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NOTICE OF PROPOSED RULEMAKING INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 333 OREGON HEALTH AUTHORITY PUBLIC HEALTH DIVISION

FILED 11/19/2024 4:52 PM ARCHIVES DIVISION

SECRETARY OF STATE

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

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 12/23/2024 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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HEARING(S)

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

DATE: 12/16/2024 TIME: 1:30 PM - 2:00 PM OFFICER: Staff

REMOTE HEARING DETAILS MEETING URL: Click here to join the meeting PHONE NUMBER: 971-277-2343 CONFERENCE ID: 393025738 SPECIAL INSTRUCTIONS:

This hearing is being held remotely via Microsoft Teams. To provide oral (spoken) testimony during this hearing, please contact publichealth.rules@odhsoha.oregon.gov to register and receive the link for the Microsoft Teams video conference via calendar appointment, or you may access the hearing using the meeting URL above. Alternatively, you may dial 971-277-2343, Phone Conference ID 393 025 738# for audio (listen) only.

The hearing will close at the posted time of 2:00PM. You are encouraged to join as close to the beginning of the hearing if you wish to provide oral testimony.

Accessibility Statement: For individuals with disabilities or individuals who speak a language other than English, OHA can provide free help. Some examples are: sign language and spoken language interpreters, real-time captioning, braille, large print, audio, and written materials in other languages. If you need help with these services, please contact the Public Health Division at 971-673-1222, 711 TTY or publichealth.rules@odhsoha.oregon.gov at least 48 hours before the meeting. All relay calls are accepted. To best ensure our ability to provide a modification please contact us if you are considering attending the meeting and require a modification. The earlier you make a request the more likely we can meet the need.

NEED FOR THE RULE(S)

The Oregon Health Authority (OHA), Public Health Division, Oregon Immunization Program (OIP) has operated a yellow fever vaccine program for over 20 years under delegation from the U.S. Centers for Disease Control and Prevention (CDC). Based on advice from the Oregon Attorney General's office, this program is being codified in the Oregon Administrative Rules.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

42 CFR 71.3: https://www.ecfr.gov/current/title-42/chapter-I/subchapter-F/part-71/subpart-A/section-71.3

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

These changes are administrative in nature and little impact on racial equity is anticipated.

FISCAL AND ECONOMIC IMPACT:

OIP does not anticipate any financial impact from promulgation of these rules to any entities.

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) OHA is required by federal agreement to purchase uniform stamps for approved providers. Local public health authorities that choose to provide yellow fever vaccination would be subject to these rules. There is no financial impact to local public health authorities. There will not be any impact on the public.

(2)(a) Clinics or pharmacies run as small businesses that choose to offer yellow fever vaccination would be subject to these rules. Currently there are 185 registered yellow fever providers. The number that are small businesses is unknown. According to the National Community Pharmacists Association, there are 90 independent community pharmacies in Oregon. The number providing yellow fever vaccine is unknown.

(b) Applying providers will be required to take the Centers for Disease Control and Prevention's yellow fever vaccine course and submit a copy of the certificate of completion.

(c) No equipment, supplies, labor or increased administration is estimated to be required for compliance.

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

A notification was sent to a listserv maintained by the Oregon Immunization Program that reaches ~5,000 immunization-related subscribers via email, including public and private health care providers and clinics, Tribal and Urban Indian health centers, health insurance and Medicaid representatives, local public health, legislative staff, and others asking for review and comment.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

RULES PROPOSED: 333-045-0410, 333-045-0420, 333-045-0430, 333-045-0440

ADOPT: 333-045-0410

RULE SUMMARY: Adopt OAR 333-045-0410: Describes the purpose of OAR chapter 333, division 45.

CHANGES TO RULE:

333-045-0410

<u>Purpose</u>

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

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

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.

<u>Statutory/Other Authority: ORS 413.042, ORS 431.110, ORS 431.115, ORS 431.141 - 431.149</u> <u>Statutes/Other Implemented: ORS 413.042, ORS 431.110, ORS 431.115, ORS 431.141 - 431.149</u>

ADOPT: 333-045-0430

RULE SUMMARY: Adopt OAR 333-045-0430: Provides definitions of terms used in OAR chapter 333, division 45.

CHANGES TO RULE:

<u>333-045-0430</u>

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.

<u>Statutory/Other Authority: ORS 413.042, ORS 431.110, ORS 431.115, ORS 431.141 - 431.149</u> <u>Statutes/Other Implemented: ORS 413.042, ORS 431.110, ORS 431.115, ORS 431.141 - 431.149</u>

ADOPT: 333-045-0440

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. \P

(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.¶

(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.

<u>Statutory/Other Authority: ORS 413.042, ORS 431.110, ORS 431.115, ORS 431.141 - 431.149</u> <u>Statutes/Other Implemented: ORS 413.042, ORS 431.110, ORS 431.115, ORS 431.141 - 431.149</u>