

## Statement on Immunization Services Under DHHS Guidance

On March 11, 2021, U.S. Department of Health & Human Services (DHHS) issued the seventh amendment to the declaration under the Public Readiness and Emergency Preparedness Act (or PREP Act). This amendment added to section V of the declaration, additional categories of qualified persons (Covered Persons) covered under the act to administer FDA authorized or approved COVID-19 vaccines as Covered Countermeasures, and to extend to these Covered Persons, PREP Act immunity. The amendment specifically authorizes qualified optometrists to administer FDA authorized or approved COVID-19 vaccines and provides liability protection under the PREP Act. The DHHS amendment and related guidance lists requirements that optometrists must satisfy.

The amended 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.

On March 22, 2021, the Oregon Health Authority (OHA) as an Authority Having Jurisdiction under the PREP Act, also issued an Authorization that expanded the list of vaccinators. That Authorization does not change the requirements for optometrists currently licensed in Oregon.

The Oregon Board of Optometry will not take disciplinary action against persons who act in accordance with the DHHS PREP Act amendment and the OHA Authorization based on the PREP Act provision that state law is preempted if those laws prohibit or effectively prohibit a qualified person from administering a COVID-19 vaccine. If a complaint is received relating to activities covered under DHHS amendment or the OHA Authorization, the Board will expect the licensee or person to provide documentation of full compliance. Failure to do so may result in disciplinary action.

1. If optometrists are currently ATI licensed, they are required to comply with all injection training requirements under OAR 852-080-0030.
2. If an optometrist is not currently licensed, or an individual is an optometry student, they must:
  - a. Have documentation of completion of the Centers for Disease Control and Prevention (CDC) COVID-19 Vaccine Training (<https://www.cdc.gov/vaccines/covid-19/training.html>) or a similar training offered by an educational institution or health system.
  - b. Have documentation of an observation period by a currently practicing health care professional experienced in administering intramuscular injections where the individual's competence as a vaccinator is confirmed.
  - c. Have current certification in basic CPR.
3. An individual who is not currently licensed, but who was licensed as an optometrist in Oregon within the last 5 years, must have been in good standing with the Board at the time the license expired or was surrendered.

4. An optometrist not currently licensed, or an optometry student, may only administer vaccinations at a location that has a currently practicing health care professional experienced in administering intramuscular injections on site who can monitor and provide supervision.



## Oregon Health Authority PREP Act Authorization for the Administration of COVID-19 Vaccines

### OVERVIEW

The Oregon Health Authority (OHA) and its partners are working diligently to administer vaccines to Oregonians swiftly and safely and bring an end to the COVID-19 pandemic in our state. Achieving this goal will require mobilizing large numbers of qualified vaccinators to administer vaccinations. The U.S. Department of Health and Human Services (HHS), under a Public Readiness and Emergency Preparedness (PREP) Act Declaration, has expanded the category of individuals who are authorized to administer COVID-19 vaccines.<sup>1</sup> In the Seventh Amendment to the PREP Act, effective March 11, 2021, HHS stated:

This amendment thus expands the pool of vaccinators to individuals who have or can obtain training and the capability to administer vaccines even if prescribing, dispensing and administering vaccines is not within the scope of their license or usual responsibilities, allowing States, Territories, local areas and Tribes to use these individuals in their vaccination programs.<sup>2</sup>

The PREP Act and the Declaration preempt state requirements that would prohibit or effectively prohibit a qualified person from administering a COVID-19 vaccine.<sup>3</sup> The PREP Act also permits

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<sup>1</sup> HHS has explained the PREP Act and the current Declarations as follows:

The PREP Act allows the Secretary of the U.S. Department of Health and Human Services (HHS) to issue a declaration that extends liability protections to entities and individuals who manufacture, distribute, or administer covered medical countermeasures against a public health threat or emergency. In March 2020, the Secretary issued a PREP Act Declaration covering COVID-19 tests, drugs, and vaccines providing liability protections to manufacturers, distributors, state, local and territorial, and tribal (SLTT), licensed healthcare professionals, and others identified by the Secretary (qualified persons) who administer COVID-19 countermeasures. The Declaration has been amended several times to expand liability protections, including prior amendments to cover licensed healthcare professionals who cross state borders and federal response teams. On March 12, 2021, the Acting Secretary of HHS issued the 7<sup>th</sup> Amendment to the PREP Act to extend liability protections to specified healthcare professionals who may not usually administer vaccines in their scope of practice or who have recently expired licenses, and students of specified healthcare professions who administer COVID-19 vaccines.

<https://www.phe.gov/emergency/events/COVID19/Documents/covid19-vaccination-wrkfrc-factsheet-508.pdf>.

<sup>2</sup> <https://www.govinfo.gov/content/pkg/FR-2021-03-16/pdf/2021-05401.pdf>.

<sup>3</sup> 42 U.S.C. § 247d-6d(b)(8)(A). See also Advisory Opinion 20-02 issued by the HHS Office of General Counsel relating to a May 19, 2020 PREP Act declaration that authorized pharmacists to order and administer COVID-19 tests. The Opinion concluded that the PREP Act declaration preempted any state or local requirement that prohibits or effectively prohibits a pharmacist from ordering and administering COVID-19 test that the FDA has authorized. <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/advisory-opinion-20-02-hhs-ogc-prep-act.pdf>. HHS has incorporated this same reasoning into the Seventh Amendment to the PREP Act Declaration making it clear that any state law that prohibits or effectively prohibits the individuals authorized in the amendment from

an agency, like OHA (an Authorizing Jurisdiction) to further expand the category of individuals who can administer COVID-19 vaccines, and HHS has actively encouraged states to do so.<sup>4</sup>

With actively practicing health care providers fully engaged in treating patients along with administering vaccines, other individuals, including health care providers who do not vaccinate as part of their practice, retired and inactive health care providers, traditional health workers<sup>5</sup>, and trained non-health care workers can play a key role in taking on the vital work of vaccinating Oregonians.

This Authorization permits the individuals who are described and meet the requirements below to administer United States Food & Drug Administration (FDA) authorized or approved COVID-19 vaccines in Oregon, notwithstanding other state laws.

## PREP ACT

The PREP Act provides broad immunity from suit and liability under federal and state law to those engaged in activities aimed at combatting the COVID-19 pandemic, including administering COVID-19 vaccines authorized by the FDA. These protections were triggered by the declaration issued by the HHS Secretary effective February 4, 2020.<sup>6</sup>

The HHS Secretary's declaration provides that the protections are in effect for *Covered Persons* for recommended activities involving *Covered Countermeasures* that are related to activities authorized in accordance with the public health and medical response of the *Authority Having Jurisdiction*, including administering Covered Countermeasures following a Declaration of Emergency.

COVID-19 vaccines that have received emergency use authorization, licensure, or other approval by the Food & Drug Administration are *Covered Countermeasures*.

On March 8, 2020, Oregon Governor Kate Brown's declared an emergency due to COVID-19, and that declaration has been renewed multiple times and is currently in effect.

*Covered Persons* include, among others, licensed health professionals who are authorized under state law to administer Covered Countermeasures, and individuals who are not currently authorized under state law to administer Covered Countermeasures, but who are expressly identified by HHS in a PREP Act declaration, and authorized in accordance with the public health and medical emergency response of the *Authority Having Jurisdiction* to administer *Covered Countermeasures*, following a Declaration of Emergency.

OHA is an *Authority Having Jurisdiction* within the meaning of the HHS Secretary's declaration because it is a public agency that has legal responsibility and authority for responding to the

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administering COVID-19 vaccine, is preempted. 86 Fed. Reg. No. 49, at 14465 (March 16, 2021), <https://www.govinfo.gov/content/pkg/FR-2021-03-16/pdf/2021-05401.pdf>.

<sup>4</sup> 86 Fed. Reg. No. 49, at 14465 (March 16, 2021), <https://www.govinfo.gov/content/pkg/FR-2021-03-16/pdf/2021-05401.pdf>.

<sup>5</sup> Traditional health workers include community health workers, personal health navigators, peer wellness specialists, peer support specialists and doulas. ORS 414.665; OAR 410, Division 180.

<sup>6</sup> See 85 Fed. Reg. 15,198 (March 17, 2020); see also Pub. L. No. 109-148, Public Health Service Act § 319F-3, 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e. The current version of the HHS Secretary's declaration may be found at <https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx>.

COVID-19 emergency in the state of Oregon as the Coordinating and Primary Agency for Emergency Support Function 8 —Public Health, Medical, and Mortuary Services, of the State of Oregon. OHA also has legal responsibility and authority in the state for investigating reportable diseases and disease outbreaks (ORS 433.004), enforcing the state's public health laws (ORS 431.150, ORS 431A.010), controlling and preventing the spread of disease (ORS 431.110), and generally protecting the public health under ORS 431 and other public health laws.

## **AUTHORIZATION**

As the Director of OHA under ORS 413.033, I hereby exercise OHA's authority as an ***Authority Having Jurisdiction*** under the PREP Act and the HHS Secretary's declaration issued thereunder to authorize any individual listed below who is already authorized under state law or who is not otherwise authorized under state law, and who meets the requirements listed below, to administer COVID-19 vaccines authorized, approved, or licensed by the FDA, and for the individuals to benefit from the PREP Act's liability protections<sup>7</sup>:

### **Health Professionals and Health Allied Professionals (currently licensed, certified, or registered or had active license, certification, or registration within the last 5 years)**

- Certified nursing assistants (CNA)
- Dentists
- Direct entry midwives
- Emergency medical services providers (EMT, AEMT, EMT Intermediate or Paramedic)
- Naturopathic physicians (ND)
- Nurses
  - Advanced practice registered nurses (APRN)(includes nurse midwives)
  - Registered nurses (RN)
  - Licensed practical nurses (LPN)
- Optometrists
- Pharmacists, pharmacy interns, and pharmacy technicians
- Phlebotomists
- Physicians (MDs and DOs)
- Physician assistants
- Podiatrists
- Respiratory therapists
- Traditional health workers<sup>8</sup>
- Veterinarians

### **Healthcare Students (in these fields of study)**

- Dental
- Emergency medical services providers (EMT, AEMT, EMT Intermediate or Paramedic)
- Medical
- Midwifery

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<sup>7</sup> This list includes all of the individuals identified by HHS in the PREP Act declarations, as well as others.

<sup>8</sup> Must be or have been registered with the state. See OAR 410, Division 180.

- Naturopathic medicine
- Nursing (including CNA programs)
- Optometry
- Pharmacy and pharmacy intern
- Physician assistant
- Podiatry
- Respiratory therapy
- Veterinary

## Requirements

1. If not currently licensed, certified, or registered but licensed, certified or registered within the past five years, the individual was in good standing with the licensing, certifying, or registering entity at the time the license, certification or registration expired or was otherwise surrendered.
2. If currently licensed, certified, or registered is in good standing with the licensing, certifying, or registering entity.
3. If not currently licensed, certified or registered, if vaccination is not currently within an individual's scope of practice, or an individual is a health care student, has documentation of completion of the Centers for Disease Control and Prevention (CDC) COVID-19 Vaccine Training (<https://www.cdc.gov/vaccines/covid-19/training.html>) or a similar training offered by an educational institution or health system.
4. For individuals who do not vaccinate as part of their health care practice or are healthcare students, has documentation of an observation period by a currently practicing health care professional experienced in administering intramuscular injections where the individual's competence as a vaccinator is confirmed.
5. For individuals who are not currently licensed health professionals or are health care students, has current certification in basic cardiopulmonary resuscitation (CPR).
6. Pharmacists, pharmacy interns, pharmacy technicians and pharmacy students must also complete a practical training program that is approved by the ACPE<sup>9</sup> as well as a minimum of two hours of ACPE-approved immunization-related continuing pharmacy education during each state licensing period.
7. Health care students and individuals who do not vaccinate as part of their health care practice, including those who are not currently licensed, certified, or registered health professionals, may only vaccinate at a location that has currently practicing health care professional experienced in administering intramuscular injections on site to provide monitoring and supervision.

**Pursuant to 42 U.S.C. § 247d-6d(b)(8), any provision of Oregon State law that would otherwise require a person to hold a license, certification, or registration to administer COVID-19 vaccines or require a delegation of authority or authorization from a licensed health care professional in order to administer COVID-19 vaccines, is preempted, for any individual who meets the requirements of this authorization. Any individual who meets the requirements of this authorization is a Covered Person as defined in the HHS Secretary's declaration, meets the requirements of subsection (b) of section VII of said declaration, and**

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<sup>9</sup> Accreditation Council for Pharmacy Education.

**qualifies as a vaccination provider as defined in the letters of authorization issued by the FDA for COVID-19 vaccines.**

Nothing in this Authorization is intended to:

- Limit an individual authorized to administer a COVID-19 vaccine under a PREP Act declaration from administering COVID-19 vaccines in accordance with the declaration.
- Limit a health care provider currently licensed, certified, or registered in Oregon, and authorized to vaccinate in accordance with Oregon law, from administering COVID-19 vaccines.
- If applicable, for individuals who are authorized to vaccinate under Oregon law, override vaccination training currently required by an individual's licensing, certification, or registration entity.
- Limit the ability of individuals registered under ORS 401.651 to 401.670 (SERV-OR) to be deployed for the purpose of administration of COVID-19 vaccines.
- Permit an individual who is not a licensed health care provider acting within their scope of practice to provide medical advice, diagnosis, monitoring, or care, other than administering COVID-19 vaccines.

This authorization shall take effect upon signing and remain in effect until amended, rescinded, or overridden.



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Patrick M. Allen  
Director

3/22/2021

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Date