



COVID-19 Vaccine Guidance

Effective Date: February 01, 2021

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

Applicability: This guidance applies to any person administering an FDA authorized or approved COVID-19 vaccine in Oregon.

Vaccine Fact Sheets

Any person administering COVID-19 vaccine is required to:

- As required by the federal government, give the individual or legally authorized health care representative, in their primary language, the Fact Sheet for Recipients and Caregivers for the specific vaccine. Fact sheets can be found on the FDA website here:
<https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines>.

Informed Consent

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 and have an opportunity to ask questions.

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

- Provide information regarding the vaccine in the individual's primary language or in a manner that the individual can understand, taking into account English language proficiency or Americans with Disabilities Act accessibility needs.
- 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.

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

- 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.

Reporting Vaccine Information to the Oregon Health Authority

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

- Report administration information into ALERTIIS, the Authority's statewide immunization registry 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>.

Questions?

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

- COVID-19 vaccine provider enrollment: Vaccine.ProviderEnroll@dhsoha.state.or.us
- COVID-19 vaccine advisory committee: Covid.vaccineadvisory@dhsoha.state.or.us

Resources

- **OHA COVID-19 Vaccine Website:** <http://healthoregon.org/covidvaccine>
 - Spanish: <http://healthoregon.org/vacunacovid>
- **Traditional Health Care Worker Registry:** <https://traditionalhealthworkerregistry.oregon.gov/>
- **Health Care Interpreter Registry:** <https://hciregistry.dhsoha.state.or.us/>

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