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

CHAPTER 333  
OREGON HEALTH AUTHORITY  
PUBLIC HEALTH DIVISION

**FILED**  
08/11/2020 4:36 PM  
ARCHIVES DIVISION  
SECRETARY OF STATE

FILING CAPTION: Dental Pilot Project Program

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 09/21/2020 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.*

*A public rulemaking hearing may be requested in writing by 10 or more people, or by a group with 10 or more members, within 21 days following the publication of the Notice of Proposed Rulemaking in the Oregon Bulletin or 28 days from the date the Notice was sent to people on the agency mailing list, whichever is later. If sufficient hearing requests are received, the notice of the date and time of the rulemaking hearing must be published in the Oregon Bulletin at least 14 days before the hearing.*

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Filed By:  
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NEED FOR THE RULE(S):

The Oregon Health Authority (Authority), Public Health Division, Oral Health Program is proposing to permanently amend administrative rules in chapter 333, division 10 "Dental Pilot Projects" to clarify the rules so that they are in alignment with statutory authority under Oregon Revised Statutes (ORS) Chapter 716, Oregon Laws 2011. The statute states that "The authority may approve a pilot project that is designed to: (a) Operate for three to five years or a sufficient amount of time to evaluate the validity of the pilot project." Oregon Administrative Rule (OAR) 333-010-0750 states that projects may operate "from between three to five years." Clarification to the rule is needed so that dental pilot projects who require additional time to evaluate the validity of their pilot project may apply to the Authority for an extension of their approved timeline.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

Documents Relied Upon, and where they are available:

- SB 738 (Oregon Laws 2011, chapter 716):

<https://olis.leg.state.or.us/liz/2011R1/Downloads/MeasureDocument/SB738/Enrolled>

- SB 606 (Oregon Laws 2015, chapter 716):

<https://olis.leg.state.or.us/liz/2015R1/Downloads/MeasureDocument/SB606/Enrolled>

- Oregon Administrative Rules, 333-010-0700 through 333-010-0820, Oregon Health Authority, Public Health Division, Chapter 333, Division 10, Health Promotion and Chronic Disease Prevention:

<https://secure.sos.state.or.us/oard/displayDivisionRules.action?selectedDivision=1225>

FISCAL AND ECONOMIC IMPACT:

There is no direct fiscal or economic impact from the proposed rule amendments to the Authority or public.

Previously approved dental pilot projects and any new approved dental pilot project are not required to extend the length of time their pilot projects are operating. If pilot projects want to extend the length of time their project is allowed to operate, then they will be required to submit a request to modify their project and must receive approval from the Authority. All dental pilot projects are self-funded and may incur additional costs to continue to operate if they extend the length of time for their pilot project.

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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. Impact on state agencies, units of local government and the public (ORS 183.335(2)(b)(E)):**

There is no cost of compliance impact to state agencies, units of local government or the public as a result of the proposed rule amendments.

**2. Cost of compliance effect on small business (ORS 183.336):**

**a. Estimate the number of small businesses and types of business and industries with small businesses subject to the rule:**

A small number of small businesses may be subject to the proposed rule amendments. Current dental pilot projects are operated by larger organizations such as educational institutions, dental care organizations, tribal organizations and federally qualified health centers. Private practice dentists that operate within a dental pilot project may be considered a small business. We cannot estimate exactly how many there are, but any entity operating in an approved dental pilot project would need to comply with the proposed rule amendments.

**b. Projected reporting, record keeping and other administrative activities required for compliance, including costs of professional services:**

Small businesses may be impacted if they operate within a dental pilot project. However, there is no requirement that small businesses must operate within a pilot project. If a dental pilot project chooses to extend the length of time to operate, then additional costs may be incurred for reporting, record keeping and administrative activities that pilot projects must complete to continue operating an approved dental pilot project.

**c. Equipment, supplies, labor and increased administration required for compliance:**

Small businesses may be impacted if they operate within a dental pilot project. However, there is no requirement that small businesses must operate within a pilot project. If a dental pilot project chooses to extend the length of time to operate, then additional labor and equipment costs may be incurred.

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

Small businesses were not involved with the proposed rule amendments since a Rule Advisory Committee (RAC) was not consulted.

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**WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? NO IF NOT, WHY NOT?**

The proposed rule amendments are for clarification purposes only. The proposed changes do not have a substantive

effect on dental pilot projects. The following groups were notified in lieu of a RAC: Dental Care Organization, Coordinated Care Organizations, Tribes, Northwest Portland Area Indian Health Board, Oregon Board of Dentistry, Oregon Dental Association, Oregon Dental Hygiene Association, Oregon Health and Science University School of Dentistry, Oregon Dental Hygiene Programs.

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AMEND: 333-010-0750

RULE SUMMARY: OAR 333-010-0750 "Dental Pilot Projects: Provisional Approval; Final Approval": Language is being proposed to clarify that dental pilot projects may apply to the Authority for an extension of their approved timeline if they require additional time to evaluate the validity of their dental pilot project.

CHANGES TO RULE:

333-010-0750

Dental Pilot Projects: Provisional Approval; Final Approval

- (1) A project sponsor that has been provisionally approved must, within 90 calendar days of provisional project approval, submit the following to the Authority for approval:
  - (a) A detailed evaluation and monitoring plan that meets the requirements in OAR 333-010-0780, Pilot Project Evaluation and Monitoring by Sponsor.
  - (b) Written standard operating policies and procedures for the project that ensure compliance with OAR 333-010-0760, Minimum Standards. Standard operating policies and procedures shall include, but are not limited to:
    - (A) Clinical policies and procedures that describe the steps required for implementation of the project at each site;
    - (B) Administrative policies and procedures that describe protocols;
    - (C) Administrative protocols for mandatory record keeping;
    - (D) Data collection policies and procedure protocols that:
      - (i) Require data capture and data entry, including identification of the staff positions or other individuals responsible for these activities;
      - (ii) Define policies for protection and security of patient data;
    - (E) The protocol for orientating supervisors to their roles and responsibilities; and
    - (F) The process for ensuring that potential problems and root causes for deviations and non-conformances are identified, possible consequences assessed, actions to prevent recurrence considered, and corrective actions are taken if necessary.
  - (2) The Authority will review the documentation required in section (1) of this rule and notify the project sponsor if the plan and policies and procedures are acceptable. The Authority may request additional information and may request that the project sponsor revise the plan or policies and procedures to meet the requirements in these rules.
  - (3) Once the Authority has received an acceptable plan and policies and procedures, it will notify the project sponsor that the project has been approved along with the plan and policies and procedures. The final approval letter shall include:
    - (a) The permitted scope of the project;
    - (b) Any conditions the Authority deems are necessary to protect patient safety or ensure minimum standards in OAR 333-010-0760 are met;
    - (c) Procedures for which the project will be required to obtain written informed consent for treatment under OAR 333-010-0770, Informed Consent; and
    - (d) The length of time the project can operate - from between three to five years or a sufficient amount of time to evaluate the validity of the project.
  - (4) The Authority shall notify the Oregon Board of Dentistry when a project is approved.
  - (5) The Authority may deny an application if:
    - (a) The project fails to submit the documents described in section (1) that satisfy these rules;
    - (b) The project fails to submit additional information or revised plans, policies, or procedures that are acceptable

to the Authority as required by section (2) of this rule; or¶¶

(c) The documentation submitted by the project under this rule fails to demonstrate that the project will meet the minimum standards or other provisions in these rules.¶¶

(6) A denial issued under this rule must be in writing and must describe the reasons for the denial.¶¶

(7) A sponsor whose project has been denied may not submit a new application within six months from the date the Authority denied the application.

Statutory/Other Authority: 2011 OL Ch. 716

Statutes/Other Implemented: 2011 OL Ch. 716