



## **Quarterly Dental Pilot Project Meeting: DPP 200 Meeting Minutes**

**Date:** Monday, January 14, 2019  
**Time:** 9:30 AM – 11:30 AM  
**Location:** OHSU  
3030 SW Moody Avenue  
Portland, Oregon  
Conference Room 129

**Committee Members Present:** Todd Beck, Fred Bremner

**Committee Members Absent:** Lesley Harbison, Jennifer Lewis-Goff

**OHA Staff:** Kelly Hansen, Sarah Kowalski, Amy Umphlett

**Project Sponsor Representatives:** Richie Kohli, Linda Mann, Meagan Newton, Katelyn Nichols, Elizabeth Palumbo, Eli Schwarz

**Public Attendees:** Cassie Leone

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### **Summary of Meeting**

#### **Agenda Item: Revised Administrative Rules; Compliance with revised OARs**

**Topic:** Oregon Administrative Rules; Compliance with revised OARs

**Summary of Discussion:** OHA amended the rule language for dental pilot projects to clarify the rules so that applicants and approved projects can better understand the applicable requirements and possible consequences for failing to adhere to requirements. Amended rules became effective December 1, 2018.

Current pilot projects have until June 1, 2019 to come into compliance with minimum standards outlined in OAR 333-010-0760. OHA sent a letter to the project on December 27, 2018 that identified areas where the project may be deficient. OHA would like the project to submit any materials/document for review by April 15, 2019. This date is flexible, as OHA will work with the project to provide any needed technical assistance in meeting the new requirements.

The amended rules added several components to the "Evaluation and Monitoring by Sponsor" section. OHA will provide further guidance to each pilot project on how to ensure compliance with the revised rules. The OHA Evaluation Team is looking at mismatches for compliance with

the evaluation requirements. OHA does not anticipate many problems with project #200. There will be an official rubric for projects going forward of criteria and requirements based on the rules.

**Decision:** No decisions made.

**Action:** Project sponsor will submit materials to OHA by April 15, 2019.

### **Agenda Item: Advisory Committee Charter**

**Topic:** Revised Advisory Committee Charter; Call for Applications, Timeline for applications

**Summary of Discussion:** Sarah Kowalski reviewed the draft of the revised charter for Dental Pilot Project Advisory Committee meetings. The committee charter was revised due to new administrative rules. Members cannot serve more than 6 consecutive years, and members whose current term is ending will need to reapply to be on the Advisory Committee. Several entity categories were added to section "C. Member Qualification" (e.g. individuals representing the target population served by the pilot project). OHA will be recruiting representatives for each category listed in section C to ensure each Advisory Committee has diverse membership.

**Decision:** No decisions made.

**Action:** Committee members were requested to review the charter and provide feedback to OHA via email.

- OHA will conduct a call for applications to each of the Advisory Committees for the Dental Pilot Project Program to meet the requirements of the new administrative rules.

### **Agenda Item: Project Sponsor Updates**

**Topic:** Presentation and update by OHSU and Capitol Dental

**Summary of Discussion:** OHSU PowerPoint Presentation

- Since the last Advisory Committee meeting, the project has had a new external evaluator and updated the criteria for ITR placement.
- Silver diamine fluoride (SDF) has been incorporated into treatment planning beginning in June 2018. The decision process for SDF includes conducting a caries risk assessment and looking at behavioral history. If a child has been referred to the dentist 2-3 times, but has not seen the dentist, then SDF is the best course of action. The technique of SDF followed by an ITR has not been used yet.
- Capitol transitioned to a new electronic medical record system in August 2018.
- A new dentist is now at the school-based health center (SBHC) in Independence, leading to a significant decrease in wait times for patients referred for treatment.
- Updating consent forms to incorporate changes made to the rules for dental pilot projects (OAR 333-010) and streamline the consent process to improve return rates. Getting consent has been an obstacle for ITR placements.
- Trainings will be provided to improve diagnostic quality of images and the placement of class II ITRs.
- The project should use their most recent training to develop standard operating procedures.

- Patients were seen at Childhood Health Associates of Salem during quarter 3 and Ash Creek Elementary School during quarter 4. Data will be submitted in the next report.
- 2017-18 school year data indicated that 43% of children were kept healthy in the community and 57% of children were referred to a dentist.
- A satisfaction survey is sent home with a patient after all services are provided during the time period (3 months). 211 responses were gathered. Among those with and without ITRs indicated, most people were very satisfied or somewhat satisfied. Patients who received an ITR were less satisfied, but it was not statistically significant.

**Decision:** No decisions made.

**Action:** OHSU will review and submit standard operating procedures. OHSU is looking to submit a request to modify the project by adding sites. There is no timeline to disclose at this time. It is under review by OHSU.

### **Agenda Item: Adverse Events Process; Chart Review Form; Overview**

**Topic:** Requirements of Adverse Events and reporting protocols, new protocols on chart review form utilized by committee reviewers.

**Summary of Discussion:** Dr. Rose McPharlin and Dr. Karla Kent from OHSU gave a presentation at the DPP #100 Advisory Committee in December on patient harm and adverse events. Based on their research, OHA has adopted the Adverse Event Classification rubric. OHA will not audit charts, but pilot projects will need to follow the rubric process to determine if an adverse event has occurred and whether a patient was harmed or not. The framework is very broad, as it needs to work for any pilot project. It is also subjective, so you as a team may need to come up with the decision based on consensus.

- OHA needs events classified as an E1 in quarterly reports, but anything E2 or greater must be reported to OHA within 24 hours. It is not meant to be punitive. OHA will review and determine what must be reported.
- OHSU School of Dentistry is already training on adverse events and root cause analysis of errors so that changes can be made to the system.
- Quality of care is different than patient harm. OHA is working with DPP #100 Advisory Committee members that review patient charts to develop a rubric framework for quality of care based on WREB materials. Committee members need calibration training on better defining quality of care versus patient harm. There is a concern with using WREB classifications. OHA is using it as a starting point and removing items that do not pertain.
- Chart reviewers would like to have images prior to the procedure (the prep). Reviewers may see two pictures of the same thing, because in general, we are not scooping for caries removal. Chart notes may need to be provided to OHA.
- Capitol is using Carestream mobile imaging. Training was completed in early January 2019 on intro-oral photos: descriptions, standardized notes and photos taken in a certain order. There will be 3 progress notes tied to a picture of ITR placement. The project will give OHA their standard note template that they use.
- Clarification is requested of the project as to what is a failure. Is it a true loss or chipping at the margin (looking at the radiograph every 3 months at recall)? Most failures are due to retention issues.

**Decision:** Adverse Event protocol has been adopted by OHA. OHA will review discussions on what to report to OHA and when.

**Action:** 1. OHSU and Capitol Dental will take images of the prep. 2. OHA will review Adverse Event form and reporting protocols. 3. OHSU/Capitol will determine what constitutes a failure of the ITR.

### **Agenda Item: Chart Reviewer Comments; Themes**

**Topic:** Discussion of chart review comments.

**Summary of Discussion:** Overall impression of the ITR quality was consistent. Average score was 4.4 (minimum standard of care is 3). There was very minimal variation in the chart review process, indicating the chart reviewers are calibrated.

OHA is using the first few chart reviews as a baseline for calibration. There is concern by both dental pilot projects of bias in scoring. Another calibration training may be needed for chart reviewers when class II ITRs are being used.

After the project submits standard operating procedures, OHA will bring together Advisory Committee members to go over the material to assist with calibration.

**Decision:** No decisions made.

**Action:** Calibration training requested by committee members. OHA will schedule meeting once there are enough charts to justify a meeting. Review this after site visit in May 2019.

### **Agenda Item: Follow Up Items, Future Meeting Dates, Future Site Visit Location(s) and Dates; Other Questions**

**Topic:** Site Visit Process and Comments

**Summary of Discussion:** In the new rules, OHA will give pilot projects 90 days before a site visit. OHA needs to schedule a site visit before the end of this school year. Advisory Committee members request Mondays for a site visit. The site visit may again be in Independence.

Another Advisory Committee meeting will be scheduled for late August or September, depending on when Eli Schwarz is back from vacation.

The Oregon Board of Dentistry will most likely ask Todd Beck at the February board meeting: Why is there such a large difference between the projects? OHA recommends responding that it is largely due to scope and size of each project. Evaluating one procedure versus more procedures leads to less consensus. DPP #100 also did not have a clinical dentist involved at the beginning, but now has one.

Fred Bremner indicated that there is inconsistency in the progress reports. Treatment was an OB, but it was actually done OL. Two people approved it, so there is something wrong with consistency. As a reviewer, he wants to review a treatment plan once and then progress reports. The project is taking steps to solve this.

**Decision:** No decisions made.

**Action:** OHA will schedule Advisory Committee meeting for the fall. Site Visit is scheduled for May 6, 2019 in Falls City, Oregon.

**Public Comments:** No comments received.

**Next Meeting:** To be determined. Site Visit scheduled for May 6, 2019 in Falls City, Oregon.



# AGENDA

Dental Pilot Project #200 “Training Dental Hygienists to Place Interim Therapeutic Restorations”  
Dental Pilot Project Program Advisory Committee Meeting DPP #200  
**January 14, 2019, 9:30am – 11:30am**

<b>Location:</b> OHSU 3030 SW Moody Avenue, Portland, Oregon, Conference Room 129 Conference line: 1-888-273-3658, participants code: 76-64-09		
9:30-9:35	Official Introductions, Agenda Review	Bruce Austin DMD Sarah Kowalski RDH, MS
9:35-10:10	Revised Administrative Rules; Compliance with revised OARs; Advisory Committee Charter	Sarah Kowalski RDH, MS
10:10-10:30	OHSU - Project Update	Eli Schwarz DDS, MPH, PhD
10:30-10:55	Adverse Events Process; Chart Review Form; Overview of Site Visit Data	Kelly Hansen
10:55-11:15	Chart Reviewer Comments; Themes	Kelly Hansen
11:15-11:20	Follow Up Items, Future Meeting Dates, Future Site Visit Location(s) and Dates; Closing	Sarah Kowalski RDH, MS
11:20-11:30	Public Comment Period	Public comments are limited to 2 minutes per individual



## **Dental Pilot Project Program Advisory Committee Charter**

### **I. Description of the Dental Pilot Project Program**

Senate Bill 738 was passed by the Oregon State Legislature in 2011. This bill allows the Oregon Health Authority (OHA) to approve Dental Pilot Projects once an application has been approved. The goal of the Dental Pilot Projects is to encourage the development of innovative practices in oral health care delivery systems with a focus on providing care to populations that evidence-based studies have shown have the highest disease rates and the least access to dental care.

Dental Pilot Projects are intended to evaluate the quality of care, access, cost, workforce, and efficacy of 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. OHA may approve a dental pilot project that is designed to operate for three to five years or a sufficient amount of time to evaluate the validity of the pilot project and evaluate the quality of care, access, cost, workforce and efficacy.

Projects must achieve at least one of the following:

1. Teach new skills to existing categories of dental personnel
2. Develop new categories of dental personnel
3. Accelerate the training of existing categories of dental personnel
4. Teach new oral health care roles to previously untrained persons

### **II. Oregon Health Authority Dental Pilot Project Program Responsibilities:**

OHA is responsible for processing initial pilot project applications, approving projects and monitoring approved pilot projects. Program staff shall review approved projects and the assessment shall include but is not limited to reviewing progress reports and conducting site visits. The program is responsible for ascertaining the progress of the project in meeting its stated objectives and in complying with program statutes and regulations.

### **III. Purpose of the Dental Pilot Project Program Advisory Committee:**

The purpose of the Dental Pilot Project Program Advisory Committee (Committee) is to provide advice to OHA regarding approved projects. OHA will convene the Committee to gather its members' collective knowledge, experience, expertise, and insight to assist the OHA in meeting its responsibilities. Members will be asked to review and provide advice on project

training, protocols, progress reports and other project issues as needed throughout the duration of the pilot project. Although the Committee provides advice to the agency, OHA makes all final decisions.

#### **IV. Committee Details and Membership:**

The Committee is an interdisciplinary team composed of representatives of dental boards, professional organizations, other state regulatory bodies and interested parties that have applied to participate and assist the Authority in meetings is responsibilities. Committee members must not be involved in the specified project in any way in order to be a member of the Committee.

A. Committee Size. The Committee shall not consist of more than 15 members, except that additional members may be added by OHA. If a member resigns from the Committee before the end of his or her term OHA will accept applications for a new member. OHA makes the final determination on acceptance of applications.

B. Process for Membership. Prospective members are required to complete an application.

C. Member Qualifications. Members may include, but are not limited to representatives from the following entities:

- Dental Care Organization(s)
- Dental care providers and allied dental care professionals
- Dental policy subject matter experts
- Federally Qualified Health Centers
- Oregon Board of Dentistry
- Oregon Dental Association
- Oregon Dental Hygiene Association
- Oregon Dental Hygiene Education Program
- Oregon Health and Sciences University (School of Dentistry)
- Oregon Oral Health Coalition
- Individuals representing the target population served by the pilot project
- Individuals with an interest in public health, oral health or expanding access to medical and dental care
- Representatives of OHP member advocate organizations
- Representatives of underserved and vulnerable populations or their advocacy groups

D. Term of Office. The term of office for each member is two years. The term begins on the approval date of the initial application. Individuals who wish to serve additional term(s) must reapply. A Committee member cannot serve more than six consecutive years.

E. Payment/Reimbursement. Dental Pilot Project Advisory Committee members are non-paid but eligible travel expenses will be reimbursed according to State of Oregon guidelines. Members are not allowed to accept gifts, meals, lodging, etc. provided by the sponsor of a pilot project or provided on behalf of the sponsor. Members are prohibited from contacting any staff member or sponsor of a pilot project outside of the confines of the Site Visits in relation to the dental pilot project activities. A member's questions or concerns about a pilot project should be voiced during a site visit or raised with the Dental Pilot Project Program manager.



F. Removal of Committee Members. OHA may remove a member who is unable to meet the responsibilities of a member or regularly attend meetings. Should committee members miss more than two committee meetings per year, they will be asked to resign from the committee.

#### V. **Meetings:**

Dental Pilot Projects operate under two distinct phases, the training/education phase and the utilization/employment phase. OHA will determine committee meeting frequency depending on which phase a project is currently operating under. OHA staff will facilitate all meetings.

- OHA will call meetings during the training phase as dictated by project and committee member needs
- Meeting frequency during the utilization/employment phase will be quarterly unless the OHA and the Committee agrees to a different frequency
- Meetings will be held at times that are agreed upon by OHA and a majority of the committee members; Meetings will be held during State of Oregon normal operating business hours
- Additional meetings may be called as dictated by project needs
- Members are required to attend the Dental Pilot Project Advisory Committee Annual Meeting

#### VI. **Committee Members Expectations:**

- Attendance at meetings
- Review materials as needed; provide feedback by deadlines
- Respect others' views of issues brought before the committee
- Engage and participate in discussions
- Bring issues forward for discussion in a professional and timely manner
- Use best-practices, evidence-based and data-driven models for analysis and evaluation of issues
- Be open to learning from one another
- Report back to representative organization accurate information on the status of the pilot project
- Comply with any confidentiality requirements established by the Authority

#### VII. **Committee Member Responsibilities & Rules:**

- Advise OHA on:
  - The efficacies of training, competencies and the collection of data
  - Project protocols related to the ongoing assurance of patient safety
  - The evaluation of project progress reports as needed
  - Dental pilot project issues, should they arise
- Participate and attend at least one site visit of a dental pilot project during each year of the pilot project
- Committee operates under an email intensive environment; Members are responsible for reviewing materials in a timely matter and responding as requested by deadlines

#### VIII. **Oregon Public Meetings Law**

- Advisory Committee meetings are subject to the Oregon Public Meetings Law ORS 192.610 to 192.690.
- Advisory Committee meetings are open to the public.

#### X. **Review of Charter**

This charter will be periodically reviewed and updated at OHA's discretion.

DRAFT



December 27, 2018

Eli Schwarz, DDS, MPH, PhD  
Department of Community Dentistry Oregon Health & Science University  
3030 SW Moody Avenue, Suite 135  
Portland, OR 97201-4869

RE: Revised Oregon Administrative Rules

Dear Dr. Schwarz,

Attached, please find a copy of the revised Oregon Administrative Rules for the Dental Pilot Project Program.

According to the revised rule, 333-010-0700, (4) A dental pilot project that was approved and was operating before December 1, 2018 has until June 1, 2019 to come into compliance with the minimum standards in OAR 333-010-0760.

Based upon review of the revised rules, the Dental Pilot Project Program is requesting the following materials to ensure that Dental Pilot Project #200 is in compliance with OAR 333-010-0760:

- 1. Informed Consent:** The project must demonstrate compliance with 333-010-0760 and as outlined under 333-010-0770.

(1) Provide for patient safety as follows:

(a) Comply with informed consent in accordance with OAR 333-010-0770, Informed Consent;  
(333-010-0760)

(1) A sponsor must ensure that each patient or person legally authorized to provide consent on behalf of the patient:

(a) Is provided written information about the dental pilot project and who will be providing treatment;  
(b) Gives written consent to be treated by the dental pilot project trainee; and  
(c) Gives informed consent for treatment by the trainee.

(2) Written information about the project and who will be providing treatment must include, but is not limited to:

(a) An explanation of the role and status of the trainee, any certification or licenses a trainee may hold, the education and training of the trainee and the availability of the trainee's supervisor for consultation;

(b) An explanation that the patient can refuse care from a trainee without penalty for such a request; and

(c) A statement that consenting to treatment by a trainee does not constitute assumption of risk by the patient.

(3) At a minimum, the following language must be included on the document that requests consent to be treated by the dental pilot project:

"I \_\_\_\_\_ [name of patient or person acting on patient's behalf] have received information about this dental pilot project and provider type. I have been given the opportunity to ask questions and have them fully answered. I have read and understand the information and I agree to the trainee of this project providing me treatment."

Signature of patient or person acting on patient's behalf      Date

(4) Informed consent for treatment:

(a) Each patient must give informed consent to the procedure. Informed consent means the consent to a procedure obtained by:

(i) Providing a thorough and easily understood explanation to the patient, or patient's guardian, of the proposed procedures, any available alternative procedures and any risks associated with the procedures; and

(ii) Asking the patient, or the patient's guardian, if there are any questions and providing thorough and easily understood answers to all questions asked.

(b) Patient records must document an entry that informed consent for treatment has been obtained and the date the informed consent was obtained. Documentation may be in the form of an acronym such as "PARQ" (Procedure, Alternatives, Risks and Questions) or "SOAP" (Subjective Objective Assessment Plan) or their equivalent;

(c) Informed consent for treatment must be obtained in writing for procedures identified by the Authority in the application approval letter, and such consent must be included and documented in the patient's record; and

(d) A trainee may not perform any procedure for which the patient or patient's guardian has not given informed consent provided; however, in the event of an emergency situation, if the patient is a minor whose guardian is unavailable or the patient is unable to respond, a trainee may render treatment in a reasonable manner according to community standards and in accordance with the trainees approved scope of practice.

(333-010-0770)

**2. Background Check:** The project must demonstrate compliance with 333-010-0720 and as outlined under 333-010-0760.

(e) Trainees:

(D) Information regarding the background check process for participants to determine compliance with OAR 333-010-0760, Minimum Standards. (333-010-0720)

(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

(333-010-0760)

**3. Standard Operating Procedures:** The project must demonstrate compliance with 333-010-0760 and as outlined under 333-010-0750.

(11) Follow written standard operating policies and procedures approved by the Authority as outlined in OAR 333-010-0750, Provisional Approval; Final Approval. (333-010-0760)

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. (333-010-0750)

**4. Evaluation and Monitoring by Sponsor:** The project must demonstrate compliance with 333-010-0760 and as outlined under 333-010-0780.

(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. (333-010-0760)

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 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;
- (4) A detailed description of baseline data and information to be collected about trainee performance, patient and community satisfaction, and cost effectiveness;
- (5) 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;
- (6) Defined measures to evaluate safety and quality of care provided;
- (7) A process for ongoing quarterly monitoring in accordance with OAR 333-010-0760, Minimum Standards; and
- (8) A process for regular evaluation of project activities across the lifecycle of the project for continuous quality improvement purposes. (333-010-0780)

Please submit all materials to the Authority for review by **April 15, 2019**.

Once the program has reviewed and approved all required materials, the Authority will issue an approval letter for the project based upon revised rule language under 333-010-0750.

(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;

(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.

Sincerely,



Sarah Kowalski, RDH, MS  
Dental Pilot Project Program Coordinator

cc: Dental Pilot Project #200 Advisory Committee

OREGON ADMINISTRATIVE RULES  
OREGON HEALTH AUTHORITY, PUBLIC HEALTH DIVISION  
CHAPTER 333

**DIVISION 10**

**HEALTH PROMOTION AND CHRONIC DISEASE PREVENTION**

**333-010-0700**

**Dental Pilot Projects: Purpose**

(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 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:

(a) Applications for Dental Pilot Projects received on or after December 1, 2018; and

(b) Dental Pilot Projects approved before or after December 1, 2018.

(4) A dental pilot project that was approved and was operating before December 1, 2018 has until June 1, 2019 to come into compliance with the minimum standards in OAR 333-010-0760.

Statutory/Other Authority: 2011 OL Ch. 716

Statutes/Other Implemented: 2011 OL Ch. 716

**333-010-0710**

**Dental Pilot Projects: Definitions**

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

(1) "Adverse event" means harm caused by dental treatment, regardless of whether it is associated with error or considered preventable.

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

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

(4) "Clinical evaluator" means a dentist, licensed in the State of Oregon or another state, who is responsible for conducting a 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's outcome.

(5) "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.

- (6) "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.
- (7) "Complications" means a disease or injury that develops during or after the treatment of an earlier disorder.
- (8) "Didactic phase" means the time period of a project during which trainees are presented with an organized body of knowledge by an instructor.
- (9) "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.
- (10) "Employment/utilization site" means an Authority approved site for use during the employment/utilization phase that provides care to populations that evidence has shown have the highest disease rates and the least access to dental care. An employment utilization site includes any location where dental health care services are provided by a project's trainees.
- (11) "Non-clinical instructor" is a person with specific training or expertise as demonstrated through a degree or experience relevant to the content of instruction.
- (12) "Program" means the Dental Pilot Projects Program administered by the Authority.
- (13) "Program staff" means the staff of the Authority with responsibility for the Dental Pilot Projects Program.
- (14) "Project" means a Dental Pilot Project approved by the Authority.
- (15) "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.
- (16) "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,
- (17) "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.
- (18) "Reviewer" means an individual designated by the Authority to review and comment on all or portions of a project application.
- (19) "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.
- (20) "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.
- (21) "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.
- (22) "These rules" means OAR 333-010-0700 through 333-010-0820.



(23) "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.

(24) "Training program" means an organized educational program within a project that includes at least a didactic phase and a clinical phase.

Statutory/Other Authority: 2011 OL Ch. 716

Statutes/Other Implemented: 2011 OL Ch. 716

### **333-010-0720**

#### **Dental Pilot Projects: Application Procedure**

(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) Trainees:
  - (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.
- (g) Employment/utilization sites:
  - (A) A list of all employment/utilization sites the proposed project intends to use; and
  - (B) Documentation that shows that each site listed meets the definition of an employment/utilization site.
- (h) Costs:
  - (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;
    - (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 intended patient outcomes and metrics as outlined in the requirements under OAR 333-010-0780, Pilot Project Evaluation and Monitoring by Sponsor.
  - (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

### **333-010-0730**

#### **Dental Pilot Projects: Application Review Process**

- (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.
- (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

### **333-010-0740**

#### **Dental Pilot Projects: Project Application Provisional Approval or Denial**

- (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 can meet the minimum standards or other provisions in these rules;
  - (b) The application does not demonstrate that the project is financially feasible; or
  - (c) 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

### **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;
  - (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.
- Statutory/Other Authority: 2011 OL Ch. 716  
Statutes/Other Implemented: 2011 OL Ch. 716

### **333-010-0760**

#### **Dental Pilot Projects: Minimum Standards**

An approved dental pilot project shall:

- (1) Provide for patient safety 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.

(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 categories 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.
- (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.
- Statutory/Other Authority: 2011 OL Ch. 716  
Statutes/Other Implemented: 2011 OL Ch. 716

### **333-010-0770**

#### **Dental Pilot Projects: Informed Consent**

- (1) A sponsor must ensure that each patient or person legally authorized to provide consent on behalf of the patient:
- (a) Is provided written information about the dental pilot project and who will be providing treatment;
  - (b) Gives written consent to be treated by the dental pilot project trainee; and
  - (c) Gives informed consent for treatment by the trainee.
- (2) Written information about the project and who will be providing treatment must include, but is not limited to:
- (a) An explanation of the role and status of the trainee, any certification or licenses a trainee may hold, the education and training of the trainee and the availability of the trainee's supervisor for consultation;
  - (b) An explanation that the patient can refuse care from a trainee without penalty for such a request; and

(c) A statement that consenting to treatment by a trainee does not constitute assumption of risk by the patient.

(3) At a minimum, the following language must be included on the document that requests consent to be treated by the dental pilot project:

"I \_\_\_\_\_ [name of patient or person acting on patient's behalf] have received information about this dental pilot project and provider type. I have been given the opportunity to ask questions and have them fully answered. I have read and understand the information and I agree to the trainee of this project providing me treatment."

\_\_\_\_\_  
Signature of patient or person acting on patient's behalf

\_\_\_\_\_  
Date

(4) Informed consent for treatment:

(a) Each patient must give informed consent to the procedure. Informed consent means the consent to a procedure obtained by:

(i) Providing a thorough and easily understood explanation to the patient, or patient's guardian, of the proposed procedures, any available alternative procedures and any risks associated with the procedures; and

(ii) Asking the patient, or the patient's guardian, if there are any questions and providing thorough and easily understood answers to all questions asked.

(b) Patient records must document an entry that informed consent for treatment has been obtained and the date the informed consent was obtained. Documentation may be in the form of an acronym such as "PARQ" (Procedure, Alternatives, Risks and Questions) or "SOAP" (Subjective Objective Assessment Plan) or their equivalent;

(c) Informed consent for treatment must be obtained in writing for procedures identified by the Authority in the application approval letter, and such consent must be included and documented in the patient's record; and

(d) A trainee may not perform any procedure for which the patient or patient's guardian has not given informed consent provided; however, in the event of an emergency situation, if the patient is a minor whose guardian is unavailable or the patient is unable to respond, a trainee may render treatment in a reasonable manner according to community standards and in accordance with the trainees approved scope of practice.

Statutory/Other Authority: 2011 OL Ch. 716

Statutes/Other Implemented: 2011 OL Ch. 716

### **333-010-0780**

#### **Dental Pilot Projects: Pilot Project Evaluation and Monitoring by Sponsor**

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 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;

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

- (5) 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;
  - (6) Defined measures to evaluate safety and quality of care provided;
  - (7) A process for ongoing quarterly monitoring in accordance with OAR 333-010-0760, Minimum Standards; and
  - (8) 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

### **333-010-0790**

#### **Dental Pilot Projects: Authority Responsibilities**

- (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/utilizations 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, quality of care, minimum standard of care and compliance with the approved or amended application.
- (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.

Statutory/Other Authority: 2011 OL Ch. 716

Statutes/Other Implemented: 2011 OL Ch. 716

### **333-010-0800**

#### **Dental Pilot Projects: Project Modifications**

- (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; or
  - (b) The modification would result in a substantial change to underlying purpose and scope of the pilot project as originally approved.
- (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

### **333-010-0810**

#### **Dental Pilot Projects: Discontinuation or Completion of Project**

- (1) An approved project must notify the Authority in writing if it intends to discontinue its status as a Dental Pilot Project, at least 60 calendar days prior to discontinuation. Notification must include a closing report that includes, but is not limited to:
- (a) The reasons for discontinuation as a pilot project;
  - (b) A summary of pilot project activities including the number of persons who entered the employment/utilization phase; and
  - (c) A description of the plan to inform trainees of the project's discontinuation and that they are precluded from performing the skills authorized under the pilot project after discontinuation unless the provider type has been legalized by the State of Oregon.
- (2) The project must obtain written acknowledgement from trainees regarding notification of the project's discontinuation and preclusion from performing skills authorized under the pilot project after discontinuation, unless the provider type has been legalized and the trainee has met necessary licensure requirements.
- (3) Project completion. A project sponsor must provide a full report of findings to the Authority within 180 calendar days of the completion of the project in a format prescribed by the Authority.

Statutory/Other Authority: 2011 OL Ch. 716

Statutes/Other Implemented: 2011 OL Ch. 716

### **333-010-0820**

#### **Dental Pilot Projects: Suspension or Termination of Project**

(1) A pilot project may be suspended or terminated for violation of 2011 Oregon Laws, chapter 716 or any of these rules.

(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 is in violation of 2011 Oregon Laws, chapter 716 or these rules, 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

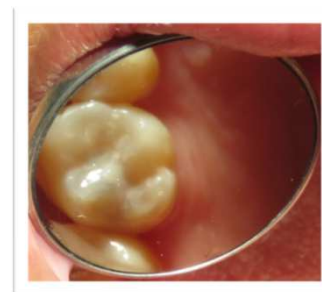
Statutes/Other Implemented: 2011 OL Ch. 716



## **Dental Pilot Project #200**

**The Oregon Telehealth Network for Oral Health:  
Placing Interim Therapeutic Restorations in Telehealth Connected Dental Teams**

**Advisory Committee Meeting Update  
January 14, 2019**



# Updates

## **2018 Programmatic changes**

- Review of ITR placements by new external evaluator, updated criteria for placement
- Incorporation of treatment with SDF beginning in June 2018 based on new evidence and ADA guidelines
- Capitol transitioned to new electronic medical record system in August 2018
- Capitol placed a new dentist at a school-based health center, Independence leading to a significant decrease in wait times for patients referred for treatment

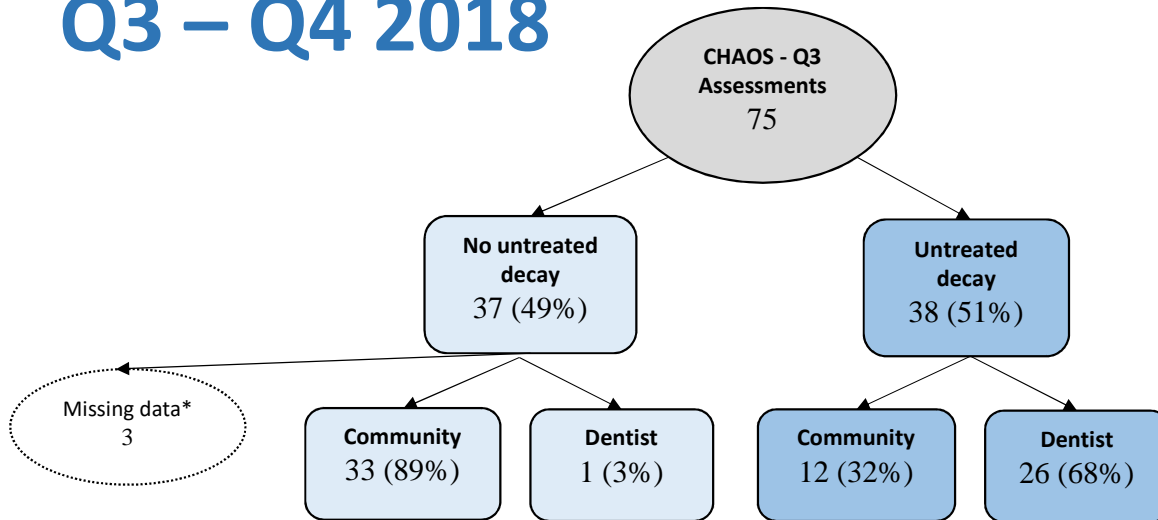
## **Presentations**

- Dr. Schwarz was invited to the WHO mOralHealth Conference in October and at the APHA conference in November
- Dr. Kohli presented on the project in India in December

## **Upcoming**

- Update consent forms to incorporate admin rules changes and streamline consent process in improve the return rate, which is a obstacle for ITR placements
- Trainings to improve diagnostic quality of images, on placement of class II ITRs

## Q3 – Q4 2018

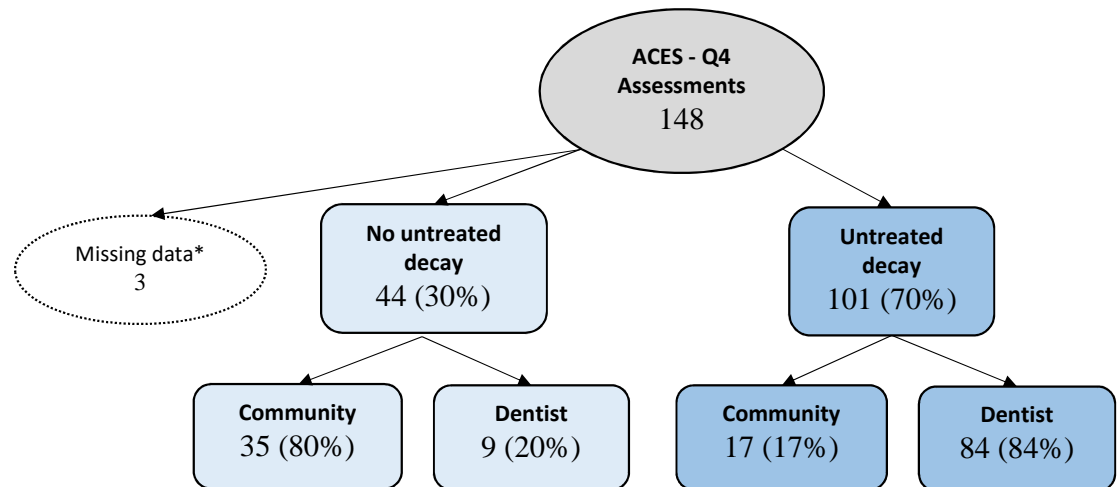


### Quarter 3

- Mobile Dental Van operating at Childhood Health Associates of Salem
- Patients aged 6 months to 16 years
- 60% kept healthy in the community

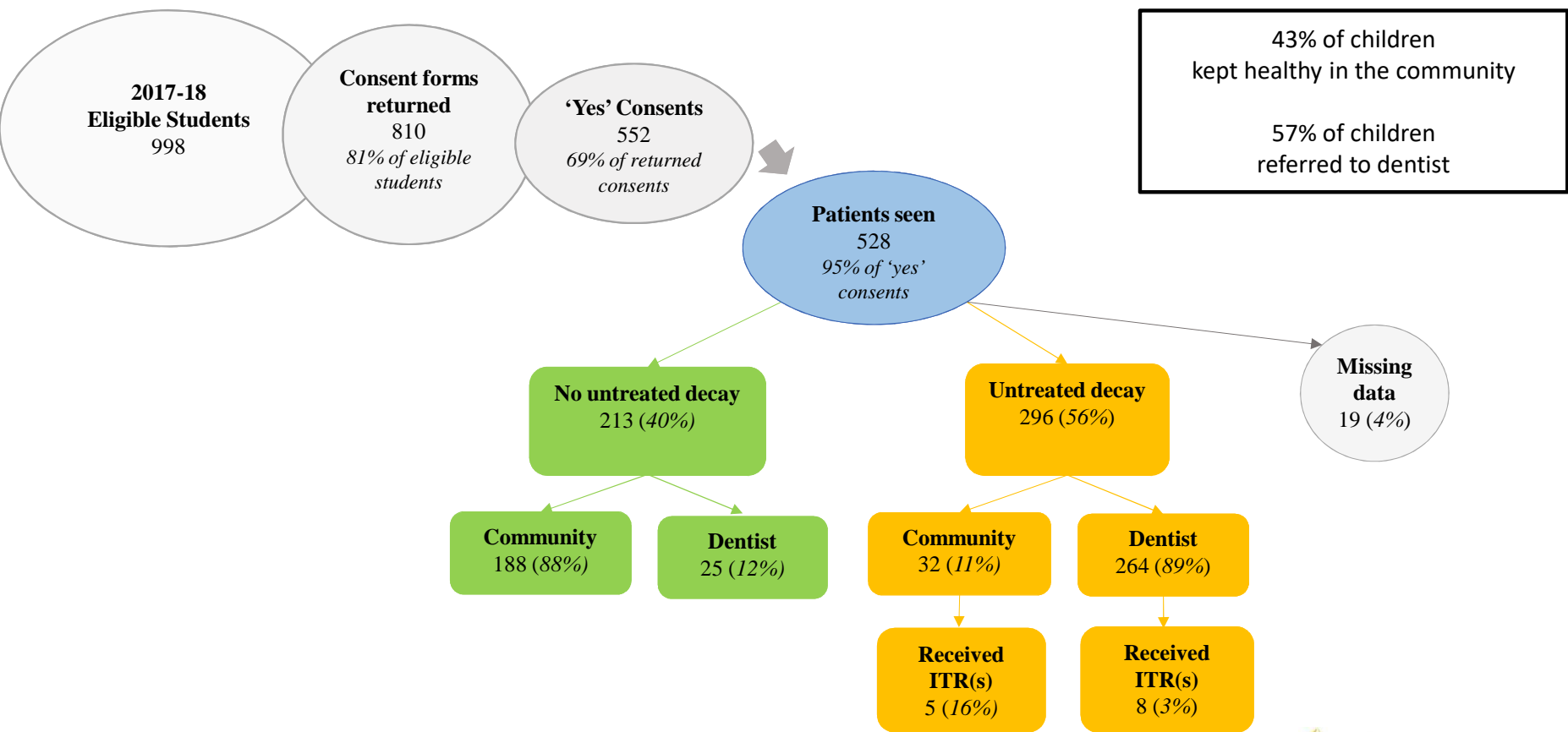
### Quarter 4

- Ash Creek Elementary School
- Program site since 2015
- Patients aged 5-11 years
- 35% kept healthy in the community



# 2017-2018 School Year Data

Three Elementary School Sites



43% of children kept healthy in the community

57% of children referred to dentist

# Satisfaction survey

## Satisfaction Among Those With and Without ITRs

Response	No ITR (N=189) n(%)	Received ITR (N=22) n(%)
Very satisfied	142 (75.1)	14 (63.6)
Somewhat satisfied	33 (17.5)	6 (27.3)
Somewhat dissatisfied	1 (0.5)	1 (4.5)
Very dissatisfied	2 (1.1)	1 (4.5)
I do not know / Missing	11 (5.8)	0

$\chi^2 = 6.75$ ;  $df=4$ ;  $p=0.08$

## If your child has future dental care needs that can be done at school, would you like that?

Response	N	%
Yes	178	84%
No	14	7%
I do not know / Missing	19	9%





## Dental Pilot Project Program Clinical Records Review Form DPP #200

Chart ID #: \_\_\_\_\_ Provider ID #: \_\_\_\_\_ Reviewer: \_\_\_\_\_ Date of Review: \_\_\_\_\_

**ALL Notations of Not Acceptable Require explanation under comments.**

CRITERIA	Acceptable / Present	Not Acceptable / Not Present	N/A	Comments
Chart and progress notes are understandable and clearly describe the treatment provided	Strongly agree / Agree / Undecided / Disagree / Strongly Disagree			
Appropriate images	Strongly agree / Agree / Undecided / Disagree / Strongly Disagree			
Any complications noted				
Incidents or Unusual Occurrences				
<b>Comment on ITR Placement by <u>tooth</u>.</b>				
Criteria for evaluation successful completion of Interim Therapeutic Restorations includes the following:				
1. Restorative Material is not in hyper-occlusion.				
2. There are no marginal voids.				
3. There is minimal excess material.				

CRITERIA	Acceptable / Present	Not Acceptable / Not Present	N/A	Comments
<b>Tooth Number: #3-OL</b> <b>Date of Service: 5-15-2017</b>				
Occlusion is <b>Acceptable</b> or <b>Not Acceptable</b> <b>#3-OL</b>				
There is minimal excess material <b>#3-OL</b>	Strongly agree / Agree / Undecided / Disagree / Strongly Disagree			
Margins are <b>Acceptable</b> or <b>Not Acceptable</b> <b>#3-OL</b>				
There are no marginal voids <b>#3-OL</b>	Strongly agree / Agree / Undecided / Disagree / Strongly Disagree			
Materials are <b>Acceptable</b> or <b>Not Acceptable</b> <b>#3-OL</b> (Material Used is the same product for all ITRs reviewed)				
Overall impression of ITR quality <b>#3-OL</b>	(Worst) 1   2   3   4   5 (Best)			
<b>Comment on Post-Treatment Evaluations/Follow up care and Case Management*</b> <b>Trainee Records Indicate Follow-Up at the following intervals: 3-Months, 6-Months, 1-Year</b>				
*3-Months				

CRITERIA	Acceptable / Present	Not Acceptable / Not Present	N/A	Comments
*6-Months				
*1 Year				
Post-treatment evaluation is appropriate				
Follow up/ recall consistent with patient needs				
Supervising Dentist reviewed ITR post-placement and deemed ITR acceptable based on ITR Placement Protocols				

**Were there any Adverse Events? Circle One: Yes or No**

***Adverse Events are categorized according to the following Dental AE Type Classification:***

**Table 1. Dental AE Type Classification<sup>1, 2</sup>**

<b>AE Category</b>
<b>1. Allergy/Hypersensitivity reactions</b>
<b>2. Aspiration of foreign body</b>
<b>3. Delayed appropriate treatment/Disease progression and/or unnecessary treatment associated with misdiagnosis</b>
<b>4. Foreign body response/rejection</b>
<b>5. Hard-tissue damage</b>
<b>6. Harm, not otherwise specified</b>
<b>7. Ingestion of foreign body</b>
<b>8. Nerve damage or injury</b>
<b>9. Ocular damage</b>
<b>10. Orofacial infection</b>
<b>11. Other orofacial complications</b>
<b>12. Other systemic complications including adverse reactions to device/materials/procedure</b>
<b>13. Other Wrong/unnecessary treatment</b>
<b>14. Poor aesthetic results post-dental treatment</b>
<b>15. Poor hemostasis/prolonged bleeding</b>
<b>16. Procedure on wrong patient</b>
<b>17. Procedure on wrong site</b>
<b>18. Psychological distress/disorder (including suicide)</b>
<b>19. Retention of foreign object(s) in patient with sequela</b>
<b>20. Soft tissue injury/inflammation</b>
<b>21. Systemic infection</b>
<b>22. Toxicity-drug overdose</b>

<sup>1</sup> Kalenderian E, Obadan-Udoh E, Maramaldi P, Etolue J, Yansane A, Stewart D et al. Classifying Adverse Events in the Dental Office. Journal of Patient Safety. 2017 Jun 30. Available from, DOI: 10.1097/PTS.0000000000000407

<sup>2</sup> Kalenderian E, Obadan-Udoh E, Ramoni R, Lessons learnt from Dental Patient Safety Case Reports. J Am Dent Assoc. 2015 May; 146(5): 318–326.e2. doi: 10.1016/j.adaj.2015.01.003

Please describe the AE Category associated with Adverse Event based on the descriptions outlined in Table 1. Dental AE Type Classification, i.e. Category 5, Hard tissue damage, etc.

Estimated time to complete chart: \_\_\_\_\_

Flag chart for further review: Circle One: Yes or No

Other Comments: