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TEMPORARY ADMINISTRATIVE ORDER
INCLUDING STATEMENT OF NEED & JUSTIFICATION

PH 5-2021

CHAPTER 333
OREGON HEALTH AUTHORITY
PUBLIC HEALTH DIVISION

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SECRETARY OF STATE
& LEGISLATIVE COUNSEL

FILING CAPTION: Temporary rules for COVID-19 Vaccine Requirements

EFFECTIVE DATE: 01/22/2021 THROUGH 07/20/2021

AGENCY APPROVED DATE: 01/22/2021

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NEED FOR THE RULE(S):

Oregon, the United States, and the World is in the midst of a global pandemic due to COVID-19. Vaccines to prevent COVID-19 are being distributed to states in limited supply making the allocation and distribution of vaccine within the state extremely complex. The vaccines have very particular cold-storage requirements that may limit who has the ability to receive doses of the vaccine. In addition, in order to properly allocate the vaccine, track how many doses are being administered, which affects how much vaccine the state can get, 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. In order to ensure compliance, there are civil penalties that may be imposed for violations of OAR 333-047-1000.

These temporary 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. In addition, the temporary 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.

JUSTIFICATION OF TEMPORARY FILING:

The Authority finds that failure to act promptly will result in serious prejudice to the public interest, the Authority, and all Oregonians who are waiting to receive COVID-19 vaccine. These rules need to be adopted promptly so that the Authority can adequately manage the distribution and allocation of COVID-19 vaccine in a manner that ensures the

vaccine is getting to the most people in the most equitable way. Without accurate data for those who have received doses of vaccine and are administering it, and without ensuring the proper handling, storage, transfer, and administration of COVID-19 vaccines, the state's vaccination efforts will be hampered and time is of the essence to prevent future illness and death from COVID-19.

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/covid19-vaccination-program-provider-agreement-Section-A-B.pdf>

RULES:

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.¶
 - (hi) "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 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.

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 temporary 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: An entity that receives COVID-19 vaccine must comply with the reporting and other requirements in the new temporary OAR 333-047-1000.

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