OFFICE OF THE DIRECTOR
Kate Brown, Governor

Oregon Health Authority

500 Summer St NE E20
Salem OR 97301
Voice: 503-947-2340
Fax: 503-947-2341

COVID-19 Vaccine Administration Site and Provider Guidance

Effective Date: May 19, 2021

Authority: ORS 431A.010, ORS 431A.015, ORS 433.441, ORS 433.443.

Applicability: This guidance applies to any person operating a vaccine administration site or staffing a site, where an FDA authorized or approved COVID-19 vaccine is being administered, including pharmacies, health clinics, or other non-health care settings.

Definitions: The following definitions apply to this guidance:

- "**ALERTIIS**" means the Oregon Health Authority's statewide immunization registry, established under ORS 433.094.
- **"Person operating a COVID-19 vaccination administration site"** means an individual, entity, or state or local government responsible for the operations and activities at a location where COVID-19 vaccine administration is occurring.
- **"Provider"** means:
  - An individual or entity who has signed a CDC COVID-19 Vaccination Program Provider Agreement (enrolled provider); and
  - A person who is administering COVID-19 vaccine.
- **"Staff"** includes employees, contractors and volunteers.

Vaccination Site Operation

A person operating a COVID-19 vaccination administration site is required to:

- Have a designated site coordinator.
- Ensure that providers at the site and the site comply with the Oregon Health Authority's:
  - COVID-19 Vaccine Management Guide
  - COVID-19 Vaccination Site Non-Discrimination, ADA and Language Access Guidance
- Post signs, in conspicuous locations with contact information for the site coordinator, so people know who to contact if there are concerns about the site or services provided.
- Provide people who received their first dose of a vaccine at the site, with the date and time to return for their second dose of a vaccine, if applicable.

- Provide a person who is vaccinated with a vaccine card that shows at a minimum the date of the COVID-19 vaccination, the location of the vaccine administration site, and which vaccine was administered.
- Take all measures necessary to ensure that there are no leftover doses in a vial, short of turning people away because of concerns about wasting doses.
    - A person operating a COVID-19 vaccination administration site:
        - Should ensure that vaccine appointments are booked appropriately so that there are not leftover doses, considering no-show rates and other operational considerations.
        - Establish a waiting list with contact information for people who are eligible for vaccination, and ideally who can arrive at the site with little advance notice.
        - Should offer leftover doses in a vial to any age eligible unvaccinated person, in any manner possible.

    *** ***While you must take measures to avoid wasting doses, providers and sites should prioritize getting someone vaccinated now even if that means you are unable to use all the doses in the vial.***

A person operating a COVID-19 vaccination administration site, and staff at the vaccination site are prohibited from:

- Asking for, or requiring, proof of eligibility for vaccination during scheduling or at the site.
    - Staff at a COVID-19 vaccination administration site may ask a person seeking to be vaccinated to self-attest that they are in a category that is currently eligible for vaccination and may ask a person what phase or group they fall into for purposes of helping to determine the state's progress in reaching eligible individuals.
- Restricting COVID-19 vaccine to a subset of eligible people unless vaccine has been allocated to an enrolled provider for the purpose of reaching a specific at-risk and hard to reach population, or the vaccination site is an employer-hosted vaccination clinic, in which case vaccine can be restricted to only those populations or employees.
    - If vaccines are restricted as permitted above, to a subset of those eligible for vaccination, the site must have clear signs at the site, and in other promotional communications, that state who can be vaccinated at the site in accordance with the eligibility categories.
- Asking a person seeking to be vaccinated to provide their social security number.
    - The site may choose to ask for a social security number for purposes of billing insurance, but it must made clear that providing a social security number is optional and will only be used for purposes of insurance billing and is not a condition to receive the vaccine.
- Denying a COVID-19 vaccine to someone who is otherwise eligible on the basis that a person:
    - Is uninsured;
    - Is a citizen of another country;

    - Is a resident of another state; or
    - Is a resident of another county.
- Charging a person seeking to be vaccinated for the vaccine or the vaccine administration fee.
    - A provider may bill insurance for the administration fee but cannot charge the person seeking to be vaccinated.
- Requiring a person to provide:
    - Proof of health insurance information (this information may be requested but it cannot be required and it must be made clear that providing the information is optional).
    - Government issued identification.
- Requiring parental or guardian consent for a minor age 15 to 17 who is exercising their right to consent to treatment under ORS 109.640 (applicable to physicians, naturopathic physicians, dentists, physician assistants, nurse practitioners and optometrists).

A person operating a vaccination administration site is strongly recommended to:

- At the time of scheduling a vaccination appointment, collect information about whether a person needs accommodations because of a disability or will require interpretation or translation of written documents.
- Have a process for people to sign up for an appointment who do not have access to a computer or the internet.
- Have a process for people to sign up for an appointment who have difficulty using a computer or accessing the internet.
- Inform people in advance which brand of vaccines will be administered at the site.
- Provide clear information that receiving a COVID-19 vaccine will not be considered for purposes of a Public Charge evaluation.
- Provide the v-safe information sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in v-safe.
    - V-safe is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. V-safe asks questions that help CDC monitor the safety of COVID-19 vaccines. V-safe also provides live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information, visit: www.cdc.gov/vsafe.

Requirements for COVID-19 Vaccine Providers: Vaccine Information to be Shared with Recipients or Their Caregivers

- The FDA and the CDC have determined that the authorized COVID-19 vaccines are safe and effective. However, it is extremely important that individuals understand the risks and benefits of the COVID-19 vaccine they are to receive and have an opportunity

to ask questions. Vaccine providers must provide information consistent with the COVID-19 vaccine's Fact Sheet for Recipients and Caregivers in the individual's primary language or in a manner that the individual can understand, taking into account English language proficiency and Americans with Disabilities Act accessibility needs.

Johnson & Johnson Vaccine

- Any vaccine provider administering the Johnson & Johnson COVID-19 (also referred to as the Janssen vaccine) vaccine must be sure that individuals or their caregivers specifically understand the new warnings associated with the Johnson & Johnson vaccine. 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 the needs of individuals with disabilities who may need accommodations under the Americans with Disabilities Act. New warning information has been updated in the FDA-approved Fact Sheet for Recipients and Caregivers.
- As the vaccination provider, ***you must communicate to the recipient or their caregiver***, information consistent with the "Fact Sheet for Recipients and Caregivers" (and provide a copy or direct the individual to the website www.janssencovid19vaccine.com to obtain the Fact Sheet) prior to the individual receiving the Johnson & Johnson COVID-19 Vaccine, including:
  - FDA has authorized the emergency use of the Johnson & Johnson COVID-19 Vaccine, which is not an FDA approved vaccine.
  - The recipient or their caregiver has the option to accept or refuse the Johnson & Johnson COVID-19 Vaccine.
  - The significant known and potential risks and benefits of the Johnson & Johnson COVID-19 vaccine, and the extent to which such risks and benefits are unknown.
  - Information about available alternative vaccines and the risks and benefits of those alternatives.

  For information on clinical trials that are testing the use of the Johnson & Johnson COVID-19 vaccine to prevent COVID-19, please see www.clinicaltrials.gov.

- Healthcare providers should understand the warning information about the Johnson & Johnson vaccine and be familiar with the diagnosis and treatment of thrombosis with thrombocytopenia. The following is the new warning information related to the Johnson & Johnson vaccine included in the Fact Sheet for Healthcare Providers:

  Thrombosis with Thrombocytopenia

  Reports of adverse events following use of the Janssen COVID-19 Vaccine under emergency use authorization suggest an increased risk of thrombosis involving the cerebral venous sinuses and other sites (including but not limited to the large blood vessels of the abdomen and the veins of the lower extremities) combined with thrombocytopenia and with onset of symptoms approximately one to two weeks after vaccination. Most cases of thrombosis with thrombocytopenia reported following the Janssen COVID-19 Vaccine have occurred in females ages 18 through 49 years; some have been fatal. The clinical course of these events shares features with autoimmune

heparin-induced thrombocytopenia. In individuals with suspected thrombosis with thrombocytopenia following the Janssen COVID-19 Vaccine, the use of heparin may be harmful and alternative treatments may be needed. Consultation with hematology specialists is strongly recommended. The American Society of Hematology has published considerations relevant to the diagnosis and treatment of thrombosis with thrombocytopenia following the Janssen COVID-19 Vaccine (https://www.hematology.org/covid-19/vaccine-induced-immunethrombotic-thrombocytopenia). (see Full EUA Prescribing Information).

Any person administering COVID-19 vaccine is strongly recommended to:

- Document written or verbal consent in the individual's medical chart or into a segregated confidential medical file as part of an employee's employment records, if applicable, that shows the associated potential risks and benefits were discussed with the individual or legally authorized health care representative.
- Provide the individual or legally authorized health care representative with interpreter access to ensure that all information provided is available in the individual's primary language, including American Sign Language if needed, and that all written documents are appropriately translated. A sample written informed consent form can be found here and a sample COVID-19 vaccine administration record form can be found here. Written consent is not required but may be obtained.
- Provide the individual who is receiving the vaccine, or their legally authorized health care representative the option of consultation with a traditional health worker or other trusted community representative. The Oregon Health Authority has a traditional health worker registry if a provider is interested in finding a traditional health worker to be available for consultations during vaccinations. See Resources below.

Providers may communicate the Johnson & Johnson vaccine fact sheet information verbally, though OHA recommends documenting the conversation.

For additional requirements and recommendations for vaccine providers and vaccination sites please review the following OHA guidance document:

- COVID-19 Vaccination Site Non-Discrimination, ADA, and Language Access Guidance.

Reporting Vaccine Information to the Oregon Health Authority

Any person administering COVID-19 vaccine in Oregon is required to:

- Collect all information required to be reported into ALERTIIS, including but not limited to race and ethnicity information from individuals being vaccinated.
- Report administration information into ALERTIIS in accordance with the Oregon Administrative Rules Chapter 333, Divisions 47 and 49. For additional information about reporting requirements and training, go to: https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/VACCINESIMMUNIZATION/IMMUNIZATIONPROVIDERRESOURCES/Pages/COVIDvaccine.aspx.

Mandatory Reporting of Serious Adverse Events

Any person administering COVID-19 vaccine in Oregon is required to:

- In accordance with federal law, report serious adverse events (irrespective of attribution to vaccination) to the Vaccine Adverse Event Reporting System (VAERS). Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html.

For more information regarding mandatory reporting requirements, see the Fact Sheet for Healthcare Providers Administering Vaccine for each specific vaccine which can be found on the FDA website here: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines.

Re-allocating Inventory

A provider who has received an allocation of second doses from the Oregon Health Authority should reserve them for a minimum of 6 weeks to ensure that individuals have time to return for their second dose. A vaccine provider may use those second doses as prime doses after waiting a minimum of 6 weeks for people to return for their second dose.

- **Please note** that OHA data shows an additional 4% of individuals receive their second dose during week 7 through week 9, with a statewide second dose completion rate of over 96%.
- Providers should check ALERT to see if individuals have already received their second dose at another location, in which case those doses can be reallocated sooner than 6 weeks.
- If it is determined that there is a need to reallocate unused second doses after 6 weeks, OHA recommends allocating half of the doses to prime doses while reserving the other half as second doses (i.e., for those who receive the reallocated prime doses). Providers should also consider reserving a small number of second doses for people who received a prime dose at a site to which they can't return (e.g., in a facility where they are no longer a resident or out of state).
- Provider sites are encouraged to monitor and manage their inventories to ensure availability of second doses.

Liability Protection

The federal Public Readiness and Emergency Preparedness Act (PREP Act), provides liability protections for "covered persons" involved in many aspects of the COVID-19 response, and includes persons operating a vaccination administration site, and providers and staff working at vaccination administration sites. For additional information go to: Read more about the PREP Act.

Questions or Concerns?

If you have questions related to COVID-19 vaccines, please send your questions to one of the following, so OHA can assist.

- General vaccine questions: ORCOVID@211info.org
- For help getting a vaccine or for general information, contact: 211

- COVID-19 vaccine provider enrollment: Vaccine.ProviderEnroll@dhsoha.state.or.us
- For complaints related to compliance with this guidance contact us at covidvaccine.complaints@dhsoha.state.or.us, or 877-642-0450 / 503-947-2346

Resources

- **OHA COVID-19 Vaccine Website:** http://healthoregon.org/covidvaccine
- **OHA COVID-19 en Español:** http://healthoregon.org/vacunacovid.
- **Traditional Health Care Worker Registry:** https://traditionalhealthworkerregistry.oregon.gov/
- **Health Care Interpreter Registry:** https://hciregistry.dhsoha.state.or.us/
- **Visual Communication Tool:** https://sharedsystems.dhsoha.state.or.us/DHSForms/Served/le2314.pdf.
- Healthcare and Face Coverings: Reducing Communication Barriers for Deaf and Hard of Hearing Patients
- FEMA Civil Rights Considerations During COVID-19 Vaccine Distribution Efforts
- HHS Ensuring Language Access and Effective Communication During Response and Recovery: A Checklist for Emergency Responders
- ADA Guidance for Emergency Managers and Local Public Health Authorities
- Communication Cards for People Who Cannot Speak

Document accessibility: For individuals with disabilities or individuals who speak a language other than English, OHA can provide information in alternate formats such as translations, large print, or braille. Contact the Health Information Center at 1-971-673-2411, 711 TTY or COVID19.LanguageAccess@dhsoha.state.or.us