



CENTER FOR PREVENTION AND HEALTH PROMOTION
Oral Health Program

Kate Brown, Governor

Oregon
Health
Authority

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NOTICE OF INTENT TO PROVISIONALLY APPROVE

Toby Absher
Willamette Dental
6950 NE Campus Way
Hillsboro, OR 9712

September 27, 2019

Dear Mr. Absher,

Willamette Dental has submitted an application for a pilot project as permitted via Senate Bill 738 (2011) and later amendments (Oregon Laws 2011, Chapter 716, Section 1, 17; Oregon Laws 2015, Chapter 812, Section 2).

The Technical Review Board (TRB) has recommended approval of the application “Dental Hygiene Restorative Function Endorsement Model” originally submitted on February 19, 2019 and revised and resubmitted on August 22, 2019. OHA has reviewed the TRB recommendations and comments and is issuing a Notice of Intent to Provisionally Approve as required under 333-010-0730.

Pursuant to 333-010-0730, 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.

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.

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.

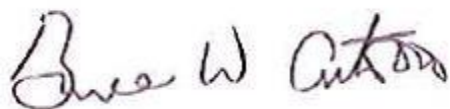
Statutory/Other Authority: 2011 OL Ch. 716

Statutes/Other Implemented: 2011 OL Ch. 716

The application will be posted on Wednesday, October 1, 2019 for public comment at healthoregon.org/dpp. Public comment will conclude on Wednesday, October 30, 2019. The applicant may be required to make additional changes to the application based on public comment. A final decision of provisional approval or denial will be issued by OHA no later than Friday, November 29, 2019. If provisionally approved, the applicant will be required to submit

an Evaluation and Monitoring Plan and Standard Operating Procedures to OHA for review and approval no later than Thursday, February 27, 2020. Upon approval, OHA will issue a letter of final approval to the project sponsor. While there is no specified timeline in the administrative rules, OHA will work with the project during the review process to ensure a timely response.

Sincerely,

A handwritten signature in black ink that reads "Bruce W. Austin". The signature is written in a cursive, slightly slanted style.

Bruce Austin
Statewide Dental Director

Enclosure: Senate Bill 738(2011) and SB606(2015) ORS 680.210
Oregon Administrative Rules

CC: Technical Review Board

Enrolled
Senate Bill 738

Sponsored by Senator MONNES ANDERSON

CHAPTER

AN ACT

Relating to dental health; creating new provisions; amending ORS 679.010, 679.020, 679.025, 680.150, 680.200, 680.205, 750.055 and 750.333; appropriating money; and declaring an emergency.

Be It Enacted by the People of the State of Oregon:

DENTAL PILOT PROJECTS

SECTION 1. (1) **The Oregon Health Authority may approve pilot projects 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. The authority may approve a pilot project that is designed to:**

(a) **Operate for three to five years or a sufficient amount of time to evaluate the validity of the pilot project;**

(b) **Evaluate quality of care, access, cost, workforce and efficacy; and**

(c) **Achieve at least one of the following:**

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

(B) **Develop new categories of dental personnel;**

(C) **Accelerate the training of existing categories of dental personnel; or**

(D) **Teach new oral health care roles to previously untrained persons.**

(2) **The authority shall adopt rules:**

(a) **Establishing an application process for pilot projects;**

(b) **Establishing minimum standards, guidelines and instructions for pilot projects; and**

(c) **Requiring an approved pilot project to report to the authority on the progress and outcomes of the pilot project, including:**

(A) **The process used to evaluate the progress and outcomes of the pilot project;**

(B) **The baseline data and information to be collected;**

(C) **The nature of program data that will be collected and the methods for collecting and analyzing the data;**

(D) **The provisions for protecting the safety of patients seen or treated in the project; and**

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

(3) **The authority shall seek the advice of appropriate professional societies and licensing boards before adopting rules under subsection (2) of this section.**

(4)(a) Notwithstanding ORS 679.020 and 680.020, a person may practice dentistry or dental hygiene without a license as part of a pilot project approved under this section under the general supervision of a dentist licensed under ORS chapter 679 and in accordance with rules adopted by the authority.

(b) A person practicing dentistry or dental hygiene without a license under this section is subject to the same standard of care and is entitled to the same immunities as a person performing the services with a license.

(5) The authority may accept gifts, grants or contributions from any public or private source for the purpose of carrying out this section. Funds received under this subsection shall be deposited in the Dental Pilot Projects Fund established under section 17 of this 2011 Act.

SECTION 2. Section 1 of this 2011 Act is repealed on January 2, 2018.

EXPANDED PRACTICE DENTAL HYGIENISTS

SECTION 3. ORS 679.010 is amended to read:

679.010. As used in this chapter and ORS 680.010 to 680.205, unless the context requires otherwise:

[1] *“Board” means the Oregon Board of Dentistry.*

[2] (1) “Dental assistant” means a person who, under the supervision of a dentist, renders assistance to a dentist, dental hygienist, dental technician or another dental assistant or renders assistance under the supervision of a dental hygienist providing dental hygiene.

[3] (2) “Dental hygiene” means that portion of dentistry that includes the rendering of educational, preventive and therapeutic dental services and diagnosis and treatment planning for such services. “Dental hygiene” includes, but is not limited to, scaling, root planing, curettage, the application of sealants and fluoride and any related intraoral or extraoral procedure required in the performance of such services.

[4] (3) “Dental hygienist” means a person who, under the supervision of a dentist, practices dental hygiene.

[5] (4) “Dental technician” means that person who, at the authorization of a dentist, makes, provides, repairs or alters oral prosthetic appliances and other artificial materials and devices which are returned to a dentist and inserted into the human oral cavity or which come in contact with its adjacent structures and tissues.

[6] (5) “Dentist” means a person who may perform any intraoral or extraoral procedure required in the practice of dentistry.

[7] (6) “Dentistry” means the healing art which is concerned with the examination, diagnosis, treatment planning, treatment, care and prevention of conditions within the human oral cavity and maxillofacial region and conditions of adjacent or related tissues and structures. The practice of dentistry includes but is not limited to the cutting, altering, repairing, removing, replacing or repositioning of hard or soft tissues and other acts or procedures as determined by the **Oregon Board of Dentistry** and included in the curricula of dental schools accredited by the Commission on Dental Accreditation of the American Dental Association, post-graduate training programs or continuing education courses.

[8] (7) “Direct supervision” means supervision requiring that a dentist diagnose the condition to be treated, that a dentist authorize the procedure to be performed, and that a dentist remain in the dental treatment room while the procedures are performed.

(8) **“Expanded practice dental hygienist” means a dental hygienist who performs dental hygiene services in accordance with ORS 680.205 as authorized by an expanded practice dental hygienist permit issued by the board under ORS 680.200.**

(9) “General supervision” means supervision requiring that a dentist authorize the procedures by **standing orders, practice agreements or collaboration agreements**, but not requiring that

a dentist be present when the authorized procedures are performed. The authorized procedures may also be performed at a place other than the usual place of practice of the dentist.

(10) "Indirect supervision" means supervision requiring that a dentist authorize the procedures and that a dentist be on the premises while the procedures are performed.

[(11) "Limited access permit dental hygienist" means a dental hygienist who renders dental hygiene services in accordance with ORS 680.205 as authorized by a limited access permit issued by the board pursuant to ORS 680.200.]

[(12) "State" means any state or territory of the United States and the District of Columbia.]

SECTION 4. ORS 679.020 is amended to read:

679.020. (1) A person may not practice dentistry without a license.

(2) Only a person licensed as a dentist by the Oregon Board of Dentistry may own, operate, conduct or maintain a dental practice, office or clinic in this state.

(3) The restrictions of subsection (2) of this section, as they relate to owning and operating a dental office or clinic, do not apply to a dental office or clinic owned or operated by any of the following:

(a) A labor organization as defined in ORS 243.650 and 663.005 (6), or to any nonprofit organization formed by or on behalf of such labor organization for the purpose of providing dental services. Such labor organization must have had an active existence for at least three years, have a constitution and bylaws, and be maintained in good faith for purposes other than providing dental services.

(b) The School of Dentistry of the Oregon Health and Science University.

(c) Institutions of higher education listed in ORS 352.002.

(d) Local governments.

(e) Institutions or programs accredited by the Commission on Dental Accreditation of the American Dental Association to provide education and training.

(f) Nonprofit corporations organized under Oregon law to provide dental services to rural areas and medically underserved populations of migrant, rural community or homeless individuals under 42 U.S.C. 254b or 254c or health centers qualified under 42 U.S.C. 1396d(1)(2)(B) operating in compliance with other applicable state and federal law.

(g) Nonprofit charitable corporations as described in section 501(c)(3) of the Internal Revenue Code and determined by the Oregon Board of Dentistry as providing dental services by volunteer licensed dentists to populations with limited access to dental care at no charge or a substantially reduced charge.

(4) For the purpose of owning or operating a dental office or clinic, an entity described in subsection (3) of this section must:

(a) Name an actively licensed dentist as its dental director, who shall be subject to the provisions of ORS 679.140 in the capacity as dental director. The dental director, or an actively licensed dentist designated by the director, shall have responsibility for the clinical practice of dentistry, which includes, but is not limited to:

(A) Diagnosis of conditions within the human oral cavity and its adjacent tissues and structures.

(B) Prescribing drugs that are administered to patients in the practice of dentistry.

(C) The treatment plan of any dental patient.

(D) Overall quality of patient care that is rendered or performed in the practice of dentistry.

(E) Supervision of dental hygienists, dental assistants or other personnel involved in direct patient care and the authorization for procedures performed by them in accordance with the standards of supervision established by statute or by the rules of the board.

(F) Other specific services within the scope of clinical dental practice.

(G) Retention of patient dental records as required by statute or by rule of the board.

(H) Ensuring that each patient receiving services from the dental office or clinic has a dentist of record.

(b) Maintain current records of the names of licensed dentists who supervise the clinical activities of dental hygienists, dental assistants or other personnel involved in direct patient care utilized by the entity. The records must be available to the board upon written request.

(5) Subsections (1) and (2) of this section do not apply to [a *limited access permit*] **an expanded practice** dental hygienist who renders services authorized by a [*limited access*] permit issued by the board pursuant to ORS 680.200.

(6) Nothing in this chapter precludes a person or entity not licensed by the board from:

(a) Ownership or leasehold of any tangible or intangible assets used in a dental office or clinic. These assets include real property, furnishings, equipment and inventory but do not include dental records of patients related to clinical care.

(b) Employing or contracting for the services of personnel other than licensed dentists.

(c) Management of the business aspects of a dental office or clinic that do not include the clinical practice of dentistry.

(7) If all of the ownership interests of a dentist or dentists in a dental office or clinic are held by an administrator, executor, personal representative, guardian, conservator or receiver of the estate of a former shareholder, member or partner, the administrator, executor, personal representative, guardian, conservator or receiver may retain the ownership interest for a period of 12 months following the creation of the ownership interest. The board shall extend the ownership period for an additional 12 months upon 30 days' notice and may grant additional extensions upon reasonable request.

SECTION 5. ORS 679.025 is amended to read:

679.025. (1) [It shall be unlawful for any] **A** person [not otherwise authorized by law to] **may not** practice dentistry or purport to be a dentist without a valid license to practice dentistry issued by the Oregon Board of Dentistry.

(2) The requirements of this section [shall] **do** not apply to:

(a) Dentists licensed in another state making a clinical presentation sponsored by a bona fide dental society or association or an accredited dental educational institution approved by the board.

(b) Bona fide full-time students of dentistry who, during the period of their enrollment and as a part of the course of study in an Oregon accredited dental education program, engage in clinical studies on the premises of such institution or in a clinical setting located off the premises of the institution if the facility, the instructional staff and the course of study to be pursued at the off-premises location meet minimum requirements prescribed by the rules of the board and the clinical study is performed under the direct supervision of a member of the faculty.

(c) Bona fide full-time students of dentistry who, during the period of their enrollment and as a part of the course of study in a dental education program located outside of Oregon that is accredited by the Commission on Dental Accreditation of the American Dental Association or its successor agency, engage in community-based or clinical studies as an elective or required rotation in a clinical setting located in Oregon if the community-based or clinical studies meet minimum requirements prescribed by the rules of the board and are performed under the direct supervision of a member of the faculty of the Oregon Health and Science University School of Dentistry.

(d) Candidates who are preparing for a licensure examination to practice dentistry and whose application has been accepted by the board or its agent, if such clinical preparation is conducted in a clinic located on premises approved for that purpose by the board and if the procedures are limited to examination only. This exception shall exist for a period not to exceed two weeks immediately prior to a regularly scheduled licensure examination.

(e) Dentists practicing in the discharge of official duties as employees of the United States Government and any of its agencies.

(f) Instructors of dentistry, whether full- or part-time, while exclusively engaged in teaching activities and while employed in accredited dental educational institutions.

(g) Dentists employed by public health agencies who are not engaged in the direct delivery of clinical dental services to patients.

(h) Persons licensed to practice medicine in the State of Oregon in the regular discharge of their duties.

(i) Persons qualified to perform services relating to general anesthesia or sedation under the direct supervision of a licensed dentist.

(j) Persons practicing dentistry upon themselves as the patient.

(k) Dental hygienists, dental assistants or dental technicians performing services under the supervision of a licensed dentist in accordance with the rules adopted by the board.

(L) A person licensed as a denturist under ORS 680.500 to 680.565 engaged in the practice of denture technology.

(m) [A *limited access permit*] **An expanded practice** dental hygienist who renders services authorized by a [*limited access*] permit issued by the board pursuant to ORS 680.200.

SECTION 6. ORS 680.150 is amended to read:

680.150. (1) Any dentist may employ a dental hygienist who may engage in the practice of dental hygiene in the office of such dentist under the general supervision of a dentist.

(2) Any public institution, health care facility or health maintenance organization, as those terms are defined in ORS 442.015, may employ a dental hygienist who may engage in the practice of dental hygiene under the general supervision of a dentist.

(3) A dental hygienist under the general supervision of a dentist may engage in the practice of dental hygiene in any place where limited access patients are located.

(4) The Oregon Board of Dentistry may adopt rules specifying other locations where dental hygienists may work and shall specify in its rules the degree of supervision a dentist must exercise over the procedures the hygienist performs.

(5) Notwithstanding ORS 679.010 [(4)] **(3)**, supervision by a dentist is not required when a dental hygienist determines the need for and appropriateness of sealants or fluoride, and applies sealants or fluoride at the locations and for persons described in ORS 680.205 (1) [*and (2)*].

SECTION 7. ORS 680.200 is amended to read:

680.200. (1) Upon application accompanied by the fee established by the Oregon Board of Dentistry, the board shall grant a permit to practice as [*a limited access permit*] **an expanded practice** dental hygienist to [*any*] **an** applicant who:

(a) Holds a valid, unrestricted Oregon dental hygiene license;

(b) Presents proof of current professional liability insurance coverage;

(c) Presents documentation satisfactory to the board of successful completion of an emergency life support course for health professionals, including cardiopulmonary resuscitation, from an agency or educational institution approved by the board; and

(d) Presents documentation satisfactory to the board that the [*person*] **applicant** has:

(A)(i) Completed 2,500 hours of supervised dental hygiene practice; and

(ii) **After licensure as a dental hygienist**, completed 40 hours of courses, **chosen by the applicant**, in [*a formal, post-secondary educational program accredited by the Commission on Dental Accreditation of the American Dental Association or its successor agency and*] **clinical dental hygiene or public health sponsored by continuing education providers** approved by the board; or

(B) Completed a course of study approved by the board that includes at least 500 hours of dental hygiene practice, **completed before or after graduation from a dental hygiene program**, on patients described in ORS 680.205 while under the direct supervision of a member of the faculty of a dental program or dental hygiene program accredited by the Commission on Dental Accreditation of the American Dental Association or its successor agency. [*Practice hours from before and after graduation from the dental hygiene program may be combined to meet the requirement of this subparagraph.*]

(2) [*All permits*] **A permit** issued pursuant to subsection (1) of this section [*expire*] **expires** two years following the date of issuance unless renewed on or before that date by:

(a) Payment of the renewal fee as set by the board;

(b) Submission to the board of satisfactory evidence of completion of at least 36 hours of continuing education; [*and*]

(c) Presentation to the board of proof of professional liability insurance coverage; and
(d) Completion of a survey developed by the board that measures the success of the expanded practice dental hygienist program against baseline data.

(3) The board may refuse to issue or renew [a limited access] **an expanded practice dental hygienist** permit or may suspend or revoke the permit of [a limited access permit] **an expanded practice dental hygienist** who has been convicted of an offense or been disciplined by a dental licensing body in a manner that bears, in the judgment of the board, a demonstrable relationship to the ability of the applicant to practice [limited access permit] **expanded practice dental hygiene** in accordance with the provisions of this chapter or ORS chapter 679, or who has falsified an application for permit, or any person for any cause described under ORS 679.140 or 679.170.

SECTION 8. ORS 680.205 is amended to read:

680.205. (1) [A dental hygienist issued a permit to act as a limited access permit] **An expanded practice dental hygienist** [under ORS 680.200 shall be authorized to] **may** render all services within the scope of practice of dental hygiene, as defined in ORS 679.010, without the supervision of a dentist and as authorized by the [limited access] **expanded practice dental hygienist** permit to:

(a) Patients or residents of the following facilities or programs who, due to age, infirmity or disability, are unable to receive regular dental hygiene treatment:

- (A) Nursing homes as defined in ORS 678.710;
- (B) Adult foster homes as defined in ORS 443.705;
- (C) Residential care facilities as defined in ORS 443.400;
- (D) Adult congregate living facilities as defined in ORS 441.525;
- (E) Mental health residential programs administered by the Oregon Health Authority;
- (F) Facilities for mentally ill persons, as those terms are defined in ORS 426.005;
- (G) Facilities for persons with mental retardation, as those terms are defined in ORS 427.005;
- (H) Local correctional facilities and juvenile detention facilities as those terms are defined in ORS 169.005, regional correctional facilities as defined in ORS 169.620, youth correction facilities as defined in ORS 420.005, youth care centers as defined in ORS 420.855, and Department of Corrections institutions as defined in ORS 421.005; or

(I) Public and nonprofit community health clinics.

(b) Adults who are homebound.

(c) Students or enrollees of nursery schools and day care programs and their siblings under 18 years of age, Job Corps and [other] similar employment training facilities, primary and secondary schools, including private schools and public charter schools, and persons entitled to benefits under the Women, Infants and Children Program.

(d) Patients in hospitals, medical clinics, medical offices or offices operated or staffed by nurse practitioners, physician assistants or midwives.

(e) Patients whose income is less than the federal poverty level.

(f) Other populations that the Oregon Board of Dentistry determines are underserved or lack access to dental hygiene services.

[2] *The Oregon Board of Dentistry may authorize the provision of dental hygiene services by a limited access permit dental hygienist at locations or to populations that are underserved or lack access to dental hygiene services.*

[(3)] **(2)** At least once each calendar year, [a dental hygienist issued a permit to act as a limited access permit] **an expanded practice dental hygienist** shall refer each patient or resident to a dentist who is available to treat the patient or resident.

(3) An expanded practice dental hygienist may render the services described in paragraphs (a) to (d) of this subsection to the patients described in subsection (1) of this section if the expanded practice dental hygienist has entered into an agreement in a format approved by the board with a dentist licensed under ORS chapter 679. The agreement must set forth the agreed-upon scope of the dental hygienist's practice with regard to:

(a) Administering local anesthesia;

(b) Administering temporary restorations without excavation;

(c) **Prescribing prophylactic antibiotics and nonsteroidal anti-inflammatory drugs specified in the agreement; and**

(d) **Overall dental risk assessment and referral parameters.**

(4) This section does not authorize [a limited access permit] **an expanded practice dental hygienist [to administer local anesthesia or temporary restorations except under the general supervision of a dentist licensed under ORS chapter 679, or]** to administer nitrous oxide except under the indirect supervision of a dentist licensed under ORS chapter 679.

(5) [A limited access permit] **An expanded practice dental hygienist** may assess the need for and appropriateness of sealants, apply sealants and write prescriptions for all applications of fluoride in which fluoride is applied or supplied to patients.

(6) [A person granted a limited access permit under ORS 680.200 shall] **An expanded practice dental hygienist must** also procure all other permits or certificates required by the board under ORS 679.250.

SECTION 9. The Oregon Board of Dentistry shall issue an expanded practice dental hygienist permit under ORS 680.200 to each person holding a limited access permit under ORS 680.200 as in effect immediately before the operative date specified in section 19 of this 2011 Act.

SECTION 10. Section 11 of this 2011 Act is added to and made a part of the Insurance Code.

SECTION 11. (1) If a policy of insurance covering dental health provides for coverage for services performed by a dentist licensed under ORS chapter 679, the policy must also cover the services when they are performed by an expanded practice dental hygienist, as defined in ORS 679.010, who has entered into a provider contract with the insurer.

(2) The provisions of ORS 743A.001 do not apply to this section.

SECTION 12. (1) The Oregon Board of Dentistry shall compile data, including baseline data, in every odd-numbered year on the use of expanded practice dental hygienists, as defined in ORS 679.010, in this state.

(2)(a) The Department of Consumer and Business Services shall adopt rules requiring health insurers to report to the department on the reimbursement of services provided by expanded practice dental hygienists.

(b) The department shall provide the information collected under paragraph (a) of this subsection to the board.

(3) The board shall report to an interim legislative committee related to dental health on the reimbursement of services provided by expanded practice dental hygienists on or before October 1 of each even-numbered year.

SECTION 13. ORS 750.055 is amended to read:

750.055. (1) The following provisions of the Insurance Code apply to health care service contractors to the extent not inconsistent with the express provisions of ORS 750.005 to 750.095:

(a) ORS 705.137, 705.139, 731.004 to 731.150, 731.162, 731.216 to 731.362, 731.382, 731.385, 731.386, 731.390, 731.398 to 731.430, 731.428, 731.450, 731.454, 731.488, 731.504, 731.508, 731.509, 731.510, 731.511, 731.512, 731.574 to 731.620, 731.592, 731.594, 731.640 to 731.652, 731.730, 731.731, 731.735, 731.737, 731.750, 731.752, 731.804, 731.844 to 731.992 and 731.870.

(b) ORS 732.215, 732.220, 732.230, 732.245, 732.250, 732.320, 732.325 and 732.517 to 732.592, not including ORS 732.582.

(c) ORS 733.010 to 733.050, 733.080, 733.140 to 733.170, 733.210, 733.510 to 733.680 and 733.695 to 733.780.

(d) ORS chapter 734.

(e) ORS 742.001 to 742.009, 742.013, 742.061, 742.065, 742.150 to 742.162, 742.400, 742.520 to 742.540, 743.010, 743.013, 743.018 to 743.030, 743.050, 743.100 to 743.109, 743.402, 743.472, 743.492, 743.495, 743.498, 743.522, 743.523, 743.524, 743.526, 743.527, 743.528, 743.529, 743.549 to 743.552, 743.560, 743.600 to 743.610, 743.650 to 743.656, 743.804, 743.807, 743.808, 743.814 to 743.839, 743.842, 743.845, 743.847, 743.854, 743.856, 743.857, 743.858, 743.859, 743.861, 743.862, 743.863, 743.864, 743.911,

743.912, 743.913, 743.917, 743A.010, 743A.012, 743A.020, 743A.036, 743A.048, 743A.058, 743A.062, 743A.064, 743A.066, 743A.068, 743A.070, 743A.080, 743A.084, 743A.088, 743A.090, 743A.100, 743A.104, 743A.105, 743A.110, 743A.140, 743A.141, 743A.144, 743A.148, 743A.160, 743A.164, 743A.168, 743A.170, 743A.175, 743A.184, 743A.188, 743A.190 and 743A.192 **and section 11 of this 2011 Act.**

(f) The provisions of ORS chapter 744 relating to the regulation of insurance producers.

(g) ORS 746.005 to 746.140, 746.160, 746.220 to 746.370, 746.600, 746.605, 746.607, 746.608, 746.610, 746.615, 746.625, 746.635, 746.650, 746.655, 746.660, 746.668, 746.670, 746.675, 746.680 and 746.690.

(h) ORS 743A.024, except in the case of group practice health maintenance organizations that are federally qualified pursuant to Title XIII of the Public Health Service Act unless the patient is referred by a physician associated with a group practice health maintenance organization.

(i) ORS 735.600 to 735.650.

(j) ORS 743.680 to 743.689.

(k) ORS 744.700 to 744.740.

(L) ORS 743.730 to 743.773.

(m) ORS 731.485, except in the case of a group practice health maintenance organization that is federally qualified pursuant to Title XIII of the Public Health Service Act and that wholly owns and operates an in-house drug outlet.

(2) For the purposes of this section, health care service contractors shall be deemed insurers.

(3) Any for-profit health care service contractor organized under the laws of any other state that is not governed by the insurance laws of the other state is subject to all requirements of ORS chapter 732.

(4) The Director of the Department of Consumer and Business Services may, after notice and hearing, adopt reasonable rules not inconsistent with this section and ORS 750.003, 750.005, 750.025 and 750.045 that are deemed necessary for the proper administration of these provisions.

SECTION 14. ORS 750.333 is amended to read:

750.333. (1) The following provisions of the Insurance Code apply to trusts carrying out a multiple employer welfare arrangement:

(a) ORS 731.004 to 731.150, 731.162, 731.216 to 731.268, 731.296 to 731.316, 731.324, 731.328, 731.378, 731.386, 731.390, 731.398, 731.406, 731.410, 731.414, 731.418 to 731.434, 731.454, 731.484, 731.486, 731.488, 731.512, 731.574 to 731.620, 731.640 to 731.652 and 731.804 to 731.992.

(b) ORS 733.010 to 733.050, 733.140 to 733.170, 733.210, 733.510 to 733.680 and 733.695 to 733.780.

(c) ORS chapter 734.

(d) ORS 742.001 to 742.009, 742.013, 742.061 and 742.400.

(e) ORS 743.028, 743.053, 743.524, 743.526, 743.527, 743.528, 743.529, 743.530, 743.560, 743.562, 743.600, 743.601, 743.602, 743.610, 743.730 to 743.773 (except 743.760 to 743.773), 743.801, 743.804, 743.807, 743.808, 743.814 to 743.839, 743.842, 743.845, 743.847, 743.854, 743.856, 743.857, 743.858, 743.859, 743.861, 743.862, 743.863, 743.864, 743.912, 743.917, 743A.012, 743A.020, 743A.052, 743A.064, 743A.080, 743A.100, 743A.104, 743A.110, 743A.144, 743A.170, 743A.175, 743A.184 and 743A.192 **and section 11 of this 2011 Act.**

(f) ORS 743A.010, 743A.014, 743A.024, 743A.028, 743A.032, 743A.036, 743A.040, 743A.048, 743A.058, 743A.066, 743A.068, 743A.070, 743A.084, 743A.088, 743A.090, 743A.105, 743A.140, 743A.141, 743A.148, 743A.168, 743A.180, 743A.188 and 743A.190. Multiple employer welfare arrangements to which ORS 743.730 to 743.773 apply are subject to the sections referred to in this paragraph only as provided in ORS 743.730 to 743.773.

(g) Provisions of ORS chapter 744 relating to the regulation of insurance producers and insurance consultants, and ORS 744.700 to 744.740.

(h) ORS 746.005 to 746.140, 746.160 and 746.220 to 746.370.

(i) ORS 731.592 and 731.594.

(j) ORS 731.870.

(2) For the purposes of this section:

(a) A trust carrying out a multiple employer welfare arrangement shall be considered an insurer.

(b) References to certificates of authority shall be considered references to certificates of multiple employer welfare arrangement.

(c) Contributions shall be considered premiums.

(3) The provision of health benefits under ORS 750.301 to 750.341 shall be considered to be the transaction of health insurance.

COMMUNITY DENTAL HEALTH COORDINATOR PILOT PROJECTS

SECTION 15. (1) The Oregon Health Authority may approve pilot projects for training and certifying community dental health coordinators to educate the community on dental health.

(2) The authority shall consult with appropriate professional organizations, educational institutions and the Oregon Board of Dentistry before approving pilot projects under this section.

(3) An approved project must require community dental health coordinators to complete 18 months of training, including an internship.

(4) The authority shall adopt rules:

(a) Establishing an application process for pilot projects;

(b) Establishing minimum standards, guidelines and instructions for pilot projects; and

(c) Requiring an approved pilot project to report to the authority on the progress and outcomes of the pilot project, including:

(A) The process used to evaluate the progress and outcomes of the pilot project;

(B) The baseline data and information to be collected;

(C) The nature of program data that will be collected and the methods for collecting and analyzing the data;

(D) The provisions for protecting the safety of patients seen or treated in the project; and

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

(5) The authority may accept gifts, grants or contributions from any public or private source for the purpose of carrying out this section. Funds received under this subsection shall be deposited in the Dental Pilot Projects Fund established under section 17 of this 2011 Act.

SECTION 16. Section 15 of this 2011 Act is repealed on January 2, 2018.

DENTAL PILOT PROJECTS FUND

SECTION 17. The Dental Pilot Projects Fund is established in the State Treasury, separate and distinct from the General Fund. Interest earned by the Dental Pilot Projects Fund shall be credited to the fund. Moneys in the fund are continuously appropriated to the Oregon Health Authority for the purposes of carrying out the provisions of sections 1 and 15 of this 2011 Act.

APPLICABILITY

SECTION 18. The amendments to ORS 680.200 by section 7 of this 2011 Act apply to applications for expanded practice dental hygienist permits submitted on or after January 1, 2012.

OPERATIVE DATE

SECTION 19. (1) Sections 9 to 12 of this 2011 Act and the amendments to ORS 679.010, 679.020, 679.025, 680.150, 680.200, 680.205, 750.055 and 750.333 by sections 3 to 8, 13 and 14 of this 2011 Act become operative on January 1, 2012.

(2) The Oregon Board of Dentistry may take any action before the operative date specified in subsection (1) of this section to enable the board to exercise, on and after the operative date specified in subsection (1) of this section, all of the duties, functions and powers conferred on the board by sections 9 to 12 of this 2011 Act and the amendments to ORS 679.010, 679.020, 679.025, 680.150, 680.200, 680.205, 750.055 and 750.333 by sections 3 to 8, 13 and 14 of this 2011 Act.

UNIT CAPTIONS

SECTION 20. The unit captions used in this 2011 Act are provided only for the convenience of the reader and do not become part of the statutory law of this state or express any legislative intent in the enactment of this 2011 Act.

EMERGENCY CLAUSE

SECTION 21. This 2011 Act being necessary for the immediate preservation of the public peace, health and safety, an emergency is declared to exist, and this 2011 Act takes effect on its passage.

Passed by Senate June 17, 2011

.....
Robert Taylor, Secretary of Senate

.....
Peter Courtney, President of Senate

Passed by House June 22, 2011

.....
Bruce Hanna, Speaker of House

.....
Arnie Roblan, Speaker of House

Received by Governor:

.....M.,....., 2011

Approved:

.....M.,....., 2011

.....
John Kitzhaber, Governor

Filed in Office of Secretary of State:

.....M.,....., 2011

.....
Kate Brown, Secretary of State

Enrolled
Senate Bill 606

Sponsored by Senator MONNES ANDERSON, Representative KENY-GUYER; Senator JOHNSON

CHAPTER

AN ACT

Relating to dental pilot project; creating new provisions; amending section 2, chapter 716, Oregon Laws 2011; and declaring an emergency.

Be It Enacted by the People of the State of Oregon:

SECTION 1. In addition to and not in lieu of any other appropriation, there is appropriated to the Oregon Health Authority, for the biennium beginning July 1, 2015, out of the General Fund, the amount of \$100,000, which may be expended for extending the dental pilot project described in section 1, chapter 716, Oregon Laws 2011.

SECTION 2. A provider of dental services in a dental pilot project approved by the Oregon Health Authority pursuant to section 1, chapter 716, Oregon Laws 2011, is eligible to be reimbursed for covered services provided to a recipient of medical assistance.

SECTION 3. Section 2, chapter 716, Oregon Laws 2011, is amended to read:

Sec. 2. (1) Section 1 [*of this 2011 Act*], chapter 716, Oregon Laws 2011, is repealed on January 2, [2018] 2025.

(2) Section 17, chapter 716, Oregon Laws 2011, as amended by section 2, chapter 113, Oregon Laws 2013, is repealed January 2, 2025.

(3) Section 2 of this 2015 Act is repealed on January 2, 2025.

SECTION 4. Section 2 of this 2015 Act applies to services provided on or after the effective date of this 2015 Act.

SECTION 5. This 2015 Act being necessary for the immediate preservation of the public peace, health and safety, an emergency is declared to exist, and this 2015 Act takes effect on its passage.

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

Passed by Senate July 1, 2015

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Lori L. Brocker, Secretary of Senate

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Peter Courtney, President of Senate

Passed by House July 3, 2015

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Tina Kotek, Speaker of House

Received by Governor:

.....M,....., 2015

Approved:

.....M,....., 2015

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Kate Brown, Governor

Filed in Office of Secretary of State:

.....M,....., 2015

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Jeanne P. Atkins, Secretary of State