Dental Pilot Project Program Rules Advisory Committee
Background Information

**Senate Bill 738 Dental Pilot Projects**

Senate Bill (SB) 738 was signed into law on August 2, 2011 authorizing the Oregon Health Authority (OHA) to implement the Dental Pilot Project Program. OHA 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 intent behind SB 738 was to:
- Authorize OHA to establish the Dental Pilot Project Program.
- Authorize OHA to adopt rules establishing an application process and minimum standards, guidelines and instructions for dental pilot projects to operate.

The legislation initially was scheduled to sunset on January 2, 2018. Senate Bill 606 was signed into law on August 12, 2015 and extended the sunset date to January 2, 2025. Copies of SB 738 and SB 606 are included in Appendix A.

In 2012, a Rules Advisory Committee (RAC) was convened to assist in drafting rule language for the Dental Pilot Project Program. Oregon Administrative Rules (OARs) 333-010-0400 through 333-010-0470 were effective February 3, 2013. In 2016, the OARs were amended to make minor clarifications to require approved pilot projects to include an evaluation by an outside evaluator who is unaffiliated with the pilot project.

**Purpose of the Dental Pilot Project RAC**

The purpose of this RAC is to amend OARs 333-010-0400 through 333-010-0470 to better define terminology; require an external dentist evaluator and dental project manager; define limitations around applications to the program; clarify the evaluation role of OHA; and clarify requirements for project data submission, project modifications, informed consent procedures, site visits and the process for suspension and/or termination of an approved dental pilot project.

OHA’s intent is to amend the current OARs by repealing the current version and replacing it with rule language that has input from this RAC. While drafting the amended rule language, it became clear that substantial portions had to be rewritten and/or reorganized into different sections so that the rules provide clarity of project requirements and programmatic requirements. The original OARs can be found in Appendix B.

**Current Dental Pilot Projects**

The OHA Dental Pilot Project Program has two approved pilot projects currently operating in Oregon:
- #100 – “Oregon Tribes Dental Health Aide Therapist Pilot Project”
- #200 – “Training Dental Hygienists to Place Interim Therapeutic Restorations”
**DRAFT Rulemaking Process**

The Oregon Health Authority, Public Health Division has policies and procedures that guide the rulemaking process. In order to have the rules effective in November 2018, we will be following the timeline below.

<table>
<thead>
<tr>
<th>Date</th>
<th>Activity</th>
</tr>
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<tbody>
<tr>
<td>April 2018</td>
<td>Notify stakeholders of RAC application process</td>
</tr>
<tr>
<td>May 2018</td>
<td>Select RAC members from applications</td>
</tr>
<tr>
<td></td>
<td>Draft proposed rules and Statement of Need and Fiscal Impact form</td>
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<tr>
<td>June-July 2018</td>
<td>Convene RAC and hold meetings to seek input on proposed rules and required forms</td>
</tr>
<tr>
<td>August 17, 2018</td>
<td>OHA Rules Coordinator needs final proposed rules and rulemaking forms</td>
</tr>
<tr>
<td>August 17-24, 2018</td>
<td>OHA Rules Coordinator will review forms and seek approval to file</td>
</tr>
<tr>
<td>August 24, 2018</td>
<td>OHA Rules Coordinator will file the notice of proposed rulemaking with the Oregon Secretary of State</td>
</tr>
<tr>
<td>August 27-31, 2018</td>
<td>Rulemaking documents will be posted to our website and interested parties will be notified</td>
</tr>
<tr>
<td>September 1, 2018</td>
<td>Notice appears in the Oregon Bulletin</td>
</tr>
<tr>
<td>September 17, 2018</td>
<td>Hold public hearings to seek public comments</td>
</tr>
<tr>
<td>September 22, 2018</td>
<td>Public comment period closes</td>
</tr>
<tr>
<td>After Public Comment Period Closes</td>
<td>Respond to comments from the public comment period</td>
</tr>
<tr>
<td>October 24, 2018</td>
<td>Final rule text showing changes and responses to public comment period due to the OHA Rules Coordinator</td>
</tr>
<tr>
<td></td>
<td>OHA Rules Coordinator will file the final rules with the Oregon Secretary of State</td>
</tr>
<tr>
<td>November 1, 2018</td>
<td>Rules are effective upon filing</td>
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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.]

[(9)] [(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.]

[(10) “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:

ORS 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(l)(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 person not otherwise authorized by law to 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 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:


(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.


(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.

(k) ORS 731.485, except in the case of a group practice health maintenance organization that wholly owns and operates an in-house drug outlet.

(l) ORS 731.488 to 733.780.

(m) ORS 731.592 and 731.594.

(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:


(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 743.001 to 743.009, 743.013, 743.061 and 743.400.


(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.100, 743A.104, 743A.141, 743A.144, 743A.160, 743A.164, 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 731.597.

(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

(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.
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, 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 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: Dental Pilot Projects

333-010-0400: Description of Dental Pilot Projects

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 oral health status of Oregonians is poor and the most vulnerable are those with the least access to services. OAR 333-010-0400 through 333-010-0470 provides administrative guidance to the required content of Dental Pilot Project applications, process for review, approval and monitoring of Dental Pilot Projects, and steps to terminate or conclude a Dental Pilot Project.

Stat. Auth.: 2011 OL Ch. 716
Stats. Implemented: 2011 OL Ch. 716
Hist.: PH 5-2013, f. & cert. ef. 2-4-13

333-010-0405: Dental Pilot Projects: Definitions

For purposes of OAR 333-010-0400 through 333-010-0470, the following definitions apply:

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

(2) "Clinical phase" means instructor supervised experience with a patient during which a trainee applies knowledge presented by an instructor.

(3) "Didactic phase" means an organized body of knowledge presented by an instructor.

(4) "Director" means the Public Health Director within the Oregon Health Authority, or his or her designee.

(5) "Employment/Utilization Phase" means ongoing application of didactic and clinical knowledge and skills in an employment setting under the supervision of a supervisor.

(6) "Employment/Utilization Site" means a health facility, any clinical setting where health care services are provided, and the facilities or programs described in ORS 680.205(1).

(7) "Evaluator" means an individual who will conduct an evaluation of the pilot project and is unaffiliated with the project and who has no financial or commercial interest in the project’s outcome.

(8) "Instructor" means a person qualified to practice or teach the knowledge or skills a trainee is to learn.

(a) "Clinical instructor" is a person who is certified or licensed in the field for which clinical instruction is occurring.

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

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

(10) "Program staff" means the staff of the Authority with responsibility for the program.
(11) “Project” means a Dental Pilot Project approved by the director or delegate.

(12) "Project director" means the individual designated by the sponsor to have responsibilities for the conduct of the project staff, instructors, supervisors, and trainees.

(13) "Reviewer" means an individual designated by program staff to review and comment on all or portions of a project application.

(14) "Sponsor" means an entity putting forth an application for a dental pilot project.

(15) "These rules" means OAR 333-010-0400 through 333-010-0470.

(16) "Training program" means an organized educational program that includes at least a didactic phase, clinical phase, and usually an employment/utilization phase.

Stat. Auth.: 2011 OL Ch. 716
Stats. Implemented: 2011 OL Ch. 716
Hist.: PH 5-2013, f. & cert. ef. 2-4-13; PH 37-2016, f. & cert. ef. 12-12-16

333-010-0410: Minimum Standards

A dental pilot project shall:

(1) Provide for patient safety as follows:

(a) Provide treatment which does not expose a patient to risk of harm when equivalent or better treatment with less risk to the patient is available;

(b) Seek consultation whenever the welfare of a patient would be safeguarded or advanced by having recourse to those who have special skills, knowledge and experience;

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

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

(e) Not attempt to perform procedures which the trainee is not capable of performing due to physical or mental disability; and

(f) Comply with the infection control procedures in OAR 818-012-0040.

(2) Provide appropriately qualified instructors to prepare trainees;

(3) Assure that trainees have achieved a minimal level of competence before they enter the employment/utilization phase;

(4) Inform trainees in writing that there is no assurance of a future change in law or regulations to legalize their role;

(5) Demonstrate that the project has sufficient staff to monitor trainee performance and to monitor trainee supervision during the employment/utilization phase;

(6) Demonstrate the feasibility of achieving the project objectives;
333-010-0415: Dental Pilot Projects: Application Procedure

(1) A sponsor may submit an application for a dental pilot project on a form prescribed by the Authority.

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

(3) An application must include, but is not limited to the following information:

(a) Sponsors:

(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, or community hospital or clinic, coordinated care organization or dental care organization;

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

(D) The funding sources for the project; and

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

(b) Trainee information:

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

(B) The number of proposed trainees.

(c) Instructor/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
(E) The criteria used to select an employment/utilization site.

(d) Costs:
(A) The average cost of preparing a trainee, including but not limited to the cost information related to instruction, instructional materials and equipment, space for conducting didactic and clinical phases, and other pertinent costs;
(B) The predicted average cost per patient visit for the care rendered by a trainee; and
(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, 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.

Stat. Auth.: 2011 OL Ch. 716
Stats. Implemented: 2011 OL Ch. 716
Hist.: PH 5-2013, f. & cert. ef. 2-4-13; PH 37-2016, f. & cert. ef. 12-12-16

333-010-0420: Trainees

(1) A dental pilot project must have a plan to inform trainees of their responsibilities and limitations under Oregon Laws 2011, chapter 716 and these rules.

(2) A project must provide notice to program staff within 14 days of a trainee entering the employment/utilization phase. The notice shall include, but is not limited to the following:

(a) Name, work address and telephone number of the trainee; and
(b) Name, work address, telephone number and license number of the supervisor.

Stat. Auth.: 2011 OL Ch. 716
Stats. Implemented: 2011 OL Ch. 716
Hist.: PH 5-2013, f. & cert. ef. 2-4-13

333-010-0425: Instructor and Supervisor Information

A dental pilot project must have:

(1) Instructors:

(a) A number and distribution of instructors sufficient to meet project objectives; and
(b) Instructors with current knowledge and skill in topics they will teach.

(2) A plan to orient supervisors to their roles and responsibilities.

Stat. Auth.: 2011 OL Ch. 716
Stats. Implemented: 2011 OL Ch. 716
Hist.: PH 5-2013, f. & cert. ef. 2-4-13

**333-010-0430: Curriculum**

A sponsor of a dental pilot project must have a curriculum plan that includes but is not limited to a description of:

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

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

(3) The skills trainees are to learn;

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

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

(6) The hours and months of the time required to complete the didactic and clinical phases.

Stat. Auth.: 2011 OL Ch. 716
Stats. Implemented: 2011 OL Ch. 716
Hist.: PH 5-2013, f. & cert. ef. 2-4-13

**333-010-0435: Dental Pilot Projects: Evaluation and Monitoring**

(1) Evaluation Plan. A sponsor of a dental pilot project must have an evaluation plan approved by the Authority that includes, but is not limited to the following:

(a) A description of the baseline data and information collected about the availability or provision of oral health care delivery, or both, prior to utilization of the trainee;

(b) A description of baseline data and information to be collected about trainee performance, acceptance among patient and community, and cost effectiveness;

(c) A description of methodology to be used in collecting and analyzing the data about trainee performance, acceptance, and cost effectiveness;

(d) A provision for reviewing and modifying objectives and methodology at least annually; and

(e) Identification of an evaluator unaffiliated with the project and with no financial or commercial interest in the outcome of the project that will conduct the pilot project's evaluation.
(2) Monitoring Plan. A sponsor of a dental pilot project must have a monitoring plan approved by the Authority that ensures at least quarterly monitoring and describes how the sponsor will monitor and ensure:

(a) Patient safety;

(b) Trainee competency;

(c) Supervisor fulfillment of role and responsibilities; and

(d) Employment/utilization site compliance.

(3) Data. A sponsor’s evaluation and monitoring plans must describe:

(a) How data will be collected;

(b) How data will be monitored for completeness; and

(c) How data will be protected and secured.

(4) A sponsor must permit project staff or their designees to visit each employment/utilization site at least monthly during the first six month period and at least quarterly thereafter.

(5) A sponsor must provide a report of information requested by the program in a format and timeframe requested.

(6) A sponsor must report adverse events to the program the day they occur.

(7) A dental pilot project must re-submit its evaluation and monitoring plan by January 2, 2017 for review and approval by the Authority.

(a) If the Authority determines that an evaluation or monitoring plan does not comply with these rules the Authority must notify the sponsor of any deficiencies and provide a deadline for the sponsor to resubmit the plan.

(b) If a sponsor does not submit an evaluation or monitoring plan that complies with these rules, after being given an opportunity to correct the deficiencies, the sponsor may be subject to suspension or termination in accordance with OAR 333-010-0470.

(c) The Authority shall notify a sponsor of its approval of an evaluation or monitoring plan.

Stat. Auth.: 2011 OL Ch. 716
Stats. Implemented: 2011 OL Ch. 716
Hist.: PH 5-2013, f. & cert. ef. 2-4-13; PH 37-2016, f. & cert. ef. 12-12-16

333-010-0440: Informed Consent

(1) A sponsor must ensure that informed consent for treatment is obtained from each patient or a person legally authorized to consent to treatment on behalf of the patient.

(2) A sponsor must submit an informed consent form and any accompanying information to program staff for review. Informed consent must include but is not limited to the following:
(a) An explanation of the role and status of the trainee, including the ready availability of the trainee’s supervisor for consultation;

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

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

(3) Informed consent shall be provided in a language in which the patient is fluent.

(4) Dental pilot project staff or trainees must document informed consent in the patient record prior to providing care to the patient.

(5) Informed consent needs to be obtained specifically for those tasks, services, or functions to be provided by a pilot project trainee.

Stat. Auth.: 2011 OL Ch. 716
Stats. Implemented: 2011 OL Ch. 716
Hist.: PH 5-2013, f. & cert. ef. 2-4-13

333-010-0445: Application Review Process

(1) The program staff shall review an application to determine if it is complete within 45 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, the program shall notify the applicant of the information that is missing, and shall allow the applicant 15 days to submit the missing information.

(b) If an applicant does not submit the missing information within the timeframe specified in the notice 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 program may have individuals outside the program review applications but no individual who has contributed to or helped prepare an application will be permitted to do a review.

(4) Program staff may request additional information from an applicant during the review process.

(5) Once project staff have completed an application review a Notice of Intent to approve or deny an application will be provided to the applicant and the Notice and application will be posted for public comment for a period of 10 business days. The Notice will be sent to interested parties.

Stat. Auth.: 2011 OL Ch. 716
Stats. Implemented: 2011 OL Ch. 716
Hist.: PH 5-2013, f. & cert. ef. 2-4-13

333-010-0450: Project Approval

(1) Once the public comment period described in OAR 333-010-0445(5) has closed the director or his or
her designee shall grant or deny approval of a pilot project applicant within 30 calendar days of receiving the application from the program.

(2) If the director grants approval, he or she will specify the length of time the project can operate.

(3) The director’s decision shall be transmitted in writing to the applicant.

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

(5) The program staff shall notify the Oregon Board of Dentistry when a project is approved.

(6) The director or his or her designee may extend the length of time a project can operate at his or her discretion.

Stat. Auth.: 2011 OL Ch. 716
Stats. Implemented: 2011 OL Ch. 716
Hist.: PH 5-2013, f. & cert. ef. 2-4-13

333-010-0455: Program Responsibilities

(1) Project evaluation. Program staff shall evaluate approved projects and the evaluation shall include but is not limited to:

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

(b) Periodic, but at least annual, site visits to project offices, locations, or both, where trainees are being prepared or utilized.

(2) 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; and

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

(b) An interdisciplinary team composed of representatives of the dental boards, professional organizations, and other state regulatory bodies may be invited to participate in the site visit.

(c) Written notification of the date, purpose, and principal members of the site visit team shall be sent to the project director at least 14 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) A report of findings and an indication of pass or fail for site visits shall be prepared by program staff and provided to the project director in written format within 60 calendar days following a site visit.

Stat. Auth.: 2011 OL Ch. 716
Stats. Implemented: 2011 OL Ch. 716
Hist.: PH 5-2013, f. & cert. ef. 2-4-13

333-010-0460: Modifications

(1) Any modifications or additions to an approved project shall be submitted in writing to program staff. Modifications include, but are not limited to the following:

(a) Changes in the scope or nature of the project. Changes in the scope or nature of the project require program staff approval;
(b) Changes in selection criteria for trainees, supervisors, or employment/utilization sites; and
(c) Changes in project staff or instructors.

(2) Changes in project staff or instructors 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.

(3) All other modifications require program staff approval prior to implementation.

Stat. Auth.: 2011 OL Ch. 716
Stats. Implemented: 2011 OL Ch. 716
Hist.: PH 5-2013, f. & cert. ef. 2-4-13

333-010-0465: 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 role has been legalized.

(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 role has been legalized and the trainee has met necessary licensure requirements.

(3) The project must inform the Oregon Board of Dentistry that the project is completed and provide a list of trainee names associated with the project at least 14 calendar days prior to discontinuation.
333-010-0470: Suspension or Termination of Project

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

(2) If the Authority determines that a dental pilot project is in violation of 2011 Oregon Laws, chapter 716 or these rules, the Authority may issue a Notice of Proposed Suspension or Notice of Proposed Termination in accordance with ORS 183.411 through 183.470. A sponsor who receives a Notice may request an informal meeting with the director and program staff. A request for an informal meeting does not toll the time period for requesting a hearing as described in section (3) of this rule.

(3) 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 days to request a hearing.

(4) 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.
333-010-XXXX
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 oral health status of Oregonians is poor and the most vulnerable are those with the least access to services.

(2) These rules establish the requirements of Dental Pilot Project applications, the process for reviewing application, 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 November 1, 2018; and

(b) Dental pilot projects approved before or after the effective date of these rules.

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

333-010-XXXX
Dental Pilot Projects: Definitions

For purposes of OAR 333-010-XXXX through 333-010-XXXX, 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) "Clinical evaluator" means a dentist, licensed in 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.

(4) "Clinical phase" means instructor supervised experience with a patient during which a trainee applies knowledge presented by an instructor.

(5) “Complications” means

(6) "Didactic phase" means an organized body of knowledge presented by an instructor.

Commented [KSE1]: Each project should have a dentist conducting chart reviews to assess for quality. This could be in addition to the evaluator described here or they could be one in the same.

Commented [s2]: RAC define
(7) “Dental Project Manager” – means an individual who is actively responsible for oversight of the dental pilot project and who is a dentist licensed in the State of Oregon.

(8) "Director" means the Public Health Director within the Oregon Health Authority, or his or her designee.

(9) "Employment/Utilization Phase" means ongoing application of didactic and clinical knowledge and skills in an employment setting under the supervision of a supervisor.

(10) "Employment/Utilization Site" means an Authority approved project site. Each site may be comprised of multiple locations and includes any setting where dental health care services are provided by the trainees, and the facilities or programs described in ORS 680.205(1).

(11) "Instructor" means a person qualified to practice or teach the knowledge or skills a trainee is to learn.

(a) "Clinical instructor" is a person who is certified or licensed in the field for which clinical instruction is occurring.

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

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

(13) “Program evaluation” means

(14) "Program staff" means the staff of the Authority with responsibility for the program.

(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 evaluation” means

(17) "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 that:

(a) Submits a dental pilot project application; and

(b) If a dental pilot project is approved, has overall responsibility for ensuring the project complies with these rules.

(18) “Supervisor” means a person designated by the project sponsor who already possesses the skills to be taught the trainees and is certified or licensed in Oregon to practice dentistry.
(19) "These rules" means OAR 333-010-0400 through 333-010-XXXX.

(20) “Trainee” means an individual who is part of an existing category of dental personnel; a new category of dental personnel or a previously untrained dental personnel who has agreed to participate in an approved dental pilot project and will be taught the scope of practice as part of an approved dental pilot project.

(21) "Training program" means an organized educational program within a dental pilot project that includes at least a didactic phase, a clinical phase, and usually an employment/utilization phase.

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

333-010-XXXX
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:

(a) Has determined that there is already a sufficient number of projects to provide a basis for testing the validity of the model as determined by the Authority.

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

(5) 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) Sponsors.
(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;

(C) A description of the functions of the project director, dental project manager, 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 hours and months of the 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) A copy of the contract that trainees will be required to enter into with the sponsor should the project be approved;

(D) The proposed scope of practice for trainees;

(E) Draft policies and procedures for ensuring compliance with OAR 333-010-XXXX(*);

and

(F) Draft policies and procedures for conducting background checks on participating trainees.

(f) Documentation that the project has sufficient staff to monitor trainee performance and to monitor trainee supervision during the employment/utilization phase.

(g) The location or locations where patient care will be provided and the criteria used to select these locations.

(h) A description of how the project will provide care to populations that evidence-based studies show have the highest disease rates and the least access to dental care.

(i) Costs:

(A) The average cost of preparing a trainee, including but not limited to the cost information 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 subsequent to the project, and the cost for provision of this care by current providers thereof.

(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, 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.

(j) An explanation of the feasibility of achieving the project objectives.

(k) A preliminary evaluation plan

[1] An identified clinical evaluator, unaffiliated with the project and with no financial or commercial interest in the outcome of the project 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-XXXX
Dental Pilot Projects: Application Review Process

(1) The program staff shall review an application to determine if it is complete within 60 business 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, the program shall notify the applicant of the information that is missing, and shall allow the applicant 30 days to submit the missing information.

(b) If an applicant does not submit the missing information within the timeframe specified in the notice 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 program may have individuals outside the program review applications but no individual who has contributed to or helped prepare an application will be permitted to do a review.

(4) Program staff may request additional information from an applicant during the review process.

(5) Once project staff complete an application review a Notice of Intent to provisionally approve or deny an application will be provided to the applicant and the Notice and application will be posted for public comment for a period of 10 business days. The Notice will be sent to interested parties.

Statutory/Other Authority: 2011 OL Ch. 716
Statutes/Other Implemented: 2011 OL Ch. 716
333-010-XXXX
Dental Pilot Projects: Project Application Provisional Approval or Denial

(1) Following the close of the public comment period described in OAR 333-010-XXXX(5) the director or his or her designee shall review the public comments that were received and issue, within 30 business days of the close of the public comment period:

(a) A provisional decision to grant 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-XXXX before it can receive final approval.

(3) If the director 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 program 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 director denied the application.

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

333-010-XXXX
Dental Pilot Projects: Provisional Approval; Final Approval

(1) A project sponsor that has been provisionally approved, must, within 3 months of provisional project approval, submit the following to the Program for approval:

(a) A detailed evaluation and monitoring plan that meets the requirements in OAR 333-010-XXXX.

(b) The project must have and follow policies and procedures for:

   (i) Data collection and storage;

   (ii) Protection and security of patient data;
(iii) Obtaining patient informed consent.

(iv) The provision of emergency treatment for patients and provide or arrange for emergency treatment for a patient currently receiving treatment as necessary;

(d) Have and follow written standard operating policies and procedures for specific use by the approved pilot project. Standard operating policies and procedures shall consist of the following:

(2) The Program 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 program 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 program 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 must include:

(a) The permitted scope of the project;

(b) Any conditions the director deems are necessary; and

(c) The length of time the project can operate, from between three to five years.

(6) The program staff shall notify the Oregon Board of Dentistry when a project is approved.

333-010-XXXX
Dental Pilot Projects: Minimum Standards

An approved dental pilot project shall:

(1) Provide for patient safety as follows:

(a) Ensure that every patient is provided information and gives informed consent prior to treatment in accordance with OAR 333-010-XXXX.

(b) Provide treatment that does not expose a patient to risk of harm when equivalent or better treatment with less risk to the patient is available;

(e) Comply with ORS 453.605 to 453.755 and OAR 333, Divisions XX to XX relating to the use of x-ray machines;

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

(g) Comply with the infection control procedures in OAR 818-012-0040, and
[h] Comply with [listed applicable sections of the Oregon Dental Practice Act].

(2) Have appropriately qualified instructors to prepare trainees.

(a) A project must have a number and distribution of qualified instructors sufficient to meet project objectives, who have been approved by the Authority; and

(b) Instructors must be currently licensed in dentistry, dental hygiene or another appropriate health discipline and have current knowledge and skill in topics they will teach.

(3) Provide instruction to trainees following the curriculum plan approved by the Authority.

(4) 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 program staff within 14 days of a trainee entering the employment/utilization phase. The notice shall include, but is not limited to the following:

(a) Name, work address, email and telephone number of the trainee; and

(b) Name, work address, email, telephone number and license number of the supervisor.

(5) Provide the following to trainees in writing prior to starting the project:

(a) Information regarding the trainee’s responsibilities and limitations under Oregon Laws 2011, chapter 716 and these rules.

(b) 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.

(6) A description of the process used to orientate supervisors to their roles and responsibilities.

(a) Training materials must be provided to the Authority upon request.

(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-XXXX.

(9) Report serious adverse events to the Authority the day they occur.

(10) Submit detailed quarterly monitoring data in a format requested by Program staff.
333-010-XXXX
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, is provided written information about the dental pilot project and who will be providing treatment, gives consent to be treated by the dental pilot project, and gives informed consent for treatment.

(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, including 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;
   (c) Identification that consenting to treatment by a trainee does not constitute assumption of risk by the patient.
   (d) A description of the trainee’s level of training and experience, whether the trainee is licensed or unlicensed, who is supervising the trainee, and the trainee’s approved scope of practice.

(3) 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 read and understand the above information concerning the treatment I can receive from this dental pilot project 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 each procedure or treatment. Informed consent means:

   (A) Explaining, in a language the patient understands, in general terms the procedure or treatment to be undertaken; that there may be alternative procedures or methods of treatment, if applicable; and the risks to the procedure or treatment, if applicable.”
(B) After the explanation in subsection (A) of this section, asking the patient if the patient wants a more detailed explanation. If the patient requests further explanation, such an explanation must be provided, including in substantial detail the procedure, the viable alternatives and the material risks unless to do so would be materially detrimental to the patient. In determining that further explanation would be materially detrimental the dental project manager shall give due consideration to the standards of practice of reasonable dental practitioners in the same or a similar community under the same or similar circumstances.

(b) Informed consent for treatment must be obtained in writing and such consent must be included and documented in the patient’s record.

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

333-010-XXXX
Dental Pilot Projects: Pilot Project Evaluation and Monitoring by Sponsor

(1) Pilot project sponsors must submit a detailed Evaluation and Monitoring Plan to the Authority in accordance with OAR 333-010-XXXX.

(2) A Project Evaluation and Monitoring Plan must include but is not limited to:

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

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

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

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

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

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

(G) A process for review of the evaluation plan for continuous quality improvement purposes.

(H) The evaluation plan must include an ongoing quarterly monitoring component that ensures at a minimum:
(i) Patient safety; The provisions for protecting the safety of patients seen or treated in the project;

(ii) Trainee competency;

(iii) Supervisor fulfillment of role and responsibilities;

(iv) Employment/utilization site compliance; and

333-010-XXXX
Dental Pilot Projects: Pilot Project Monitoring and Evaluation by Program

(1) Program staff shall monitor and evaluate approved pilot projects to determine the project's compliance with these rules and to check on the progress of the project. Monitoring and evaluation may include but is not limited to:

(a) Requesting written information or documents from the project;

(b) Interviews with the project sponsor, instructors, supervisors, other staff or trainees; and

(d) Quarterly submitted data as described in [Minimum Standards].

(2) Program staff shall conduct site visits, at least once a year, to project offices, locations, or both, where trainees are being prepared or utilized.

(a) An interdisciplinary team composed of representatives of the dental boards, professional organizations, and other state regulatory bodies may be invited to participate in site visits.

(b) 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; and

   (C) Reviews of patient records to evaluate patient safety and trainee competency and quality.

(b) The program will, unless there are concerns about patient or trainee safety, provide at least 14 business days notice to the sponsor prior to a site visit.

(c) Following a site visit the program will:

(a) Within 60 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.
(b) Within 180 days of receipt of a plan of correction, issue a final report to the sponsor.

(c) If there are no corrections needed, the program will issue a final report within 180 days.

(4) Failure of a sponsor or anyone involved with an approved pilot project to cooperate with a request for records, interviews or a site visit is grounds for the program 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 program or within the timeframe requested by the program.

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

333-010-XXXX
Dental Pilot Projects: Project Modifications

(1) An approved dental pilot project may make minor modifications to the project with written approval of the program. Proposed minor modifications must be submitted to the program in writing for approval or disapproval, except as described in section (3) of this rule.

(2) Minor modifications include but are not limited to:

(a) Changes in selection criteria for trainees or supervisors

(b) Changes in employment/utilization sites; removing sites or adding sites within the approved scope or nature of the project.

(c) Changes in project staff or instructors.

(3) Changes in project staff or instructors 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.

(4) Any modification to an approved pilot project that is not a minor modification is not permitted though the project sponsor could submit a new application.

Statutory/Other Authority: 2011 OL Ch. 716
Statutes/Other Implemented: 2011 OL Ch. 716
333-010-XXXX
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 business 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 role has been legalized.

(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 role has been legalized and the trainee has met necessary licensure requirements.

(3) Project completion.

(a) A project sponsor must:

(A) Provide a full report of findings to the Authority within 180 days of the completion of the project.

(B) Inform the Oregon Board of Dentistry that the project is completed and provide a list of trainee names associated with the project at least 14 business days prior to discontinuation.

(4) Program staff shall conduct an independent evaluation of the project upon its completion and prepare a final report that may include but is not limited to:

(a) The new dental skills taught or extent that existing skills have been reallocated.

(b) Implication of the project for existing licensure laws with suggestions for changes in the law where appropriate.

(c) Implications of the project for dental services curricula and for the health care delivery systems.

(d) Teaching methods used in the project.

(e) The quality of care and patient acceptance in the project.
(f) The extent that persons with the new skills could find employment in the dental health care system, assuming laws were changed to incorporate their skill.

(g) The cost of care provided in the project, the likely cost of this care if performed by the trainees subsequent to the project, and the cost for provision of this care by current dental providers thereof.

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

333-010-XXXX
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) 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) Work with the project to bring the project into compliance; or

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

(3) A sponsor who receives a Notice may request an informal meeting with the director and program staff. A request for an informal meeting does not toll the time period for requesting a hearing as described in section (4) of this rule.

(4) 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 days to request a hearing.

(5) 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