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PERMANENT ADMINISTRATIVE ORDER

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CHAPTER 333
OREGON HEALTH AUTHORITY
PUBLIC HEALTH DIVISION

FILING CAPTION: Dental Pilot Project Program

EFFECTIVE DATE: 10/28/2020

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AMEND: 333-010-0750

RULE TITLE: Dental Pilot Projects: Provisional Approval; Final Approval

NOTICE FILED DATE: 08/11/2020

RULE SUMMARY: 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.

ORS Chapter 716, Oregon Laws 2011 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 dental pilot projects may operate “from between three to five years.” The rule needs to be amended 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.

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.

RULE TEXT:
(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