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CHAPTER 333

OREGON HEALTH AUTHORITY

PUBLIC HEALTH DIVISION

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FILING CAPTION: Oregon Immunization Program - Adoption of rules for the yellow fever vaccine program

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RULES:

333-045-0410, 333-045-0420, 333-045-0430, 333-045-0440

ADOPT: 333-045-0410

NOTICE FILED DATE: 11/19/2024

RULE SUMMARY: Adopt OAR 333-045-0410: Describes the purpose of OAR chapter 333, division 45 for the Yellow Fever Vaccine Program.

CHANGES TO RULE:

333-045-0410

Purpose

International health regulations allow countries to require arriving travelers to provide proof of yellow fever vaccination. The U.S. Centers for Disease Control and Prevention (CDC) Director has delegated the authority to designate yellow fever vaccination centers authorized to issue international certificates of vaccination or prophylaxis to the Oregon Health Authority (Authority) under 42 CFR Part 71.3. OAR 333-045-0410 to 333-045-0440 set out the Authority's process and the requirements for designation as a yellow fever vaccination center. Statutory/Other Authority: ORS 413.042, ORS 431.110, ORS 431.115, ORS 431.141 - 431.149 Statutes/Other Implemented: ORS 413.042, ORS 431.110, ORS 431.115, ORS 431.141 - 431.149

ADOPT: 333-045-0420

NOTICE FILED DATE: 11/19/2024

RULE SUMMARY: Adopt OAR 333-045-0420: Adopts outside standards and publications by reference.

CHANGES TO RULE:

333-045-0420

Adoption by Reference

Outside standards, listings and publications referred to in these rules are by reference made a part of these rules as if fully set forth.

Statutory/Other Authority: ORS 413.042, ORS 431.110, ORS 431.115, ORS 431.141 - 431.149

Statutes/Other Implemented: ORS 413.042, ORS 431.110, ORS 431.115, ORS 431.141 - 431.149

ADOPT: 333-045-0430

NOTICE FILED DATE: 11/19/2024

RULE SUMMARY: Adopt OAR 333-045-0430: Provides definitions of terms used in OAR chapter 333, division 45 for the Yellow Fever Vaccine Program.

CHANGES TO RULE:

333-045-0430

Definitions

The following definitions apply to OAR 333-045-0410 to 333-045-0440.

(1) "Authority" means the Oregon Health Authority.

(2) "CDC" means the U.S. Centers for Disease Control and Prevention.

(3) "Designated prescriber" means a prescriber who is currently designated under OAR 333-045-0440 as a yellow fever vaccination center authorized to issue international certificates of vaccination or prophylaxis as described in 42 CFR Part 71.3.

(4) "International Certificate of Vaccination or Prophylaxis" or "yellow card" means the official, internationally recognized document that travelers use to document proof of vaccination for diseases included under international health regulations.

(5) "Prescriber" means a medical provider with prescription writing privileges currently licensed in Oregon including physicians (MD, DO), physician associates, nurse practitioners, naturopaths (ND), dentists (DMD, DDS), and certified immunizing pharmacists.

(6) "Uniform stamp" means a stamp provided by the Authority to a designated prescriber.

(7) "Yellow fever vaccine manufacturer" means a pharmaceutical company with a biologics license application to distribute yellow fever vaccine in the United States.

Statutory/Other Authority: ORS 413.042, ORS 431.110, ORS 431.115, ORS 431.141 - 431.149

Statutes/Other Implemented: ORS 413.042, ORS 431.110, ORS 431.115, ORS 431.141 - 431.149

RULE SUMMARY: Adopt OAR 333-045-0440: Sets out the application and ongoing requirements for designation as a yellow fever vaccination center. Requires completion of the CDC's Yellow Fever Vaccine Course before applying for designation. Describes initial application and renewal process.

CHANGES TO RULE:

333-045-0440

Prescriber Participation

(1) Application.¶

(a) Only a prescriber may apply for or obtain designation as a yellow fever vaccination center as described in 42 CFR Part 71.3.¶

(b) Prior to applying and to be eligible for designation, an applicant must obtain and submit a copy of the certificate of completion from the U.S. Centers for Disease Control and Prevention (CDC)'s Yellow Fever Vaccine Course.¶

(c) An applicant must submit a complete Yellow Fever Uniform Stamp application in the form provided by the Oregon Health Authority (Authority) and a copy of the Yellow Fever Vaccine Course certification of completion with the application. The applicant must sign and date the application, agree to all of the control measures and requirements in the application agreement.¶

(d) An applicant shall submit the application and a copy of the Yellow Fever Vaccine Course certificate of completion by mail or electronic mail to the Authority.¶

(e) The Authority may deny an application if the application or the applicant fails to satisfy the requirements of this rule.¶

(2) Designation term.¶

(a) Designation as a yellow fever vaccination center is valid for three years.¶

(b) Designation is valid only for the prescriber identified in the application.¶

(3) The Authority shall provide the yellow fever vaccine manufacturer a current list of designated prescribers and the organization identified on an approved application. The Authority shall notify the yellow fever vaccine manufacturer when a prescriber is no longer designated.¶

(4) After approving an application, the Authority shall order and mail an official uniform stamp to the address provided on the application.¶

(5) Designated prescribers must:¶

(a) Record all yellow fever vaccines on an International Certificate of Vaccination, available from the U.S. Government Bookstore. Other vaccines may also be documented on the record, but it is not required.¶

(b) Comply with all other control measures and requirements in the application agreement.¶

(6) The name, address and phone number of designated prescribers is publicly available information.¶

(7) Designated prescribers may only use the uniform stamp while their designation is current.¶

(8) The Authority retains the right to revoke yellow fever designation if a provider fails to maintain adequate storage and handling of yellow fever vaccine. Written notification will be sent by certified mail to the designated provider.¶

(9) A prescriber whose designation is revoked may re-apply for a new certification once documentation is provided of adequate storage conditions.¶

(10) Prescribers must reapply for designation using the application procedures to obtain a new designation if their designation expires. The Authority will notify stamp holders when re-certification is due. Failure to respond to the re-certification request will result in the authorized prescriber being blocked from ordering yellow fever vaccine until re-certification is complete.¶

(11) Designation is only valid for yellow fever vaccinations administered in Oregon. Prescribers operating in multiple states will need a uniform stamp for each state where they practice.

Statutory/Other Authority: ORS 413.042, ORS 431.110, ORS 431.115, ORS 431.141 - 431.149

Statutes/Other Implemented: ORS 413.042, ORS 431.110, ORS 431.115, ORS 431.141 - 431.149