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**NOTICE OF PROPOSED RULEMAKING**  
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 333  
OREGON HEALTH AUTHORITY  
PUBLIC HEALTH DIVISION

**FILED**  
05/14/2021 12:53 PM  
ARCHIVES DIVISION  
SECRETARY OF STATE

FILING CAPTION: COVID-19 vaccine requirements

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 06/21/2021 5:00 PM

*The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.*

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Filed By:  
Brittany Hall  
Rules Coordinator

HEARING(S)

*Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.*

DATE: 06/16/2021

TIME: 1:00 PM

OFFICER: Staff

ADDRESS: VIA CONFERENCE CALL  
ONLY

Following direction from the Gov/CDC  
public meetings are via conference call  
Portland, OR 97232

SPECIAL INSTRUCTIONS:

Due to COVID-19, public meetings are  
being held remotely. To provide oral  
testimony during this hearing, please  
dial 1-877-848-7030,  
Access Code: 2030826#

NEED FOR THE RULE(S):

Oregon is experiencing a continuing global pandemic due to COVID-19. Limited supplies of vaccines to prevent COVID-19 are being distributed to states making the allocation and distribution of vaccine within the state complex. To properly allocate the vaccine, track how many doses are being administered, and to ensure the vaccine is being allocated to those who have through-put to administer it to those who are eligible, it is imperative that the state have current information from those with the vaccine about how many doses they have on hand, how many have been administered, whether any inventory has been transferred and to whom, and whether any has been wasted.

Persons receiving vaccines must undergo specific training to ensure proper storage and administration, and the state

must have the ability to re-direct state-supplied vaccine where it is most needed, or take back state-supplied vaccine that is not being appropriately handled. Lastly, the state must be able to request additional information from those who have the COVID-19 vaccine for oversight purposes. To ensure compliance, there are civil penalties that may be imposed for violations of OAR 333-047-1000.

These rules align state rule requirements with the requirements in the Centers for Disease Control and Prevention (CDC)'s COVID-19 Vaccination Program Provider Agreement, that is required to be signed by any person who receives COVID-19 vaccine for administration. Additionally, the rules make clear the state's authority to manage and oversee the COVID-19 vaccine inventory that is distributed and allocated within the state, clearly establish additional state requirements for persons receiving COVID-19 vaccine, and establishes civil penalties for violations of the rules, not to exceed \$500 per violation per day. These proposed permanent rules will replace temporary rules currently in effect and scheduled to expire on July 20, 2021.

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DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

CDC COVID-19 Vaccination Program Provider Agreement available at

<https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/VACCINESIMMUNIZATION/IMMUNIZATIONPROVIDERRESOURCES/program-provider-agreement-Section-A-B.pdf>

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FISCAL AND ECONOMIC IMPACT:

There is no fiscal impact to the Oregon Health Authority. Medical clinics, tribal health clinics, Local Public Health Authority clinics, pharmacies and other sites that were receiving vaccine supplied by the Oregon Health Authority prior to the availability of COVID-19 vaccines will see no impact other than the need to submit data in a shorter timeframe. Clinics enrolling with the Authority to receive COVID-19 vaccine only will need to submit data to Oregon's immunization registry, ALERT Immunization Information System. This could incur slight costs in staff time or in having their electronic health record set up to submit data automatically. There is no fiscal impact to the general public.

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COST OF COMPLIANCE:

*(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).*

(1) Local Public Health Authority clinics, other state-operated health clinics, tribal health facilities, pharmacies and private medical clinics are required to report vaccine administration to Oregon's immunization registry, ALERT Immunization Information System. Under typical conditions, clinics have up to two weeks to submit data. Under the new rules, clinics will have to submit administered doses of COVID-19 vaccine within 24 hours. These clinics have been operating under these same rules, filed as temporary in January 2021. There is no anticipated cost of compliance impact on the public.

(2)(a) Several hundred private medical clinics and solo practitioners that are unaffiliated with a major health system.

(b) Clinics that do not use an electronic health record that exports administration data would need to submit doses

through an online user interface. Adding each record requires less than a minute of staff time. Most clinics voluntarily submit their data because of usefulness of registry data to their own practice.

Clinics that use an electronic health record that exports administration data can submit data electronically. For most clinics, once the initial programming is complete, the process is automatic with no human interaction needed on the part of the clinic.

(c) None.

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DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

Medical providers are represented on the Immunization Policy Advisory Team that served as our Rules Advisory Committee.

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WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

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RULES PROPOSED:

333-047-0010, 333-047-0040, 333-047-0050, 333-047-1000, 333-049-0050

AMEND: 333-047-0010

RULE SUMMARY: 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"

CHANGES TO RULE:

333-047-0010

Definitions Used in the Vaccine Accountability Rules ¶¶

(1) All definitions of ORS 433.090 and 433.235 apply to these rules.¶¶

(2) In addition to the definitions of ORS 433.090 and 433.235, the following definitions apply:¶¶

(a) "Authority" means the Oregon Health Authority.¶¶

(b) "Authority's Immunization Registry" means the immunization information system (IIS) established by the Authority under ORS 433.094 and OAR chapter 333, division 49.¶¶

(c) "Certify" means to attest, in writing, on a form prescribed by Oregon Health Authority that at least two employees, owners or partners have completed required vaccine-related trainings as provided or approved by Oregon Health Authority.¶¶

(ed) "Entity" means a health clinic or provider, pharmacy or pharmacist who receives state-supplied vaccine.¶¶

(de) "Oregon Immunization Program" means Oregon Health Authority, Public Health Division, Immunization Program.¶¶

(ef) "Public Health Division" means the Oregon Health Authority, Public Health Division.¶¶

(fg) "Receives vaccines" means an entity is supplied with vaccines by the Oregon Immunization Program, including vaccines acquired with federal and state funds, including the Vaccines for Children Program (VFC), the Section 317 Vaccine Program, state Special Project vaccine, and state Billable Project vaccine.¶¶

(gh) "State supplied vaccine" means vaccine provided by the federal government or the Oregon Immunization Program.¶¶

(hj) "State-supplied Vaccine User Vaccine Accountability Reporting Requirements and Timelines" means the schedule of reporting timelines found in the Vaccine User Accountability Reporting Table of OAR 333-047-0050, or OAR 333-047-1000.

Statutory/Other Authority: ORS 433.103  
Statutes/Other Implemented: ORS 433.103

AMEND: 333-047-0040

RULE SUMMARY: Amend OAR 333-047-0040: An entity that receives COVID-19 vaccine must comply with the new 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.

CHANGES TO RULE:

333-047-0040

Accounting for Vaccine ¶

(1) Any entity receiving state supplied vaccine shall account for vaccines through data submission and inventory management via the Authority's Immunization Registry, as outlined in OAR 333-049-0010 through 333-049-0050 and for COVID-19 vaccine, as outlined in OAR 333-047-1000. (See the Vaccine User Accountability Reporting Table, OAR 333-047-0050).¶

~~[ED. NOTE: Tables referenced are available from the agency.]~~(2) An entity receiving state supplied vaccine may only transfer or redistribute vaccine to another Authority enrolled provider.

Statutory/Other Authority: ORS 433.103

Statutes/Other Implemented: ORS 433.103

AMEND: 333-047-0050

RULE SUMMARY: Amend OAR 333-047-0050: An entity that receives COVID-19 vaccine must comply with the reporting requirements in the new administrative rule OAR 333-047-1000.

CHANGES TO RULE:

333-047-0050

Timeline for Reporting ~~¶~~

An entity receiving state supplied vaccine shall submit vaccine accounting information required under OAR 333-047-0040 according to the schedule set out in the Vaccine User Accountability Reporting Table. ~~¶~~

~~[ED. NOTE: Tables referenced are available from the agency.]~~ or for COVID-19 vaccine, in accordance with OAR 333-047-1000.

Statutory/Other Authority: ORS 433.103

Statutes/Other Implemented: ORS 433.103

RULE ATTACHMENTS DO NOT SHOW CHANGES. PLEASE CONTACT AGENCY REGARDING CHANGES.

**Oregon Immunization Program  
Vaccine User Accountability Reporting Table (OAR 333-047-0050)**

User Status	VFC Enrolled as of 12/31/2011		New VFC Sites as of 1/1/2012	
Submission Type	Registry User Interface	Electronic	Registry User Interface	Electronic
Timeliness - All data must be submitted within 14 days of vaccine administration.	On or before 12/31/12	On or before 12/31/12	Within 30 days of enrollment	Within 90 days of enrollment
Population - All doses administered (including state-supplied and privately purchased) to patients of all ages.				
Ordering Module - All state-supplied doses must be ordered using the Oregon Health Authority registry Ordering module.				
Inventory Module - All state-supplied doses must be managed using the Oregon Health Authority registry Inventory Module. Sites are encouraged but not required to also use the Inventory Module for privately purchased doses.		On or before 12/31/13		Within 180 days of enrollment
Vaccine Eligibility by Dose - Every dose administered (including state-supplied and privately purchased) must be submitted with an accompanying Vaccine Eligibility code.	On or before 12/31/13			

ADOPT: 333-047-1000

RULE SUMMARY: Adopt OAR 333-047-1000:

A person or entity that receives, stores, administers or transfers COVID-19 vaccine must report:

- o All COVID-19 vaccine dose administration within 24 hours of administration.
- o All on-hand inventory on a weekly basis, no later than 5 p.m. Pacific Time on Sunday.
- o All spoiled, expired, or wasted COVID-19 vaccine to ALERT or through an OHA survey within 24 hours of knowledge or discovery.
- o 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.

CHANGES TO RULE:

### 333-047-1000

#### COVID-19 Vaccine Requirements

(1) A person or entity receiving, storing, administering, or transferring COVID-19 vaccine must report: ¶

(a) All COVID-19 vaccine dose administration and adjuvant (if applicable) within 24 hours of administration. ¶

(b) All on-hand inventory of COVID-19 vaccine on a weekly basis, no later than 5 p.m. Pacific Time on Sunday. ¶

(c) All spoiled, expired, or wasted COVID-19 vaccine to the Authority's Immunization Registry or through a survey managed by the Authority within 24 hours of knowledge or discovery of the spoilage, expiration or wasting. ¶

(d) All transfers of COVID-19 vaccine within 24 hours of the transfer. ¶

(2) A person or entity must report the information required under this rule in the Registry in accordance with OAR chapter 333, division 49. ¶

(3) A person or entity receiving state-supplied COVID-19 vaccine must promptly (within 24 hours) respond to requests for information from the Authority or a Local Public Health Authority about its COVID-19 vaccine storage, handling, use, administration plans, transfers, or inventory, including temperature logs. ¶

(4) If the Authority determines that a person or entity with COVID-19 vaccine cannot make immediate use of the vaccine and that the vaccine is needed more urgently elsewhere, the Authority may request the vaccine be transferred to another enrolled provider and the vaccine must be transferred within 24 hours of the Authority's request. ¶

(5) If the Authority determines that a person or entity with COVID-19 vaccine is not appropriately storing or handling COVID-19 vaccine, the Authority may demand return of the vaccine or appear on-site to collect and remove the vaccine. ¶

(6) A person or entity receiving state-supplied COVID-19 vaccine must, in addition to any requirements in OAR 333-047-0030, complete trainings identified on the Authority's COVID-19 Training for Vaccine Provider's webpage:

<https://www.oregon.gov/oha/ph/PreventionWellness/VaccinesImmunization/RulesLaws/Pages/index.aspx>. ¶

(7) A person or entity who violates any provision of this rule is subject to a civil penalty of \$500 per day per violation.

Statutory/Other Authority: ORS 433.103, 431A.010

Statutes/Other Implemented: ORS 433.103, 431A.010





AMEND: 333-049-0050

RULE SUMMARY: Amend OAR 333-049-0050: Adds reference to OAR 333-047-1000 for the purposes of COVID-19 vaccine reporting.

CHANGES TO RULE:

333-049-0050

Reporting to the Immunization Information System (IIS) ¶¶

(1) Any provider who participates in the IIS and who administers immunizations shall report such immunization to the IIS within 14 calendar days of such immunization, or for COVID-19 immunizations, in accordance with OAR 333-047-1000.¶¶

(2) Any pharmacist who immunizes must report all immunizations administered to the IIS in accordance with OAR 855-019-0290, or for COVID-19 immunizations, in accordance with OAR 333-047-1000.¶¶

(3) Reports shall be submitted to the IIS in a manner as required by the program.¶¶

(4) Any authorized user may report immunizations, and other such information, permitted under ORS 433.090(3) and (5), as prescribed by the program, to the IIS without the consent of the client or the parent or guardian of the client. Reporting this information without the consent mentioned above shall not subject a person to liability or civil action.¶¶

(5) Any authorized user who administers state-supplied vaccine must report in a manner prescribed by the Oregon Health Authority the following data elements for all administered doses to the Statewide Immunization Information System in accordance with Public Health Division timelines in the Vaccine User Accountability Reporting Table (OAR 333-047-0050) and for COVID-19 vaccine, in accordance with OAR 333-047-1000:¶¶

(a) The name, address, phone number, gender, and date of birth of a client;¶¶

(b) The date of administration of the vaccine;¶¶

(c) The CPT, CVX, or NDC code of the vaccine administered;¶¶

(d) The dose-level vaccine eligibility code;¶¶

(e) The organizational identifier of the administering or reporting clinic or site;¶¶

(f) The lot number of the vaccine;¶¶

(g) The dose amount and manufacturer of the vaccine, when available; and¶¶

(h) Other data elements as specified by the Public Health Division.¶¶

(6) Any authorized user who administers state-supplied vaccine shall utilize, in accordance with OAR 333-047-0050 and 333-047-1000:¶¶

(a) The ordering module for ordering state-supplied vaccines; and¶¶

(b) The inventory module for tracking public or public and private vaccine supply.

Statutory/Other Authority: ORS 433.096, 433.103, 689.645

Statutes/Other Implemented: ORS 433.096, 433.103, 689.645