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OREGON HEALTH AUTHORITY
PUBLIC HEALTH DIVISION

FILING CAPTION: Dental Pilot Project Program

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RULES:
333-010-0700, 333-010-0710, 333-010-0720, 333-010-0730, 333-010-0740, 333-010-0750, 333-010-0760, 333-010-0780, 333-010-0790, 333-010-0800, 333-010-0820

AMEND: 333-010-0700

RULE TITLE: Dental Pilot Projects: Purpose

NOTICE FILED DATE: 01/24/2020

RULE SUMMARY: Amendments to OAR 333-010-0700 “Dental Pilot Projects: Purpose”: Language is being amended to clarify purpose of the Dental Pilot Project Program, clarify who the rules apply to and outline timeline for implementation of existing dental pilot projects.

RULE TEXT:
(1) The Dental Pilot Projects are intended to evaluate the quality of care, access, cost, workforce, and efficacy by teaching new skills to existing categories of dental personnel; developing new categories of dental personnel; accelerating the training of existing categories of dental personnel; or teaching new oral health care roles to previously untrained persons. The purpose of Dental Pilot Projects are to encourage the development of innovative practices in oral health care delivery systems with a focus on providing care to underserved populations that evidence-based studies have shown have the highest disease rates and the least access to dental care.
(2) These rules establish the requirements of Dental Pilot Project applications; the process for reviewing applications; approval or denial of applications; minimum standards for approved projects; evaluation and monitoring of Dental Pilot Projects; suspension or termination of an approved Dental Pilot Project; and discontinuation or closure of a project.
(3) These rules apply to all dental pilot projects. Dental pilot projects must come into compliance with new minimum standards requirements in OAR 333-010-0760 by July 1, 2020.

STATUTORY/OTHER AUTHORITY: 2011 OL Ch. 716

STATUTES/OTHER IMPLEMENTED: 2011 OL Ch. 716

AMEND: 333-010-0710

RULE TITLE: Dental Pilot Projects: Definitions

NOTICE FILED DATE: 01/24/2020

RULE SUMMARY: Amendments to OAR 333-010-0710 “Dental Pilot Projects: Definitions”: Language is being amended to specify and define terminology used throughout the administrative rules.

RULE TEXT:

For purposes of OAR 333-010-0700 through 333-010-0820, the following definitions apply:

(1) "Adverse event" means unnecessary harm due to dental treatment.

(2) "Applicable standard of care" means the standard of care that applies to a trainee and is the same standard of care that applies to a person performing the same services with a license.

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

(4) "Business day" means any 24-hour day other than a Saturday, Sunday or federal or state legal holiday.

(5) "Clinical evaluator" means a dentist, licensed in the State of Oregon or another state, who is responsible for conducting an independent clinical evaluation of an approved dental pilot project; who is unaffiliated with the project; and who has no financial or commercial interest in the project.

(6) "Clinical instructor" means a person who:

(a) Is certified or licensed in the field for which clinical instruction is occurring;

(b) Is currently licensed in dentistry or dental hygiene or licensed or certified in another appropriate health discipline; and

(c) Has current knowledge and skill in topics they will teach.

(7) "Clinical phase" means the time period of an approved project where a trainee treats patients, supervised by an instructor, applying knowledge presented by an instructor.

(8) "Complications" means a disease or injury that develops during or after the treatment of an earlier disorder.

(9) "Didactic phase" means the time period of a project during which trainees are presented with an organized body of knowledge by an instructor.

(10) "Employment/utilization phase" means the time period of a project where trainees are applying their didactic and clinical knowledge and skills in an employment setting under the supervision of a supervisor.

(11) "Employment/utilization site" means an Authority approved location, locations, or class of locations where a trainee or trainees provide care during the employment/utilization phase.

(12) "Non-clinical instructor" is a person with specific training or expertise as demonstrated through a degree or experience relevant to the content of instruction.

(13) "Program" means the Dental Pilot Projects Program administered by the Authority.

(14) "Program staff" means the staff of the Authority with responsibility for the Dental Pilot Projects Program.

(15) "Project" means a Dental Pilot Project approved by the Authority.

(16) "Project director" means the individual designated by the sponsor of a dental pilot project who is responsible for the conduct of the dental pilot project staff, instructors, supervisors, and trainees.

(17) "Project Dental Director" means an individual who is actively responsible for oversight of the dental pilot project and who is a dentist or dental hygienist:

(a) Licensed in the State of Oregon; or

(b) A dentist authorized to practice in the State of Oregon but is exempt from state licensure under ORS 679.020 or 679.025; or

(c) A dental hygienist authorized to practice in the State of Oregon but is exempt from state licensure under ORS 680.020.

(18) "Project evaluation" means a systematic method for collecting, analyzing and using data to examine the effectiveness and efficiency of a pilot project by the project sponsor.

(19) "Reviewer" means an individual designated by the Authority to review and comment on all or portions of a project

application.
(20) "Sponsor" means an entity that is a non-profit educational institution, professional dental organization, community hospital or clinic, coordinated care organization or dental care organization, tribal organization or clinic that:
(a) Submits a dental pilot project application; and
(b) If a dental pilot project is approved by the Authority, has overall responsibility for ensuring the project complies with these rules.
(21) "Standard operating procedures" means the written documented processes that describe the project's regularly recurring operations to ensure that the operations are carried out correctly and consistently and in accordance with these rules.
(22) "Supervisor" means an individual, licensed in the State of Oregon to practice dentistry, designated by the sponsor to oversee trainees at each approved employment/utilization site, with the skills necessary to teach trainees the scope of practice outlined in the approved project.
(23) "These rules" means OAR 333-010-0700 through 333-010-0820.
(24) "Trainee" means an individual who is part of an existing category of dental personnel; a new category of dental personnel; or a category of previously untrained dental personnel who has agreed to participate in a project and will be taught the scope of practice identified by the project.
(25) "Training program" means an organized educational program within a project that includes at least a didactic phase and a clinical phase.
(26) "Underserved populations" means groups of individuals that evidence-based studies have shown have the highest disease rates and the least access to dental care including, but not limited to:
(a) American Indians or Alaska Natives;
(b) Individuals earning up to 200 percent of the federal poverty level;
(c) Medicaid-eligible individuals;
(d) Migrant farmworkers and their family members; and
(e) Uninsured individuals.

STATUTORY/OTHER AUTHORITY: 2011 OL Ch. 716

STATUTES/OTHER IMPLEMENTED: 2011 OL Ch. 716

AMEND: 333-010-0720

RULE TITLE: Dental Pilot Projects: Application Procedure

NOTICE FILED DATE: 01/24/2020

RULE SUMMARY: Amendments to OAR 333-010-0720 “Dental Pilot Projects: Application Procedure”: Language is being amended to clarify components required in an application to the program. Rule language quantifies the minimum percentage of underserved populations that a dental pilot project must focus on at each site or by each trainee.

RULE TEXT:

(1) A sponsor who wishes to operate a pilot project must submit an application in a form and manner prescribed by the Authority.

(2) The application must demonstrate how the pilot project will comply with the requirements of these rules.

(3) The Authority will not accept new applications if it determines:

(a) There are a sufficient number of projects to provide a basis for testing the validity of the model as determined by the Authority.

(b) It does not have adequate resources to provide an appropriate level of oversight required by these rules.

(4) An application must include, at a minimum, the following information and documentation:

(a) The goals of the project, including whether the project can achieve at least one of the following:

(A) Teach new skills to existing categories of dental personnel;

(B) Accelerate the training of existing categories of dental personnel;

(C) Teach new oral health care roles to previously untrained personnel; or

(D) Develop new categories of dental personnel.

(b) Sponsor information:

(A) A description of the sponsor, including a copy of an organizational chart that identifies how the project relates organizationally to the sponsor;

(B) A copy of a document verifying the sponsor’s status as a non-profit educational institution, professional dental organization, community hospital or clinic, coordinated care organization or dental care organization, or a tribal organization or clinic;

(C) A description of the functions of the project director, project dental director, instructors, and other project staff;

(D) Documentation of the funding sources for the project;

(E) Documentation of liability insurance relevant to services provided by trainees; and

(F) A statement of previous experience in providing related health care services.

(c) Instructor and Supervisor information:

(A) The criteria used to select instructors and supervisors;

(B) Instructor-to-trainee ratio;

(C) The background of instructors in training techniques and methodology;

(D) The number of proposed supervisors and qualification of supervisors; and

(E) An explanation of how instructors and supervisors will be oriented to their roles and responsibilities and these rules.

(d) A training program that includes, but is not limited to, a description of:

(A) The instructional content required to meet the level of competence;

(B) The skills trainees are to learn;

(C) The methodology utilized in the didactic and clinical phases;

(D) The evaluation process used to determine when trainees have achieved the level of competence;

(E) The amount of time required to complete the didactic and clinical phases; and

(F) The level of competence the trainee shall have before entering the employment/utilization phase of the project.

(e) Trainee information:

(A) The criteria that will be used to select trainees;

(B) The number of proposed trainees;

(C) The proposed scope of practice for trainees; and
(D) Information regarding the background check process for participants to determine compliance with OAR 333-010-0760, Minimum Standards.
(f) Employment/utilization site information: A list of all locations or class of locations the proposed project intends for use during the employment/utilization phase where a trainee may provide care.
(g) Underserved population information:
(A) A list of the underserved populations the project intends to serve;
(B) Documentation demonstrating that the populations the pilot project intends to serve are underserved populations; and
(C) Documentation demonstrating that each of the project's trainees or employment/utilization sites shall provide services to the underserved populations identified in the application at a rate of at least 51 percent of all individuals served by the trainee or employment/utilization site on a quarterly basis.
(h) Cost information:
(A) The average cost of preparing a trainee, including but not limited to the costs related to instruction, instructional materials and equipment, space for conducting didactic and clinical phases, and other pertinent costs;
(B) The estimated cost of care provided in the project; the likely cost of this care if performed by the trainees of the project; and the cost for provision of this care by current providers;
(C) A budget narrative that lists costs associated with key project areas, including but not limited to:
(i) Personnel and fringe benefits for project director, project dental director, instructors, and staff associated with the project;
(ii) Contractors and consultants to the project;
(iii) Materials and supplies used in the clinical, didactic, and employment/utilization phases of the project;
(iv) Equipment and other capital costs associated with the project; and
(v) Travel required for implementing and monitoring the project.
(i) An explanation of the feasibility of achieving the project objectives.
(j) A preliminary evaluation plan that includes, but is not limited to:
(A) How the project sponsor will monitor and evaluate the project, including but not limited to:
(i) How the project sponsor will monitor and evaluate the rate of underserved populations served by the pilot project's trainees or employment/utilization sites; and
(ii) How the project sponsor will monitor and evaluate to ensure trainees are adequately supervised. Supervision of trainee must protect patient health and ensure minimum standards in OAR 333-010-0760 are met.
(B) A description of the key project activities and their intended effects;
(C) How the project sponsor intends to use the evaluation results for program improvement and decision making; and
(D) A description of how the project will measure its progress toward meeting the goals listed in the application, as described in subsection (4)(a) of this rule. The project must track and identify measurable project outcomes and metrics as outlined in the requirements under OAR 333-010-0780.
(k) An identified clinical evaluator who will conduct the clinical evaluation of the project in accordance with the evaluation plan.

STATUTORY/OTHER AUTHORITY: 2011 OL Ch. 716

STATUTES/OTHER IMPLEMENTED: 2011 OL Ch. 716

AMEND: 333-010-0730

RULE TITLE: Dental Pilot Projects: Application Review Process

NOTICE FILED DATE: 01/24/2020

RULE SUMMARY: Amendments to OAR 333-010-0730 “Dental Pilot Projects: Application Review Process”: Language is being amended to clarify the review process conducted by the Authority.

RULE TEXT:
(1) The Authority shall review an application to determine if it is complete within 60 calendar days from the date the application was received.
(a) If an applicant does not provide all the information required, and the application is considered incomplete, then the Authority shall notify the applicant of the information that is missing and shall allow the applicant 30 calendar days to submit the missing information.
(b) If an applicant does not submit the missing information within the timeframe specified in the notice, then the application shall be rejected as incomplete. An applicant whose application is rejected as incomplete may reapply at any time.
(2) An application deemed complete will continue through a review process.
(3) The Authority may have individuals outside the Authority, including representatives of appropriate professional societies and licensing boards, review applications, but no individual who has contributed to or helped prepare an application will be permitted to conduct a review of that application.
(4) The Authority may request additional information from an applicant during the review process.
(5) Once the Authority completes an application review, a Notice of Intent to provisionally approve or deny an application will be provided to the applicant. The Notice will be sent to interested parties and will be posted for public comment for a period of 30 calendar days, along with a link to the application and other materials submitted by the applicant.

STATUTORY/OTHER AUTHORITY: 2011 OL Ch. 716

STATUTES/OTHER IMPLEMENTED: 2011 OL Ch. 716

AMEND: 333-010-0740

RULE TITLE: Dental Pilot Projects: Project Application Provisional Approval or Denial

NOTICE FILED DATE: 01/24/2020

RULE SUMMARY: Amendments to OAR 333-010-0740 “Dental Pilot Projects: Project Application Provisional Approval or Denial”: Language is being amended to clarify the review process conducted by the Authority.

RULE TEXT:

(1) Following the close of the public comment period described in OAR 333-010-0730, Application Review Process, the Authority shall review the public comments that were received and issue within 30 calendar days of the close of the public comment period:

(a) A provisional decision to grant approval of an application; or

(b) A denial of the application.

(2) If the application is provisionally approved, the project sponsor must comply with the requirements in OAR 333-010-0750, Provisional Approval; Final Approval, before it can receive final approval. Projects that receive provisional approval may begin to provide didactic training however they may not operate or treat live patients until final approval is received from the Authority.

(3) If the Authority denies the application, the denial must be in writing and must describe the reasons for the denial. An application may be denied for any of these reasons:

(a) The application does not demonstrate that the project will meet the minimum standards or other provisions in these rules;

(b) The application does not demonstrate each of the project’s trainees or employment/utilization sites shall provide services to the underserved populations identified in the application at a rate of at least 51 percent of the individuals served by the trainee or employment/utilization site on a quarterly basis;

(c) The application does not demonstrate that the project is financially feasible; or

(d) The Authority has previously approved a similar project.

(4) 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

AMEND: 333-010-0750

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

NOTICE FILED DATE: 01/24/2020

RULE SUMMARY: Amendments to OAR 333-010-0750 “Dental Pilot Projects: Provisional Approval; Final Approval”: Language is being amended to clarify the reasons for denial of an application by the Authority.

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.

(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

AMEND: 333-010-0760

RULE TITLE: Dental Pilot Projects: Minimum Standards

NOTICE FILED DATE: 01/24/2020

RULE SUMMARY: Amendments to OAR 333-010-0760 “Dental Pilot Projects: Minimum Standards”: Language is being amended that clarifies supervision requirements and the evaluation of trainees by a supervisor. It clarifies processes required by an approved dental pilot project in the event a deficiency is found. Language requires approved dental pilot projects to submit the percentage of underserved populations served in the project’s quarterly report, unless the project meets certain exemption criteria outlined. It requires approved dental pilot projects to demonstrate that each of the pilot project’s trainees or employment/utilization sites is providing care to the underserved populations identified in their approved application at a rate of at least 51% of the total individuals served by the trainee or employment/utilization site on a quarterly basis.

RULE TEXT:

An approved dental pilot project must:

(1) Provide for patient safety and that the applicable standard of care is met as follows:

(a) Comply with informed consent in accordance with OAR 333-010-0770, Informed Consent;

(b) Prohibit a trainee from performing procedures the trainee is not capable of performing based on the trainee’s level of education, training and experience, physical or mental disability, or which are outside of the trainee’s approved scope of practice as outlined in the approved application by the Authority;

(c) Provide or arrange for emergency treatment for a patient currently receiving treatment and needs emergency care;

(d) Not use the behavior management technique of Hand Over Mouth (HOM) or Hand Over Mouth Airway Restriction (HOMAR) on any patient;

(e) Comply with ORS 419B.005 to 419B.010 related to the mandatory reporting of child abuse;

(f) Comply with ORS 453.605 to 453.755 or rules adopted pursuant thereto relating to the use of X-ray machines;

(g) Comply with ORS 679.520 or rules adopted pursuant thereto relating to the treatment of dental waste materials;

(h) Comply with ORS 679.535 or rules adopted pursuant thereto relating to the requirement to test heat sterilization devices; and

(i) Ensure that project participants involved in direct patient care:

(A) Have not been convicted of any crimes, within the last 10 years, that is a crime of violence or crime of dishonesty.

(B) Have not been denied or disciplined by a state entity that issues licenses or certificates.

(j) Ensure adequate supervision and evaluation of trainees, including but not limited to:

(A) Timely review of trainee procedures and addressing any deficiencies;

(B) Monitoring for adverse events and addressing any deficiencies; and

(C) Monitoring and evaluating trainees and addressing any deficiencies.

(2) Ensure that participants in the project, including trainees, do not engage in unprofessional conduct as that is defined in ORS 676.150.

(3) Ensure that an accurate patient record is prepared and maintained for each person receiving dental services, regardless of whether any fee is charged. The record shall contain the name of the trainee rendering the service and include, but is not limited to:

(a) Name and address and, if a minor, name of guardian;

(b) Date and description of examination and diagnosis;

(c) An entry that informed consent has been obtained in accordance with OAR 333-010-0770, Informed Consent;

(d) Date and description of treatment or services rendered;

(e) Date and description of all radiographs, study models, and periodontal charting;

(f) Health history; and

(g) Date, name of, quantity of, and strength of all drugs dispensed, administered, or prescribed.

(4) Have a sufficient number and distribution of qualified clinical and non-clinical instructors to meet project objectives,

as identified in the approved application.
(5) Provide instruction to trainees following the training program outlined in the approved application by the Authority.
(6) Assure that trainees achieve a minimal level of competence before they are permitted to enter the employment/utilization phase. The sponsor must provide notice to the Authority within 14 business days of a trainee entering the employment/utilization phase. The notice shall include, but is not limited to, the following:
(a) Name, work address, electronic mail address and telephone number of the trainee;
(b) Name, work address, electronic mail address, telephone number and license number of the supervisor;
(c) Information regarding the trainee's responsibilities and limitations under Oregon Laws 2011, chapter 716 and these rules; and
(d) A disclaimer that there is no assurance of a future change in law or regulations that will allow them to practice without a license outside an approved dental pilot project.
(e) Trainee monitoring records shall be provided to the Authority.
(7) Comply with the requirements of the Dental Pilot Projects statute, Oregon Laws 2011, chapter 716; these rules; and the approved application including, but not limited to, the evaluation and monitoring plan.
(8) Evaluate quality of care, access, cost, workforce, and efficacy in accordance with the evaluation and monitoring plan approved by the Authority and as described in OAR 333-010-0780, Pilot Project Evaluation and Monitoring by Sponsor.
(9) Within 24 hours of any incident involving a patient in the care of a trainee which results in any medical occurrence that is life-threatening, requires hospitalization, results in disability or permanent damage, requires medical or surgical intervention or results in death, the sponsor must ensure that a detailed written report, along with the patient's complete dental records, is submitted to the Authority by the supervising dentist.
(10) Submit detailed quarterly monitoring reports in a format prescribed by the Authority that include but are not limited to the following information for the previous quarter:
(a) Accomplishments or highlights.
(b) Challenges faced and continuous quality improvement activities.
(c) Updated project timeline.
(d) Data reports:
(A) A comprehensive breakdown of each of the data points the project is capturing in its approved evaluation and monitoring plan including anonymized client level data.
(B) Data generated by the clinical evaluator.
(C) Number and type of any adverse event or complication that occurred during the reporting period.
(D) Underserved population report: Information identifying the percentage of patients served by each of the pilot project's trainees or employment/utilization sites that are within the underserved population identified in the application.
(11) Follow written standard operating policies and procedures approved by the Authority as outlined in OAR 333-010-0750, Provisional Approval; Final Approval.
(12) Use templates and follow guidelines for the submission of documents and other reporting requirements as prescribed by the Authority.
(13) Provide care only at Authority approved employment/utilization sites.
(14) Demonstrate that each of the pilot project's trainees or employment/utilization sites provides care to the underserved populations identified in the application at a rate of at least 51 percent of the total individuals served by the trainee or employment/utilization site on a quarterly basis.
(15) Exemption:
(a) Pilot projects may seek an exemption for each employment/utilization site as defined in OAR 333-010-0710 from the requirement to submit quarterly underserved population reports by submitting documentation demonstrating the employment/utilization site falls within an exemption category listed below. The Authority shall respond to the exemption request in writing.
(b) The Authority may request additional documentation demonstrating the employment/utilization site currently

qualifies for an exemption or the rate described in section (14).
(c) A pilot project must immediately notify the Authority if an employment/utilization site no longer qualifies for exemption and begin submitting quarterly underserved population reports for that employment/utilization site.
(d) Exemption-eligibility. Employment/utilization sites as defined in OAR 333-010-0710 that only provide services via the following are eligible for an exemption:
(A) Community Mental Health Centers (CMHC);
(B) Federally-Qualified Health Centers (FQHCs) that are recipients of Public Health Service Act Section 330 grant funds;
(C) U.S. Health Resources & Services Administration (HRSA) Designated Health Centers;
(D) Indian Health Service Facilities;
(E) Tribally-Operated 638 Health Programs as defined by HRSA;
(F) Urban Indian Health Programs (ITUs) as defined by the Indian Health Service;
(G) State or local health departments;
(H) Substance Abuse and Mental Health Services Administration (SAMHSA) certified opioid treatment programs, office-based opioid treatment programs and non-opioid outpatient substance use disorders treatment facilities; and
(I) Other designation or criteria as determined by the Authority.

STATUTORY/OTHER AUTHORITY: 2011 OL Ch. 716

STATUTES/OTHER IMPLEMENTED: 2011 OL Ch. 716

AMEND: 333-010-0780

RULE TITLE: Dental Pilot Projects: Pilot Project Evaluation and Monitoring by Sponsor

NOTICE FILED DATE: 01/24/2020

RULE SUMMARY: Amendments to OAR 333-010-0780 “Dental Pilot Projects: Pilot Project Evaluation and Monitoring by Sponsor”: Language is being amended to describe requirements of project sponsors in their evaluation of the approved dental pilot project.

RULE TEXT:

A Project Evaluation and Monitoring Plan required under OAR 333-010-0750, Provisional Approval; Final Approval, must include, but is not limited to:

(1) A logic model to depict the project activities and intended effects;

(2) A description of key evaluation questions to be addressed by the pilot project, including relevant process and outcome measures;

(3) A description of how the project will measure progress towards the goals identified in the application. Progress measurements must include quantitative metrics;

(4) A detailed description of the baseline data and information to be collected about the availability or provision of oral health care services, or both, prior to utilization phase;

(5) A detailed description of baseline data and information to be collected about trainee performance, patient and community satisfaction, and cost effectiveness;

(6) A detailed description of the methodology and data sources to be used in collecting and analyzing the data about trainee performance, acceptance by patients, quality of care and cost effectiveness;

(7) Defined measures to evaluate safety and quality of care provided;

(8) A detailed description of how the project sponsor shall comply with:

(a) All minimum standards in OAR 333-010-0760, including but not limited to adequate supervision of trainees; and

(b) All terms and conditions of the approved application, including any amendments.

(9) A process for ongoing quarterly monitoring in accordance with OAR 333-010-0760, Minimum Standards; and

(10) A process for regular evaluation of project activities across the lifecycle of the project for continuous quality improvement purposes.

STATUTORY/OTHER AUTHORITY: 2011 OL Ch. 716

STATUTES/OTHER IMPLEMENTED: 2011 OL Ch. 716

AMEND: 333-010-0790

RULE TITLE: Dental Pilot Projects: Authority Responsibilities

NOTICE FILED DATE: 01/24/2020

RULE SUMMARY: Amendments to OAR 333-010-0790 “Dental Pilot Projects: Authority Responsibilities”: Language is being amended to clarify the process for corrective action in the event the Authority conducts a site visit and finds the project is in non-compliance.

RULE TEXT:

(1) Project monitoring. Program staff shall monitor and evaluate approved projects which shall include, but is not limited to:

(a) Periodically requesting written information from the project to ascertain the progress of the project in meeting its stated objectives and in complying with program statutes and regulations:

(b) Periodic, but at least annual, site visits to one or more project offices, employment/utilization sites, or other locations where trainees are being prepared or utilized; and

(c) Reviewing the quarterly reports submitted by the project as described in OAR 333-010-0760, Minimum Standards.

(2) Advisory committee. The Authority may convene an advisory committee for each approved dental pilot project.

(a) Individuals eligible to serve on an advisory committee include but are not limited to:

(A) Representatives from:

(i) The Oregon Board of Dentistry;

(ii) Professional dental organizations or societies;

(iii) Educational institutions;

(iv) Health systems; and

(v) Individuals representing the target population served by the pilot project.

(B) Individuals with an interest in public health, oral health or expanding access to medical and dental care.

(b) The purpose of the advisory committee is to gather its members’ collective knowledge, experience, expertise, and insight to assist the Authority in meeting its responsibilities.

(c) If the Authority convenes an advisory committee it will solicit members for an advisory committee by public announcement; Individuals interested in serving on the committee are required to complete an application.

(d) From the applications received, the Authority will appoint no more than 15 members who are willing to undertake the duties of an advisory committee member and adhere to the committee charter adopted by the Authority. The Authority will notify each applicant in writing whether they have been appointed to the committee.

(e) An advisory committee member must:

(A) Attend meetings;

(B) Review approved pilot project quarterly reports at the request of the Authority;

(C) Attend approved pilot project site visits if invited; and

(D) Comply with any confidentiality requirements established by the Authority.

(3) Site visits.

(a) Site visits shall include, but are not limited to:

(A) Determination that adequate patient safeguards are being utilized;

(B) Validation that the project is complying with the approved or amended application;

(C) Interviews with project participants and recipients of care; and

(D) Reviews of patient records to monitor for patient safety and the applicable standard of care.

(b) If the Authority has convened an advisory committee, representatives of the committee may be invited by the Authority to participate in the site visit though the Authority may, at its discretion, limit the number of members who can participate;

(c) Written notification of the date, purpose and principal members of the site visit team shall be sent to the project director at least 90 calendar days prior to the date of the site visit;

(d) Plans to interview trainees, supervisors, and patients or to review patient records shall be made in advance through the project director;
(e) An unannounced site visit may be conducted by program staff if program staff have concerns about patient or trainee safety;
(f) The Authority will provide the project sponsor with at least 14 business days to submit to the Authority required patient records, data or other documents as required for the site visit; and
(g) Following a site visit the Authority will:
(A) Within 60 calendar days, issue a written preliminary report to the sponsor of findings of the site visit, any deficiencies that were found, and provide the sponsor with the opportunity to submit a plan of corrective action;
(i) A signed plan of correction must be received by the Authority within 30 calendar days from the date the preliminary report of findings was provided to the project sponsor;
(ii) The Authority shall determine if the written plan of correction is acceptable no later than 30 calendar days after receipt. If the plan of correction is not acceptable to the Authority, the Authority shall notify the project sponsor in writing and request that the plan of correction be modified and resubmitted no later than 10 business days from the date the letter of non-acceptance was mailed to the project sponsor;
(iii) The project sponsor shall correct all deficiencies within 30 calendar days from the date of correction provided by the Authority, unless an extension of time is requested from the Authority. A request for such an extension shall be submitted in writing and must accompany the plan of correction.
(iv) If the project sponsor does not come into compliance by the date of correction reflected on the approved plan of correction, the Authority may propose to suspend or terminate the project as defined under OAR 333-010-0820, Suspension or Termination of Project.
(B) Within 90 calendar days of receipt of a plan of correction, issue a final report to the sponsor; and
(C) If there are no corrections needed, the Authority will issue a final report within 180 calendar days.
(4) The Authority may also provide the sponsor with the opportunity to submit a corrective action plan to address any deficiencies found by the Authority during any project monitoring as described in section (1) of this rule. The Authority shall notify the sponsor in writing of the requirement to submit a plan of correction. The sponsor must submit, and the Authority must receive the plan of correction by the deadline set in the notification. All of the requirements and deadlines described in section (3) of this rule for corrective action plans apply to a project sponsor when directed to submit a corrective action plan under this section (4).

STATUTORY/OTHER AUTHORITY: 2011 OL Ch. 716

STATUTES/OTHER IMPLEMENTED: 2011 OL Ch. 716

AMEND: 333-010-0800

RULE TITLE: Dental Pilot Projects: Project Modifications

NOTICE FILED DATE: 01/24/2020

RULE SUMMARY: Amendments to OAR 333-010-0800 “Dental Pilot Projects: Project Modifications”: Language is being amended to clarify a modification denial by the Authority in the event the proposed modification does not meet criteria outlined in rule.

RULE TEXT:
(1) Any modifications to an approved project shall be submitted in writing to program staff, except as specified in section (4) of this rule. All modifications require Authority approval. Modifications include, but are not limited to the following:
(a) Changes in selection criteria for trainees, supervisors, or employment/utilization sites;
(b) Addition of employment/utilization sites; and
(c) Changes in the scope of practice for trainees.
(2) Upon receipt of a request for a modification approval, the Authority will inform the project sponsor in writing on the timeline for review of the request and decision response deadline.
(3) If the Authority has convened an advisory committee for an approved project, the Authority may confer with the advisory committee regarding the proposed modification.
(4) Changes in project staff or instructors are not considered a modification and do not require prior approval by program staff, but shall be reported to the program staff within two weeks after the change occurs along with the curriculum vitae for the new project staff and instructors.
(5) The Authority may approve or deny a request for modification. A modification may be denied if:
(a) It does not demonstrate that the project can meet the minimum standards or other provisions in these rules;
(b) The modification would result in a substantial change to underlying purpose and scope of the pilot project as originally approved;
(c) As a result of the modification, the project would no longer demonstrate that each of the project’s trainees or employment/utilization sites shall provide services to the underserved populations identified in the application at a rate of at least 51 percent of the individuals served by the trainee or employment/utilization site on a quarterly basis; or
(d) The Authority has previously approved a similar project.
(6) Projects are not permitted to implement the proposed modification until approval has been rendered by the Authority.

STATUTORY/OTHER AUTHORITY: 2011 OL Ch. 716

STATUTES/OTHER IMPLEMENTED: 2011 OL Ch. 716

AMEND: 333-010-0820

RULE TITLE: Dental Pilot Projects: Suspension, Denial or Termination of Project

NOTICE FILED DATE: 01/24/2020

RULE SUMMARY: Amendments to OAR 333-010-0820 “Dental Pilot Projects: Suspension or Termination of Project”: Language is being amended to align the title of the rule with language in the section around the insertion of the word "denial" for consistency with rule language. Language clarifies reasons for suspension, denial or termination. The Authority may suspend or terminate an approved dental pilot project if the project fails to meet the applicable standard of care.

RULE TEXT:

(1) A pilot project may be suspended, terminated, or denied if:

(a) A pilot project violates any provision of 2011 Oregon Laws, chapter 716;

(b) A pilot project violates any of these rules; or

(c) A pilot project fails to provide care that meets the applicable standard of care.

(2) Failure of a sponsor or anyone involved with an approved pilot project to cooperate with a reasonable request for records, interviews or a site visit is grounds for the Authority to suspend or terminate a project. Failure to cooperate includes, but is not limited to, failure to provide information or documents in a manner requested by the Authority or within the timeframe requested by the Authority.

(3) If the Authority determines that a dental pilot project has violated 2011 Oregon Laws, chapter 716, violated one or more of these rules, or failed to provide care that meets the applicable standard of care, the Authority may:

(a) Require the sponsor to implement an approved corrective action plan in accordance with OAR 333-010-0790, Authority Responsibilities; or

(b) Issue a Notice of Proposed Suspension or Notice of Proposed Termination in accordance with ORS 183.411 through 183.470.

(4) A sponsor who receives a Notice may request an informal meeting with the Authority. A request for an informal meeting does not toll the period for filing a timely request for a contested case hearing as described in section (5) of this rule.

(5) If the Authority issues a Notice of Proposed Suspension or Notice of Proposed Termination the sponsor is entitled to a contested case hearing as provided under ORS chapter 183. The sponsor has 30 calendar days to request a hearing.

(6) If the Authority terminates a dental pilot project, the order shall specify when, if ever, the sponsor may reapply for approval of a dental pilot project.

STATUTORY/OTHER AUTHORITY: 2011 OL Ch. 716

STATUTES/OTHER IMPLEMENTED: 2011 OL Ch. 716