharmacy.board@oregon.gov

COVID-19 UPDATE – Oregon Board of Pharmacy (OBOP) Information April 13, 2021

Johnson & Johnson (J&J) COVID-19 Vaccine Pause- Effective immediately

Please pause all use of the Johnson & Johnson (J&J) COVID-19 vaccine immediately, in accordance with this joint announcement from CDC and FDA this morning. This recommendation is made in the wake of reports of six cases of cerebral venous sinus thrombosis in women 18–48 years of age, with approximately 6.8 million doses of J&J vaccine administered to date. Symptoms in these patients began 6–13 days following vaccination.

CDC is convening its Advisory Committee on Immunization Practices (ACIP) April 14, 2021 to review the relevant data. This pause in vaccination is recommended until ACIP and FDA review are completed. Today, CDC and FDA will provide additional information and answer questions at a media briefing.

These cases were flagged in the Vaccine Adverse Events Reporting System (VAERS), a component of national post-licensure vaccine safety monitoring. People who have received the J&J vaccine who develop severe headache, abdominal pain, leg pain, or shortness of breath within three weeks after vaccination should contact their health care provider.

COVID-19 UPDATE – Oregon Board of Pharmacy (OBOP) Information March 3, 2021

COVID-19 Updates from the Food and Drug Administration (FDA)

- **Emergency Use Authorization (EUA) issued for Janssen/Johnson & Johnson Covid-19 Vaccine**

  On 2/27/2021 the U.S. Food and Drug Administration issued an emergency use authorization (EUA) for the third vaccine for the prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The EUA allows the Janssen COVID-19 Vaccine to be distributed in the U.S for use in individuals 18 years of age and older.
  - Janssen COVID-19 Vaccine EUA Letter of Authorization
  - Janssen COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers
  - Janssen COVID-19 EUA Fact Sheet for Recipients and Caregivers

- **Pfizer-BioNTech Vaccine Storage/Transportation Temperature Changes-**

  On 2/25/2021 the U.S. Food and Drug Administration announced that it is allowing undiluted frozen vials of the Pfizer-BioNTech COVID-19 Vaccine to be transported and stored at conventional temperatures commonly found in pharmaceutical freezers -25°C to -15°C (-13°F to 5°F) for a period of up to two weeks. This reflects an alternative to the preferred storage of the undiluted vials in an ultra-low temperature freezer between -80ºC to -60ºC (-112ºF to -76ºF). The change is being reflected in updates to the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers).

COVID-19 Updates from the Oregon Health Authority (OHA)

- **Updated OHA COVID-19 Vaccine Protocol**

  On 3/2/2021, the Oregon Health Authority Public Health Division Immunization Program updated the COVID-19 Vaccine Pharmacy Protocol for Immunization to include the Janssen/Johnson & Johnson COVID-19 vaccine.
- **Updated OHA COVID-19 Vaccine Training**

  The list of required COVID-19 Vaccine trainings for COVID-19 vaccine providers has been updated to include the Janssen/ Johnson & Johnson COVID-19 vaccine specific trainings.

- **Updated Timeline for COVID-19 Vaccine Sequencing Phases**
  On 2/26/2021, the Oregon Health Authority and Governor Brown announced an updated schedule for vaccine distribution. An updated vaccine sequencing infographic is available with key dates and newly identified groups.

- **Updated OHA Guidance Documents**
  As a reminder, Per OAR 855-007-0086 during a declared emergency, unprofessional conduct includes failing to comply with Oregon Health Authority (OHA) guidance implementing an Executive Order. Pharmacies are responsible for keeping up to date with the most recent guidance. The updates below are provided for pharmacy convenience.
    - On February 10, 2021 the Oregon Health Authority issued revised Statewide Reopening Guidance – Masks, Face Coverings, Face Shields
    - On January 29, 2021 the Oregon Health Authority issued revised Sector Guidance — General Guidance for Employers and Organizations
    - On January 13, 2021 the Oregon Health Authority issued revised Sector Guidance – Retail Stores.

COVID-19 UPDATE – Oregon Board of Pharmacy (OBOP) Information February 9, 2021

COVID-19 Updates from Oregon Health Authority (OHA)

- **OHA Partner Toolkit: Helping Older Adults Get COVID-19 Vaccinations**
    - Oregon Health Authority has created a toolkit to help older adults get COVID-19 vaccinations. The toolkit will be updated twice weekly updates with the most relevant information.
    - OHA is asking healthcare providers such as pharmacists and pharmacy staff to help ensure older adults have the information they need to get COVID-19 vaccines.
    - The toolkit contains: A message from the Oregon Health Authority, Talking Points for Older Adults, Know Before You Go, Frequently Asked Questions, Template Email, Newsletter blurb, and Social cards/infographic copy.

- **OHA Get Vaccinated Oregon Tool**
    - Oregon Health Authority launched a new tool at covidvaccine.oregon.gov called Get Vaccinated Oregon.
    - OHA hopes this tool will help reduce confusion and frustration as we work together to support older adults at a time when vaccines remain in critically short supply in the U.S. and here in Oregon.
    - This tool allows all Oregonians to determine if they are currently eligible for a vaccine and register to get email alerts or text notifications when they become eligible.
    - Once eligible to be vaccinated, this tool directs users to vaccine events in their area.
    - Using this tool does not guarantee users a specific "spot in line."
    - Once eligible, notified users may use the tool to find a vaccine event in their area.
    - Visitors should scroll down to “Let’s get started” and click on the blue rectangular box.

- A chat tool will show up on the right side of the screen, and users should click affirmatively that they are seeking to find out about "vaccine eligibility."

- **OHA COVID-19 Vaccine Protocol**
  - On 2/2/2021, the Oregon Health Authority Public Health Division Immunization Program temporarily updated the COVID-19 Vaccine Pharmacy Protocol for Immunization. The 2/2/2021 update strengthened the protocol language around allergies; however, after additional consultation with allergy experts at OHSU, OHA decided that the original protocol issued 12/20/2021, which was in line with CDC recommendations, should be adhered to. OHA has pulled the 2/2/2021 version of the protocol.
  - If your pharmacy printed the protocol version posted 2/2/2021-2/5/2021, please discard this version. Please print and adhere to the protocol that is posted as of 2/8/2021 (v. 12/20/2021).

  - **VAERS Reporting Requirements After a COVID-19 Vaccination**
    - Vaccine Adverse Event Reporting System (VAERS) is a national early warning system to detect possible safety problems in U.S.-licensed vaccines. VAERS is co-managed by the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA).
      - Online reporting form or pdf-fillable form
      - YouTube video on how to fill out the form
      - VAERS and COVID FAQ
    - In addition to being required in the COVID-19 Vaccine Pharmacy Protocol, OAR 855-019-0280(5) states: The pharmacist must report adverse events as required by the Vaccine Adverse Events Reporting System (VAERS) and to the primary care provider as identified by the patient.
    - Healthcare providers are required to report to VAERS the following adverse events after COVID-19 vaccination [under Emergency Use Authorization (EUA)], and other adverse events if later revised by CDC:
      - Vaccine administration errors, whether or not associated with an adverse event (AE)
      - Serious AEs regardless of causality. Serious AEs per FDA are defined as:
        1. Death;
        2. A life-threatening AE;
        3. Inpatient hospitalization or prolongation of existing hospitalization;
        4. A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
        5. A congenital anomaly/birth defect;
        6. An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.
      - Cases of Multisystem Inflammatory Syndrome
      - Cases of COVID-19 that result in hospitalization or death
    - Healthcare providers are encouraged to report to VAERS any additional clinically significant AEs following vaccination, even if they are not sure if vaccination caused the event.

- Also report any additional select AEs and/or any revised safety reporting requirements per FDA's conditions of authorized use of vaccine(s) throughout the duration of any COVID-19 Vaccine being authorized under an Emergency Use Authorization (EUA).

US Department of Health and Human Services (DHHS) PREP Act 5th Amendment

On 1/28/2021 the U.S. Department of Health and Human Services (DHHS) issued a Fifth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act (PREP Act) for Medical Countermeasures Against COVID–19 and Republication of the Declaration. This amendment:

- Authorizes any healthcare provider who is licensed or certified in a state to prescribe, dispense, and/or administer COVID-19 vaccines in any other state or U.S. territory.
- Authorizes any physician, registered nurse, or practical nurse whose license or certification expired within the past five years to prescribe, dispense and/or administer COVID-19 vaccines in any state or U.S. territory so long as the license or certification was active and in good standing prior to the date it went inactive.
- Requires any healthcare professional described above to complete Centers for Disease Control and Prevention (CDC) COVID-19 Vaccine Training and, for healthcare providers who are not currently practicing or whose license or certification is expired, requires an on-site observation period by a currently practicing healthcare professional.

Under the PREP Act and the Declaration, a qualified person is a covered person. Subject to certain limitations, a covered person is immune from suit and liability under federal and state law with respect to all claims for loss resulting from the administration or use of a covered countermeasure if a declaration under the PREP Act has been issued with respect to such countermeasure.

On 11/30/2020, the Oregon Board of Pharmacy issued a statement that it will not take disciplinary action against persons who act in accordance with DHHS guidance considering DHHS's position that state law is preempted. The Board does not take a position on whether DHHS's position on the preemption of state law is valid. If a complaint is received relating to activities covered under DHHS guidance, the Board will expect the licensee to provide documentation of full compliance. Failure to do so may result in disciplinary action.

COVID-19 UPDATE – Oregon Board of Pharmacy (OBOP) Information January 28, 2021

SERV-OR Vaccination Call for Immunizers

The Oregon Health Authority is putting out a call to current and previously licensed healthcare workers in Oregon (including Pharmacists, Interns and Pharmacy technicians*) to register with SERV-OR to volunteer in support of COVID-19 vaccination efforts.

As you know, health care resources are strained, and communities need health care professionals who can make themselves available to join the response. Sign up today.

- What is SERV-OR? The State Emergency Registry of Volunteers in Oregon (SERV-OR) is a statewide pool of licensed physicians, nurses, pharmacists, Emergency Medical Technicians (EMTs), behavioral health providers, respiratory therapists and other health care professionals who are willing to volunteer in response to Federal, State, and/or local emergencies.
- As a licensed health care professional, you can register with SERV-OR with your local Medical Reserve Corps Unit (MRC) and the State Manager Volunteer Pool (SMVP). If you do not have a MRC unit in your area, you should join the SMVP if you meet the licensure requirements. If you do join

an MRC, you should apply to this statewide unit in addition to the local MRC in order to access statewide volunteer and training opportunities.
    - You will receive a no-cost background check and be asked to complete required training before you can deploy.
- How can you help as a volunteer professional, after registering with SERV-OR? There are several ways you may be asked to help, depending on the need. You may be asked to:
    - Administer COVID-19 Vaccine
    - Fill various logistical, administrative, or clinical support roles at mass vaccination events
    - Work from home supporting public health vaccine data entry
- You also may have colleagues who are former health care professionals, and they can be part of this effort too!
    - Previously licensed health care professional volunteers may register in SERV-OR to volunteer if their licenses expired fewer than 10 years ago and were in good standing at the time their licenses lapsed.
        - They may register at SERV-OR with their local Medical Reserve Corps Unit and the State Managed Volunteer Pool for Previously Licensed Volunteers. If they do not have a MRC unit in your area, they should join the SMVP for Previously Licensed Volunteers. If they do join an MRC, they should apply to this statewide unit in addition to the local MRC in order to access statewide volunteer and training opportunities.
        - They will receive a no-cost background check and be asked to complete required training before they can deploy.

*Note: Pharmacy technicians are not authorized to vaccinate under Oregon scope of practice laws but are authorized under the federal PREP Act.

COVID-19 UPDATE – Oregon Board of Pharmacy (OBOP) Information January 22, 2021

Oregon Health Authority (OHA) Temporary Rules for COVID-19 Vaccine Requirements

OHA recently adopted temporary rules for COVID-19 Vaccine Requirements (amending OAR 333-047-0010, 333-047-0040, 333-047-0050, adopting 333-047-1000, amending 333-049-0050) effective 01/21/2021.

- Amend OAR 333-047-0010: Adds a definition of "Authority's Immunization Registry"; Amends the definition of "State-supplied Vaccine User Vaccine Reporting Requirements and Timelines"
- Amend OAR 333-047-0040: An entity that receives COVID-19 vaccine must comply with the new temporary rule OAR 333-047-1000, in addition to the requirements of OAR 333-047-0040. Clarifies that an entity may only transfer or redistribute vaccine to an Authority enrolled provider.
- Amend OAR 333-047-0050: An entity that receives COVID-19 vaccine must comply with the reporting requirements in the new temporary OAR 333-047-1000
- Adopt OAR 333-047-1000:
    - A person or entity that receives, stores, administers or transfers COVID-19 vaccine must report:
        - All COVID-19 vaccine dose administration within 24 hours of administration.
        - All on-hand inventory on a weekly basis, no later than 5 p.m. Pacific Time on Sunday.
        - All spoiled, expired, or wasted COVID-19 vaccine to ALERT or through an OHA survey within 24 hours of knowledge or discovery.

        - All transfers within 24 hours of the transfer.
    - Vaccine related information must be reported in accordance with this rule and OAR chapter 333, division 49.
    - A person or entity receiving state-supplied COVID-19 vaccine must respond promptly (within 24 hours) to requests for information from OHA or a LPHA about vaccine storage, handling, use, administration plans, transfers, or inventory, including temperature logs.
    - Permits OHA to ask for the vaccine to be transferred to another enrolled provider if the person cannot make immediate use of the vaccine and the vaccine is needed more urgently elsewhere.
    - OHA can demand return of the vaccine or go get it if a person is not appropriately storing or handling the vaccine.
    - A person or entity receiving COVID-19 vaccine must undergo specific training
    - Civil penalties are established of $500 per day per violation of the rule
- Amend OAR 333-049-0050: An entity that receives COVID-19 vaccine must comply with the reporting and other requirements in the new temporary OAR 333-047-1000.

COVID-19 UPDATE – Oregon Board of Pharmacy (OBOP) Information January 12, 2021

Immunization Clinics

Oregon pharmacy statutes and rules allow pharmacists to participate in immunization clinics that are not affiliated with an Oregon pharmacy. When participating in immunization clinics that are not affiliated with an Oregon pharmacy, pharmacy personnel must assure that records are maintained in accordance with OAR 855-019-0290. The immunization must be documented in the patient's permanent record and the ALERT Immunization Information System. Immunizers must also have documentation of current CPR and immunization provider training. If CPR certification has lapsed during the COVID-19 public health emergency (since March 8, 2020), it should be renewed as soon as possible which may include after the public health emergency has ended if the immunizer is unable to receive updated certification during the PHE.

COVID-19 Updates from Oregon Health Authority (OHA)

- **OHA COVID-19 Vaccine Information and Training for Providers**

  Information: OHA has established a website that provides resources to support providers in COVID-19 vaccination efforts to achieve community immunity. This page is a COVID-19 vaccine providers one stop shop for all resources related to the provision of COVID-19 vaccine. On this page you can find links to key documents such as Oregon's COVID-19 Vaccination Plan, Vaccine Sequencing Plans & FAQs and links to information from the CDC, training programs, liability protection, presentations and other resources.

  Training/references: This OHA website contains links to required ALERT-IIS trainings and vaccine specific trainings and materials for providers of COVID-19 vaccine

- **OHA/OIP Vaccine Storage and Handling Equipment Funding**

  The OHA/Oregon Immunization Program (OIP) is announcing the availability of funding for vaccine storage and handling equipment for any site/facility participating in OIP's vaccine supply programs, including the Vaccines for Children (VFC) and COVID-19 vaccine programs. Allowable purchases will be reimbursed up to $1,000 per vaccination facility.

  Allowable purchases include:

- Vaccine storage units (i.e., refrigerators and freezers approved for vaccine storage). Note: NO dorm-style combined refrigerator/freezer units allowed under any circumstances.
- Temperature monitoring equipment
- Portable 'phase change material' (PCM) vaccine coolers

Click here for complete instructions and to access the required documentation and submission form.

- **OHA Updated General Guidance for Employers**

  On December 22, 2020 the Oregon Health Authority issued revised Statewide Reopening Guidance – General Guidance for Employers.

COVID-19 UPDATE – Oregon Board of Pharmacy (OBOP) Information December 22, 2020

Updates Regarding COVID-19 Temporary Rules

On 12/22/2020, temporary rule OAR 855-007-0080(11) was adopted. It states:
(11) For immunization clinics, an immunizing pharmacist may supervise as many Oregon-licensed immunizing interns as that pharmacist determines, in their own professional judgement, will maintain public health and safety.

COVID-19 Updates from Oregon Health Authority (OHA)

- **OHA COVID-19 Vaccine Protocol**
  - On 12/22/2020, the Oregon Health Authority Public Health Division Immunization Program published a COVID-19 Pharmacy Protocol for Immunization.

- **Connecting with the OHA COVID- 19 Vaccine Planning Unit:**
  - For general COVID-19 vaccine questions, please email mailto:COVID19.vaccine@dhsoha.state.or.us.
    - Depending on the volume of requests, we may not be able to respond directly to every email. We will triage questions and either refer them to the appropriate subject matter expert for response, or for more frequently received questions incorporate the responses into our communication.
  - For questions related to provider enrollment for COVID-19 vaccine, please email mailto:Vaccine.ProviderEnroll@dhsoha.state.or.us.
  - Please refer media questions related to COVID-19 and COVID-19 vaccine to the OHA Health Information Center email box: mailto:orcovid19.media@dhsoha.state.or.us.

- **CDC Communication Toolkit and EUA Fact Sheets:**
  - CDC has issued its CDC COVID-19 Communications Toolkit
    - Vaccine information for consumers, including:
      - What to expect at your vaccination appointment
      - What to expect after getting vaccinated
      - Post-vaccination considerations for healthcare personnel
      - Post-vaccination considerations for long-term care residents

- Emergency Use Authorizations (EUA) Fact Sheets
    - The FDA requires manufacturers to provide an EUA fact sheets (Pfizer-BioNTech and Moderna). These should be provided to patients and their caregivers.
        - Please note: You will not find a Vaccine Information Sheet (VIS). VIS documents are not issued for vaccines are under emergency use authorizations.
    - Translations of EUA fact sheets: CDC has indicated that we can expect FDA to translate the EUA fact sheets and post them on the FDA website by the end of the week. FDA has not indicated the specific link they will use. They have previously made materials available on their Emergency Use Authorization website. Languages that will be available include: Spanish, Russian, Chinese (Mandarin, Simplified and Traditional), Vietnamese, Somali, Korean, Arabic, Yiddish, Marshallese, Chuukese, Hmong, Mam, Burmese, Portuguese, Khmer, Mein, Haitian Creole, Polish, Hindi, Gujarati, Filipino-Tagalog.

- **OHA COVID-19 Vaccine Information Online:**
    - OHA COVID-19 vaccine landing page and
    - OHA COVID-19 provider page.

US Department of Health and Human Services (DHHS) PREP Act 4th Amendment
On 12/3/2020 the U.S. Department of Health and Human Services (DHHS) issued a Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act (PREP Act) for Medical Countermeasures Against COVID–19 and Republication of the Declaration

This amendment makes explicit that the requirement in Section V for certain qualified persons to have a current certificate in basic cardiopulmonary resuscitation (CPR) is satisfied by, among other things, a certification in basic CPR by an online program that has received accreditation from the American Nurses Credentialing Center, the Accreditation Council for Pharmacy Education (ACPE), or the Accreditation Council for Continuing Medical Education.

It also amends Section V's training requirements for licensed pharmacists to order and administer certain childhood or COVID-19 vaccines. To order and administer vaccines, the licensed pharmacist must have completed the immunization training that the licensing State requires in order for pharmacists to administer vaccines. If the State does not specify training requirements for the licensed pharmacist to order and administer vaccines, the licensed pharmacist must complete a vaccination training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE) to order and administer vaccines. This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.

On 11/30/2020, the Oregon Board of Pharmacy issued a statement that it will not take disciplinary action against persons who act in accordance with DHHS guidance considering DHHS's position that state law is preempted. The Board does not take a position on whether DHHS's position on the preemption of state law

is valid. If a complaint is received relating to activities covered under DHHS guidance, the Board will expect the licensee to provide documentation of full compliance. Failure to do so may result in disciplinary action.

COVID-19 UPDATE – Oregon Board of Pharmacy (OBOP) Information December 9, 2020

COVID-19 Vaccine Storage and Distribution

It is anticipated that in the next few weeks, Oregon will receive distribution of COVID-19 vaccine. Please be aware of the following guidance:

- If COVID-19 vaccine will be stored inside of a pharmacy currently registered with the board then additional registration is **not** needed with the board for receipt, storage and distribution of COVID-19 vaccine.
- If COVID-19 vaccine will be stored outside of a pharmacy currently registered with the board then then additional registration ***is*** needed with the board for receipt, storage and distribution of COVID-19 vaccine.
    - The pharmacy will need to register the outside location as a Drug Room by completing the COVID-19 Vaccine – Drug Room Application
    - Applicable rules include: OAR 855-007-0060 SNS and State Stockpile Emergency Drugs and OAR 855-007-0080 Emergency Immunization and Drug Distribution.

If the pharmacy and/or drug room is licensed with the Board as outlined above, then no further registration is needed as a Wholesaler or Drug Distribution Agent in order to store or distribute COVID-19 vaccine.

COVID-19 UPDATE – Oregon Board of Pharmacy (OBOP) Information December 4, 2020

Oregon OSHA Regulations

Oregon OSHA recently adopted a Temporary COVID-19 rule (OAR 437-001-0744) that combats the spread of coronavirus in all workplaces by requiring employers to carry out a comprehensive set of risk-reducing measures.

The rule was effective 11/16/2020, with certain parts phased in, and is expected to remain in effect until 05/04/2021. It is a continuation of the guidance produced by the Oregon Health Authority and enforced in the workplace by Oregon OSHA, including physical distancing, use of face coverings, ventilation, exposure risk assessment, infection control plan, information/training, notification/testing/medical removal, and special measures for high risk jobs (i.e. direct patient care). The rule is intended to further improve the current structure for reducing risks in the workplace by requiring several measures many employers have voluntarily implemented. For example, it requires employers to notify employees of a workplace infection and provide training to workers on how to reduce risks. Likewise, employers must formally assess the risk of exposure, develop infection control plans, and address indoor air quality within their current capability. A fact sheet is available that outlines the provisions of OAR 437-001-0744.

In addition on 11/25/2020, Oregon OSHA published a COVID-19 Workplace Advisory Memo: Application of COVID-19 Rule to Direct Patient Care within Retail Pharmacies that includes a distinction between the rules for all workplaces and those additional requirements that apply to work activities defined as involving "exceptional risk." One of the triggers for exceptional risk is "direct patient care." The Temporary COVID-19

rule's definition of "direct patient care" includes the following statement: "Direct patient care does not include customer service activities provided in retail settings that have embedded healthcare offices, such as retail pharmacies." While that language clearly excludes all activities in a retail pharmacy that do not directly involve the treatment of patients, it does not exclude the provision of services such as vaccinations. However, in the interest of ensuring that the rule does not discourage vaccinations and any health screening services provided by retail pharmacies or similar establishments, Oregon OSHA will not be enforcing most of the "exceptional risk" requirements found in Subsection 4 of the temporary rule in relation to such activities. Click on the link above to read detail on what will and will not be enforced.

Oregon Health Authority (OHA) Updated Face Covering Guidance

On December 3, 2020 the Oregon Health Authority issued revised Statewide Reopening Guidance – Masks, Face Coverings, Face Shields.

Oregon Board of Pharmacy Statement on Immunization Services Under DHHS Guidance & PREP Act 3rd Amendment

See updated statement on 4/22/2023 communication.

~~On October 20, 2020, U.S. Department of Health & Human Services (DHHS) issued the third amendment to a declaration under the Public Readiness and Emergency Preparedness Act (or PREP Act). This declaration provides liability protection and authorizes both qualified pharmacy technicians and State-authorized pharmacy interns acting under the supervision of a qualified pharmacist to administer FDA-authorized or FDA-licensed COVID-19 vaccines to persons ages three or older and to administer FDA-authorized or FDA-licensed ACIP-recommended vaccines to persons ages three through 18 according to ACIP's standard immunization schedule. The DHHS guidance lists requirements that qualified pharmacy technicians and State-authorized pharmacy interns must satisfy.~~

~~The declaration states that the authorization preempts any state and local law that prohibits or effectively prohibits those who satisfy requirements as set forth in the declaration from administering COVID-19 or routine childhood vaccines. The Oregon Board of Pharmacy will not take disciplinary action against persons who act in accordance with this DHHS guidance considering DHHS's position that state law is preempted. The Board does not take a position on whether DHHS's position on the preemption of state law is valid. If a complaint is received relating to activities covered under DHHS guidance, the Board will expect the licensee to provide documentation of full compliance. Failure to do so may result in disciplinary action.~~
~~This statement is available on the Board website.~~

List-Servs of Interest

The board has been forwarding other agency newsletters and list-serv announcements pertinent to COVID-19 vaccine distribution via the board's list-serv. With the upcoming deployment of COVID-19 vaccine, licensees may find it helpful to subscribe to the following list-servs for the most up to date vaccine information at the state and federal levels:

- OHA Immunization Partners
- OHA CD Summary- The CD Summary is a publication of the Oregon Health Authority, Public Health Division. Its intended audience is: licensed health care providers, public health and health care agencies, media representatives, medical laboratories, hospitals, and others with an interest in epidemiology and public health.
- FDA Advisories

COVID-19 Resources

Additional links specific to COVID-19 vaccines and vaccination distribution plans have been added to the list of COVID-19 Resources at the end of the comprehensive communication document.COVID-19 UPDATE – Oregon Board of Pharmacy (OBOP) Information October 23, 2020

COVID-19 Resources

The list of COVID-19 Resources at the end of the comprehensive communication document on the Board's website has been updated to make searching for specific information easier. Information is arranged into international, US and Oregon sections.

US Department of Health and Human Services (HHS) Vaccine Guidance

On October 21, 2020 the U.S. Department of Health and Human Services (HHS) issued guidance under the Public Readiness and Emergency Preparedness Act (PREP Act) authorizing qualified pharmacy technicians and State-authorized pharmacy interns to administer childhood vaccines, COVID-19 vaccines when made available, and COVID-19 tests, all subject to several requirements. The latest guidance document is also listed under the COVID-19 Resources at the end of the board's comprehensive communication document. The board will not be issuing additional guidance on these expanded authorities at this time.

Centers for Disease Control and Prevention (CDC) Pharmacy Partnership for Long-Term Care Program for COVID-19 Vaccination

On October 16, 2020 the U.S. Department of Health and Human Services (HHS) and Department of Defense (DoD) announced that the Centers for Disease Control and Prevention (CDC) is partnering with CVS and Walgreens to offer on-site COVID-19 vaccination services for residents of long-term care facilities (LTCFs – nursing homes and assisted living facilities) once vaccination is recommended for them. The program provides end-to-end management of the COVID-19 vaccination process, including cold chain management, on-site vaccinations, and fulfillment of reporting requirements, to facilitate safe vaccination of this patient population, while reducing burden on LTCFs and local health departments. The services will be available in rural areas that may not have easily accessible pharmacies. Facility staff who have not received COVID-19 vaccine can also be vaccinated as part of the program. A program description and FAQ document provide additional information.

Oregon Health Authority (OHA) Updated Face Covering Guidance

On October 19th, 2020 the Oregon Health Authority issued revised Statewide Mask, Face Covering, Face Shield Guidance.

COVID-19 UPDATE- Oregon Board of Pharmacy (OBOP) Information July 17, 2020

Pharmacy Provision of Vaccines and Other Routine Services

Due to the ongoing nature of the COVID-19 pandemic and the impending flu season, it is advised for pharmacies to develop robust vaccination strategies and communicate clearly to patients how their immunization plan/processes will be carried out to prevent disease spread. Related reference links are provided in this document's COVID-19 Resources (pg. 19)

Updates Regarding COVID-19 Temporary Rules

On 7/14/2020, the OBOP 'repealed' the temporary rule related to hydroxychloroquine/chloroquine (HCQ/CQ) prescription dispensing, effective immediately. Pharmacists and prescribers are expected to utilize professional judgment for appropriate clinical decision-making.

On 7/14/2020, the OBOP voted to send two current COVID-19 temp rules through the formal rulemaking hearing process, due to the ongoing nature of the PHE. One is related to pharmacist supervision of technician and interns for certain remote processing tasks; if adopted, this will remain in effect through the declared emergency timeframe only, unless repealed sooner. The second rule is related to SRI intern ratio for the 2020-2021 academic year. See 9/9/2020 Rulemaking Hearing Notices for details.

On 7/16/2020, temporary rule OAR 855-007-0086 was adopted. It obligates OBOP licensees and registrants to comply with the Governor's Executive Orders enacted during declared emergencies.

FDA Updates Compounding Guidance

On 7/15/2020, the FDA sent a update: The FDA's Intergovernmental Affairs (IGA) team would like to bring your attention that the Agency has added dexamethasone sodium phosphate to the lists of drugs for temporary compounding by outsourcing facilities and pharmacy compounders during the COVID-19 public health emergency.

COVID-19 UPDATE- Oregon Board of Pharmacy (OBOP) Information May 22, 2020

Considerations for Reopening of Oregon and the End of the Declared Public Health Emergency (PHE)

Temporary rules and advisories will end and change options at the end of declared PHE. For example, items permitted under Division 007 rules will no longer be in effect when the state's public health emergency is over; these include such emergency permissions as Temporary Pharmacy registration, temporary employment under EMAC/PNEMA, and reactivation of retired pharmacist licensure. The Board's temporary rules specific to the PHE will also be repealed, effective the date of the end of the declared PHE; these are OARs 855-006-0005(29) (remote supervision of technicians), 855-007-0085 (HCQ), and 855-031-0026 (Intern SRI ratio/supervision).

If a pharmacy would like to continue pharmacist remote processing functions beyond the end of the PHE, it will be necessary to complete and submit the customary Remote Processing designation application for Board review and approval.

Manufacturer registrations issued to permit the temporary manufacturing of hand sanitizer via FDA guidance expire on 9/30/2020. Any location that wishes to continue this activity shall re-apply with the OBOP as a traditional manufacturer after 9/30/2020 and the end of the declared PHE.

If a pharmacy's annual CS inventory came due during the COVID-19 PHE *and* you were unable to complete the written inventory of all controlled substances annually within 365 days of the last written inventory, the pharmacist must complete and document the inventory within 15 days of the end of the declared PHE.

OBOP plans to continue to provide information with as much lead time as possible of the end of the declared PHE, and pharmacies should consider transitioning away from temporary processes for those that are no longer needed, in preparation for the end of the PHE.

Clarification of 4/8/2020 Statement Related to Vaccines and Routine Pharmacy Services

In the update sent on 4/8/2020 the message stated expectations and considerations for pharmacists and pharmacies: *"….pharmacists shall use professional judgment per individual circumstances and pharmacies should avoid offering routine services, such as adult vaccinations and blood pressure monitoring, that require person-to-person contact and are not required for the immediate health and safety of the individual."*

This statement is not written, nor was not meant to be interpreted as an overall prohibition on vaccination. Rather, as intentionally stated and in alignment with routine professional decision-making rationale, a pharmacist is expected to use judgment to assess the individual circumstances of an identified patient need, in tandem with assessing whether the service, such as administering a vaccine, can be provided safely, considering such things as whether the location has proper PPE, etc. Please work directly with individual patients and other care providers, in consideration of pharmacy supplies and policies, to take care of your patients and maintain a safe environment in your pharmacy.

New Links Added to Resources

Refer to pg. 19 of this document for COVID19-related resources.

COVID-19 UPDATE- Oregon Board of Pharmacy (OBOP) Information May 7, 2020

General Statement Related to Ongoing Public Health Emergency (PHE)

All temporary rules will remain in effect for the duration of the declared public health emergency unless modified or rescinded. The Board will continue to issue COVID-19 updates to communicate advice, clarifications, and changes to temporary rules.

In-State Pharmacy Drug Compounding

A registered Oregon pharmacy drug outlet, located in Oregon, may compound drugs in shortage in accordance to all requirements set forth in the FDA's Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Pharmacy Compounder Not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency and the following requirements:

1. The in-state pharmacy must maintain written documentation of a request for the compounding of drugs in shortage by a medical director of a hospital or an Oregon licensed pharmacist who is authorized by the hospital to act on behalf of the medical director. The documentation of a request is not required if the hospital owns and operates the compounding pharmacy. NOTE: For the purposes of this guidance, hospital includes free-standing emergency departments and any satellite location of a hospital that is being used to treat COVID-19 patients.

2. The in-state compounding pharmacy shall maintain documentation of a drug shortage for three years.

3. If the compounding pharmacy is not owned or operated by the hospital, both the compounding pharmacy and the recipient hospital pharmacy shall maintain the following records for three years of any non-patient specific drug transferred, sold or received:

- The name, strength, dosage form, expiration date and quantity of each drug transferred, sold or received;
- The address of the location where the drugs were transferred, sold or received; and
- The date of transfer, sale, or receipt; and
- Invoices containing the above information will suffice as records of transfer, sale, or receipt.

4. The compounding pharmacy and recipient hospital pharmacy must submit notification via email (pharmacy.compliance@oregon.gov) to the Board of Pharmacy of the intent to transfer, sell or receive non-patient specific drugs in shortage. The notification email must include the following:
    - Name and address of the pharmacy;
    - Contact telephone number of the pharmacy;
    - Oregon registration number of the pharmacy; and
    - A complete list of non-patient specific drugs in shortage that the pharmacy will be compounding or receiving (if the pharmacy intends to compound or receive additional drugs after submission, a new notification email from each pharmacy is required).

This FDA guidance is in effect for no longer than the duration of the public health emergency related to COVID-19 declared by HHS, including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (PHS Act) (42 U.S.C. 247d(a)(2)). Records must be produced for review no later than three business days to an agent or inspector of the Board.

Emergency Rule for COVID-19 Testing at Waived Laboratories

On April 24, 2020, the Oregon Health Authority's Public Health Clinical Laboratory Division adopted temporary rule OAR 333-024-3000, related to pharmacist provision of COVID-19 tests. It is expected that any pharmacist and pharmacy performing testing shall comply with all related rules (see message dated 4/22/2020). Additionally, locations not otherwise registered with OBOP as a pharmacy shall register with OBOP as a Temporary Pharmacy for the purposes of pharmacists performing COVID-19 lab testing**.**

COVID-19 UPDATE- Oregon Board of Pharmacy (OBOP) Information April 22, 2020

Oregon Pharmacist Legal Scope and COVID-19 Testing

Per ORS 689.661, it is within a registered Oregon pharmacist's scope to perform point-of-care CLIA-waived tests. Please refer to HHS and OHA Laboratory Regulation Division for regulations and requirements a pharmacist must follow to perform CLIA-waived COVID-19 tests. It is essential that the pharmacy has written policies and procedures and retains documentation of personnel training associated with lab tests. Further, it is expected that pharmacy employers implement infection control practices in their pharmacies to protect workers and patients, in accordance with the state's social/physical distancing guidelines (see "Safe Work Environment and Routine Pharmacy Services" in OBOP's 4/8/2020 update).
The following related resources are provided:

- United States Department of Health and Human Services
    - Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity under the PREP Act
    - HHS Statement- Authorizing Licensed Pharmacists to Order and Administer COVID-19 Tests

    - Centers for Medicare and Medicaid Services
- Oregon Health Authority – Clinical Laboratory Regulation
    - Rules and Regulations
    - Guidelines for Emergency Testing Authorization
    - Health Screen Testing Permit Program
- CDC/FDA Clarification Re: CLIA-waived Status for Point-of-Care SARS-CoV-2 Tests under Emergency Use Authorizations
- CDC Guidance – Reduce risk during COVID-19 testing and other close-contact pharmacy care services
    - CDC Guidance for Pharmacists and Pharmacy Technicians in Community Pharmacies during the COVID-19 Response
    - Personal Protective Equipment

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

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 adult* 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

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.

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

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.*

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. 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."

Prescription Refills – Options for Oregon Pharmacists to Issue Emergency Fills/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) 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, such as prescribing of:

- Any post-diagnostic drugs and devices listed in the Formulary Compendium

- Medications/patient care services listed in the Protocol Compendium
    - 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.
        - Note: For patients seeking > 30 day supply of certain psychotherapeutic drugs, seek prescriber authorization, particularly in consideration of the potential risk for suicide.
            - 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

Executive Order – "Stay Home, Save Lives"

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.
> - 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
    - 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

- **Inactive Pharmacist License Reactivation:**
    - Per OAR 855-007-0050(4), the Pharmacist License Reactivation Application is available.
    - 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:**
    - 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".

- 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:
  - Pharmacy closure
  - Request for extension of NABP, MPJE, reciprocity deadlines
- Other issues and considerations:
  - 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
  - CPR certification for vaccine-certified pharmacists that lapse during the PHE should be completed as soon as practical after end of the PHE.
  - Do what you can to reduce fax refill requests that can be managed at pharmacy; clinics are inundated
  - Discontinue all auto-faxes regarding proactive refill requests, if possible
  - Consider alternative methods to get prescriptions to patients – drive-thru, curbside delivery, home delivery, mailing
  - Consider providing special hours for high-risk persons to help with social distancing

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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
  - 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 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)**
  - **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

State of Emergency

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
- 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!

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

COVID-19 Resources:

INTERNATIONAL

- World Health Organization (WHO)

UNITED STATES

- Centers for Disease Control and Prevention (CDC)
  - CDC Guidance for Pharmacies
  - CDC Framework for Healthcare Systems Providing Non-COVID-19 Clinical Care During the COVID-19 Pandemic
  - CDC Reopening Guidance for Cleaning and Disinfecting Public Spaces, Workplaces, Businesses, Schools, and Homes
  - Optimizing Personal Protective Equipment (PPE) Supplies (General Optimization Strategies, N95, Facemasks, Eye Protection, Gowns, Gloves)
  - CDC Healthcare Facility Tools
  - CDC Interim Guidance for Businesses and Employers Responding to Coronavirus Disease 2019 (COVID-19)
  - CDC Criteria for Return to Work for Healthcare Personnel with SARS-CoV-2 Infection (Interim Guidance)
  - CDC Discontinuation of Isolation for Persons with COVID-19 Not in Healthcare Settings
  - CDC Interim U.S. Guidance for Risk Assessment and Work Restrictions for Healthcare Personnel with Potential Exposure to COVID-19
  - For more guidance on this topic and a comprehensive list, see CDC Guidance Documents Directory

- Centers for Medicare and Medicaid Services (CMS)
  - Clinical Laboratory Improvement Amendments (CLIA)
  - COVID-19 Partner Toolkit

- Drug Enforcement Administration (DEA)
  - DEA COVID-19 Prescribing Guidance
  - DEA Registrant Guidance on Controlled Substance Prescription Refills
  - DEA Exception to Separate Registration Requirements Across State Lines
  - DEA Exception to Regulations Emergency Oral CII Prescription
  - DEA Guidance: Q&A Remote Identity Proofing EPCS at hospital/clinics.
  - For more guidance on this topic and a comprehensive list, see DEA COVID-19 Guidance Documents Directory

- Food and Drug Administration (FDA)
    - Clinical Trials
        - FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency
    - Compounding
        - Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Outsourcing Facilities During the COVID-19 Public Health Emergency
            - FDA has identified the following list of drugs for the purposes of this guidance.
        - Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency Guidance for Industry
            - FDA has identified the following list of drugs for the purposes of this guidance.
        - Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency
        - Temporary Policy Regarding Non-Standard PPE Practices for Sterile Compounding by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency
    - Emergency Use Authorizations
        - Medical Devices
            - Lab Update: FDA Clarifies CLIA-waived Status for Point-of-Care SARS-CoV-2 Tests under Emergency Use Authorizations
        - Therapeutics
        - Vaccines
    - Immunizations
        - Vaccine Development 101
        - Emergency Use Authorization for Vaccines Explained
            - Path for COVID-19 Vaccine (Research to EUA)
        - COVID-19 Vaccines
            - Guidance for Industry: Development and Licensure of Vaccines to Prevent COVID-19
        - Vaccine Adverse Event Reporting System (VAERS)
            - Online reporting form or pdf-fillable form
            - YouTube video on how to fill out the form
            - VAERS and COVID FAQ
    - List-Serv(s) of Interest
        - FDA Advisories
        - Repackaging
            - Temporary Policy on Repackaging or Combining Propofol Drug Products During the COVID-19 Public Health Emergency
        - For more guidance on this topic and a comprehensive list, see COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders.

- Health and Human Services (HHS)
  - Public Readiness and Emergency Preparedness Act
    - Declaration and Amendments
    - Advisory Opinions of the General Counsel
    - HHS Guidance
  - For more guidance on this topic and a comprehensive list, see HHS COVID-19-Related Guidance Documents.

- United States Pharmacopeia (USP)
  - USP Response to Shortages of Garb and Personal Protective Equipment (PPE) for Sterile Compounding During COVID-19 Pandemic
  - USP Compounding Alcohol-Based Hand Sanitizer during COVID-19 Pandemic
  - USP Hand Sanitizer Toolkit (Information for Compounders, OTC drug manufacturers, other facilities like distilleries and USP standards for hand sanitizer ingredients)
  - USP COVID-19 Vaccine Handling Toolkit

- White House
  - Guidance: Opening Up America Again

OREGON

- Oregon Board of Pharmacy
  - Application/Registrations
    - Temporary Pharmacy
    - Pharmacist License Reactivation
    - Remote Processing Designation (non-COVID process)
      - Remote Processing Checklist for Use During COVID-19 Public Health Emergency
  - Position Statements
    - Statement on Immunization Services Under DHHS Guidance
  - Rules and Regulations
    - Division 7- PUBLIC HEALTH EMERGENCY
    - Division 20- PHARMACIST PRESCRIPTIVE AUTHORITY
    - Rulemaking Information

- Oregon Health Authority (OHA)
  - Clinical Laboratory Regulation
    - Rules and Regulations
    - Guidelines for Emergency Testing Authorization for Oregon CLIA Certified Laboratories
    - Health Screen Testing Permit Program
    - Data Dashboards
    - List-Serv(s) of Interest

        - OHA Immunization Partners
        - OHA Communicable Disease Summary
    - COVID-19 Vaccine
        - Information for Providers
            - Vaccination Plan
        - Training for Providers
        - State Supplied Vaccine Accountability rules OAR 333-047-0010 thru OAR 333-047-2000
        - Pharmacy Partnership for Long-Term Care Program for COVID-19 Vaccination
            - FAQ
        - Toolkits:
            - OHA Partner Toolkit: Helping Older Adults Get COVID-19 Vaccinations
            - Get Vaccinated Oregon (tool to determine vaccine eligibility and locate appointments)
    - Statewide Guidance
        - As of July 27, 2021, OHA recommends universal mask use for all public indoor settings. Masks are required in health care settings.
        - ~~Mask, Face Covering, Face Shield Guidance~~
        - Mask, Face Covering, Face Shield Guidance for Health Care Offices
        - Statewide Reopening Guidance – General Guidance for Employers
        - ~~Statewide Reopening Guidance – Retail Stores (includes pharmacies)~~
        - ~~Guidance on Resumption and Continued Provision of Non-Emergent and Elective Procedures in Medical and Dental Offices, and Other Health Care Settings~~
        - ~~Guidance on Resumption and Continued Provision of Non-Emergent and Elective Procedures at Hospitals~~
        - Minor Consent Statement

- Oregon Occupational Safety and Health (OSHA)
    - COVID-19 rule (OAR 437-001-0744)
        - COVID-19 Hazards Poster
        - COVID-19 Workplace Advisory Memo: Application of COVID-19 Rule to Direct Patient Care within Retail Pharmacies

- State Emergency Registry of Volunteers in Oregon (SERV-OR)
    - Agreement

- Governor Kate Brown
    - Building a Safe & Strong Oregon
    - Executive Orders
    - State of Oregon Newsroom