



AGENDA

Dental Pilot Project #100 "Oregon Tribes Dental Health Aide Therapist Pilot Project"
Quarterly Dental Pilot Project Program Advisory Committee Meeting DPP #100
April 23, 2018, 10:00am – 12:00pm

Location: Portland State Office Building, 800 NE Oregon Street, Room 1D, Portland Conference Line: Dial-In Number: 1-888-273-3658 Participant Code: 76 64 09		
10:00-10:05	Official Introductions, Agenda Review	Bruce Austin DMD Sarah Kowalski RDH, MS
10:05-11:00	Site Visit Conclusions; Initial Report of Findings Overview of Stipulated Agreement; Summarized data; Site Visit Next Steps	Bruce Austin, DMD Kelly Hansen
11:00-11:40	Update Project Modification Request; OHA approval and denial; Extraction Criteria	Bruce Austin DMD Sarah Kowalski RDH, MS
11:40-11:45	Oregon Administrative Rules; Rules Advisory Committee Process	Sarah Kowalski RDH, MS Amy Umphlett, MPH
11:45-11:50	Follow Up Items, Future Meeting Dates, Closing	Sarah Kowalski RDH, MS
11:50-12:00	Public Comment Period	Public comments are limited to 2 minutes per individual

Future Meetings:

Monday, June 18, 2018, Portland State Office Building 800 NE Oregon Street Portland, Oregon, Room 1E, 9:00am – 4:00pm

Monday, September 10, 2018, Portland State Office Building 800 NE Oregon Street Portland, Oregon, Room 1D, 10:00am – 12:00pm

Monday, December 3, 2018, Portland State Office Building 800 NE Oregon Street Portland, Oregon, Room 1E, 10:00am – 12:00pm

Site Visit: Tuesday, May 22, 2018, CTCLUSI Dental Clinic, Coos Bay, Oregon



Quarterly Dental Pilot Project Meeting: DPP 100 Meeting Minutes

Date: Monday, April 23, 2018
Time: 10:00 AM – 12:00 PM
Location: OHA Public Health Division
800 NE Oregon Street
Portland, OR 97232
Conference Room 1A – First Floor

Committee Members Present:

Len Barozzini, Paula Hendrix, Connor McNulty, Carolyn Muckerheide

Committee Members Present Phone:

Jennifer Clemens, Kyle Johnstone, Jill Jones, Richie Kohli, Linda Mann, Karen Shimada, Gita Yitta

Committee Members Absent:

Leon Asseal, Kelli Swanson Jaecks, Brandon Schwindt, Kenneth Wright

OHA Staff:

Bruce Austin, Danna Drum, Kelly Hansen, Sarah Kowalski, Jonathan Modie, Amy Umphlett, Cate Wilcox

Public Attendees:

Azma Ahmed, Sam Barber, Todd Beck, Kyle Isaacs, Pam Johnson, Paul Kleinstub, Christina Peters, Joe Finkbonner, Teresa Haynes, Jennifer Lewis-Goff, Allyson Lecatsas

Official Introductions, Agenda Review: Bruce Austin

Site Visit Conclusion- Bruce Austin

OHA conducted first site visit to NARA Dental Clinic in Portland, Oregon on February 26, 2018.

Discussion: Project failed, discussion of findings, review of stipulated agreement contents. Concerns regarding information contained in the preliminary site visit report being distributed. Information that is distributed to the Advisory Committee is public record; not a confidential report of findings. Project stated that they would like to have an opportunity to respond to findings first. Project has prepared a response, it was not received until after COB on Friday evening, OHA staff have not had an opportunity to read the response. It will be disseminated to the committee.

SITE VISIT FINDINGS: NITROUS OXIDE

FINDINGS: DHAT trainees at the pilot sites provided services to patients who were under the use of nitrous oxide. Nitrous oxide was administered by the supervising dentist under direct supervision.

- Project was notified if it is the intention of the project trainees to utilize nitrous oxide or work on patients under nitrous oxide, then the project must apply for a modification to their application.
- Project did not wish to modify their application around nitrous.
- DHAT trainees worked on patients under nitrous oxide, outside of the approved scope of practice in the approved pilot project's application.
- Dentists at both pilot sites indicated they were unaware of directives issued by OHA to the project sponsors.

Nitrous Oxide concerns: last word we got that therapist would not treat patients receiving nitrous oxide even if by a licensed dentist. It happened in a few cases as discovered at site visit.

Next steps: OHA ANAD NPAIHB signed Stipulated Agreement.

Not treating patients receiving nitrous oxide. Asking NPAIHB to develop standard operating procedures to be presented in training sessions by Aug. 1. Moved up site visit to Coos Bay for May 22. Site visit at NARA in late August. May need to determine a new date.

Discussion: Questions on why allowing nitrous oxide to be included as part of DHAT approved scope of practice. NPAIHB is reviewing incorporating nitrous oxide into the pilot sites.

SITE VISIT FINDINGS: EXTRACTIONS

FINDINGS: Review of the chart records indicate that on three separate occasions the trainee completed extractions or attempted to complete extractions, which are outside of the trainees approved scope of practice

1. Approved application requires extractions are completed only if a medical emergency.
 - None of the extractions met the criteria of a medical emergency
2. If a medical emergency, trainees are authorized to complete uncomplicated extractions.
3. Two extractions became surgical in nature and should not have been authorized for extraction by the DHAT trainee

Discussion: Regardless of criteria suitable for removal, this was only to be done in a medical emergency. These were planned appointments sometimes and some patients said they had 0/10 on pain scale. Not a dental or a medical emergency.

Two extractions became surgical and needed intervention from supervising dentist. Completed successfully. Each of the cases the preceptorship form indicated it was acceptable.

Under the Stipulated Agreement, NPAIHB agreed to criteria for extractions, List of criteria for acceptable extractions by dental therapists:

1. All extractions must be under indirect supervision.
2. Trainee must first receive authorization from their supervising dentist for both primary and permanent extractions.

3. Primary teeth must exhibit some degree of mobility. Trainee will not extract teeth that are unerupted, impacted, fractured or decayed to the gum line or need to be sectioned for removal.
4. For permanent teeth, the trainee may perform non-surgical extractions of periodontally diseased teeth with evidence of bone loss and +2 degree of mobility. The trainee will not extract a tooth if it is unerupted, impacted, fractured or decayed to the gum line, or needs to be sectioned for removal.
5. Document all information related to extractions as specified above along with the criteria required for the project evaluation which include a recent radiograph of the tooth to be extracted, a pre-operative intra-oral image of the tooth to be extracted, and a post-operative image of the extracted tooth

Standard operation procedures to be shared with OHA staff by Aug. 1.

Discussion: Questions on suturing. Unclear on sutring training. Trainee stated he is not able to suture. NPAIHB previously clarified that students are taught this. Trained to use if needed or are they not trained? NPAIHB responded that in the dental therapy education program, they did not account for what the trainees are leaning today vs. six years ago. A lot of changes in those six years since Ben, DHAT trainee, went through the program. It is our intention for Ben to have additional education as those who go through the program today. A gap analysis will be done around the pieces not learned. Suturing is is the current curriculum.

Suggested change from about changing verbiage to 'direct or indirect supervision' on #1.

Question around suture training was discussed at a previous meeting. NPAIHB pointed questions back to that previous explanation.

SITE VISIT FINDINGS: INFORMED CONSENT

FINDINGS: Project failed to obtain written informed consent for services by the trainee on the date of service

- On 4 occasions, informed consent was obtained after the date of service
- On 2 occasions, informed consent there was no patients name on the form
- On 1 occasion, informed consent was absent entirely.
- Consent was missing for treatment of three minors.
- In all, 26% of the charts were missing informed consent for treatment by the DHAT.
- Written consent for oral surgery is missing entirely for one chart.

One chart number included that hadn't been seen. Overall lack of accuracy in submission.

Detailed data report. After review, 61 procedures hadn't been identified on detailed data report. This was cause for concern; OHA wonder how many procedures how many were done that weren't documented.

Code D7210- surgical extraction- recording error/ billing error. Some inconsistencies in charts.

Comments: Dr. Muckerheide stated that as pediatric dentist she noticed there was lack of patient weight when dosing analgesics. Not able to say with certainty patient safety wasn't compromised when reviewing chart records. Dr. Austin stated that a weight must be recorded in the chart before drugs are administered.

Questions/ Discussion

Discussion: NPAIHB failed to meet with advisory committee and members didn't know they were on the advisory committee. Need to have meetings quarterly. They haven't come together as a group, but consult as needed. OHA requires that the NPAIHB conducts regularly meetings; NPAIHB indicated there will be a in-person meeting.

NPAIHB responded to each finding in the preliminary site visit report. There were questions on some findings/questions before responding to clarifications. NPAIHB submitted a letter in response to the report. OHA has not had an opportunity to read the response.

Question: How were 23 charts selected? A random sample.

Question: Will advisory committee get stipulated agreement? Answer: The materials sent out include more details than the Stipulated Agreement. I don't know that we will distribute the legal document with signatures on it. NPAIHB agreed to the Stipulated Agreement.

Question: Does a stipulated agreement make these actions observed stop now? Answer: That stopped the day OHA spoke with NPAIHB. Answer: NPAIHB - We don't know when new parameters are in place so we stopped all extractions now to be safe. We weren't sure if modification needed to be approved before moving forward.

MODIFICATIONS

CDT CODE D4341: Periodontal scaling and root planning – four or more teeth per quadrant. NPAIHB submitted an update to the CDT code list. There was confusion about whether there was a request for modification of CDT codes around including SRP for scope of practice. NPAIHB clarified that DHAT trainee in the pilot project will not be doing SRP. Further conversation needed. At June 2017 meeting- code was not on the list of codes that were referenced later. Why is the code there? Confusion around code. Will clarify later.

Experienced DHAT Modification: NPAIHB has requested to remove the requirement to bring an experienced DHAT from AK. Request to waive this requirement. Difficult to get someone down. Compromise to bring DHAT down for a period of time to help with orientation of new graduates.

NPAIHB: This has presented a big challenge. NPAIHB is wondering if Ben could fill this role. A further discussion must be had about a potential compromise on this issue.

OHA: Dr. Austin asked if there was any feedback on this point. There were no comments from committee members.

Coquille: NPAIHB indicated that there are challenges at the Coquille pilot site. There are 2 students completing training in Alaska. One of the students will stay in Alaska. They are trying to determine other options for the second student. A possible solution is that she can be an EFDA (dental assistant).

Question: Are there no dentists or clinic at Coquille? Answer: No, they are a particularly deliberative government for the tribe and have not built a clinic.

Question: What are the alternatives to dental clinic in Coquille? Answer: They have a medical clinic. A medical clinic could add dental at some point, discussion around preceptorship to provide chair in medical clinic.

MOUs: Questions about why the MOUs between NPAIHB and the pilot sites were only extended to June 30, 2018. NPAIHB stated that they are operating under a temporary extension while the main funder approves their newly submitted grant application. NPAIHB is unable to provide funding they don't have secured yet. Once they have word about new funding, they will be ready to go with new MOU.

NPAIHB: The project will not be sending anyone for the class of 2020.

OAR/RAC: OARs for DPP will be opening. Process starting soon. Details to be determined on dates and ability to participate. Will be accepting applications for the RAC. Announcement made next week.

Upcoming meetings discussion.

Comments/Discussion/Questions from Advisory Committee:

Question: From the March 22nd letter, last paragraph speaks about extraction of primary teeth. What does consult mean when working under general supervision? Or do they not already consult? Answer: Clarified this question. NPAIHB will follow language under Stipulated Agreement.

Question: There are concerns about getting good quality data to show how this worked. Can you speak to how this will be handled? Answer: The project needs to demonstrate and show why the proposal was ultimately successful or not.

Question/Statement: There are concerns around the the chart pull and data process. Answer: NPAIHB is returning quarterly aggregate data on measurable outcomes. At that point previously, NPAIHB was told it met OARs. Baseline and quarter 3, 4 reports. NPAIHB stated that they are required to do data pulls per procedure.

Question: Where was the communication breakdown around how did the rules breakdown occur with rules being ignored? Answer: NPAIHB stated that extractions that were scheduled were designed to be simple. The supervising dentist is comfortable with him practicing at top of his scope, if there was a complication, he did what he was supposed to do. NPAIHB stated that during the time in preceptorship, if you never push them to to the top of their skill set, they won't know their level of care. The supervising dentist needed to know what his skills are and it was an important time for them to learn how to work together to provide best care.

Question/Statement: Preceptorship discussion around practice plan. Practice plans are in place after preceptorship. The preceptorship demonstrate you can do these things and then the supervising dentist is comfortable with the DHAT working under general supervision.

Question/Statement: The description and language sounds like the preceptorship is fluid and makes it hard to do chart reviews. Answer: Post preceptorship the language becomes more concrete and it stated in their practice plan.

Question/Statement: Is it confusing to trainees to teach skillset that they wont be able to practice? Answer: NPAIHB stated it is within the DHAT scope to extract.

Meeting adjourned

Public Comments: Kyle Isaacs, Oregon Dental Hygiene Association stated that the ODHA has concerns with the proposed modifcaiton to allow DHAT trainees to do scaling and root planing. The NPAIHB clarified that DHAT trainees do not do SRP. ODHA is nuetral on the project concept.



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DATE: April 9, 2018

TO: Joe Finkbonner
Northwest Portland Area Indian Health Board

FROM: Bruce Austin, Statewide Dental Director
Oregon Health Authority

RE: Status of February 26, 2018 Site Visit
Findings & Further Clarification Needed on Dental Pilot Project #100

SITE VISIT

On February 26, 2018, the Oregon Health Authority (OHA) conducted the second required site visit for Dental Pilot Project #100, "Oregon Tribes Dental Health Aide Therapist Pilot Project."

The OHA Dental Pilot Projects Program is responsible for monitoring approved pilot projects. The primary role of the Oregon Health Authority is monitoring for patient safety. Secondly, program staff shall evaluate approved projects and the evaluation shall include, but is not limited to, reviewing progress reports and conducting site visits. OHA is responsible for ascertaining the progress of the project in meeting its stated objectives and in complying with program statutes and regulations.

Per Oregon Administrative Rule (OAR) 333-010-0455, a report of findings and an indication of pass or fail for site visits shall be provided to the project director in written format within 60 calendar days following a site visit. The Oregon Health Authority has determined that Dental Pilot Project #100 is in non-compliance with the requirements set forth in OARs 333-010-0400 through 333-010-0470, and therefore has **failed** the site visit.

As outlined in OARs 333-010-0400 – 333-010-0470, dental pilot projects are required to operate according to their approved applications and modifications. Projects that operate outside of the approved provisions in their application or modifications are in violation of the OARs. A pilot project may be suspended or terminated during the term of approval for violation of 2011 Oregon Laws, chapter 716 or any of the OARs 333-010-0400 through 333-010-0470.

STIPULATED AGREEMENT

On April 3, 2018, the Northwest Portland Area Indian Health Board (NPAIHB) entered into a signed Stipulated Agreement which states that the NPAIHB and OHA agree that OHA has

adequate grounds to issue a Notice of Proposed Suspension to NPAIHB. In lieu of OHA issuing a Notice of Suspension to the project, NPAIHB agreed to the terms outlined in the agreement. NPAIHB agrees that if they violate the terms of the agreement, OHA may suspend its approval of the project until such time as it can come into compliance with its approved plan and OARs 333-010-0400 to 333-010-0470.

SITE VISIT FINDINGS & ITEMS NEEDING FURTHER CLARIFICATION

As part of the site visit, there are several items that need to be addressed or require further clarification from NPAIHB:

- 1. Failure to Follow OHA Directives:** On November 27, 2017, OHA issued a notice to NPAIHB requiring the project to cease providing planned extractions by dental health aide therapist (DHAT) trainees since it is outside of the scope of practice requirements as outlined in the approved application. NPAIHB failed to inform the project sites of the directives issued by OHA. DHAT trainees at the pilot project sites continued to perform planned extractions outside of the requirements that they be a medical emergency. Medical emergencies are defined under ORS 682.025 and OAR 141-120-0000.

Corrective Action: On February 28, 2018, OHA informed both the NPAIHB and clinic sites verbally of the concerns discovered in the oral interviews with the Native American Rehabilitation Association (NARA) clinicians. A commitment to cease procedures that are not allowed under the approved application was obtained from both the NPAIHB and pilot sites. On April 3, 2018, NPAIHB entered into a signed Stipulated Agreement agreeing that in lieu of OHA issuing a Notice of Suspension to the project, the NPAIHB will agree to follow clinical parameter criteria for extractions outlined in the agreement.

- 2. Nitrous Oxide:** DHAT trainees at the pilot sites provided services to patients who were under the use of nitrous oxide. Nitrous oxide was administered by the supervising dentist under direct supervision.

In an addendum to their approved application, NPAIHB states “The DHATs are not trained to use it; they will not be using Nitrous Oxide.” At subsequent Advisory Committee meetings, the NPAIHB was questioned as to the methodology and logic of excluding DHAT trainees from receiving training on nitrous oxide when it is used at each pilot site.

On October 31, 2017, the NPAIHB stated that “Nitrous is used at both NARA and CTCLUSI, but for the purposes of this pilot, we have decided at this point not to modify our application to include additional training in Oregon on Nitrous Oxide for DHATs. DHATs are able to provide treatment to a patient that is placed under Nitrous Oxide or other analgesics.”

On November 21, 2017, OHA informed the NPAIHB in writing of the following requirements:

- I. If DHAT trainees are providing treatment to patients under “nitrous oxide or other analgesics,” then OHA requires that the trainees participating in the approved pilot project follow the Oregon Board of Dentistry administrative rules for

Anesthesia OARs 818-026-0000 through 818-026-0120.

- II. The project must provide clarification on the intention of using nitrous oxide by DHATs in the pilot project, as well as the training received and competency if operating as an Anesthesia Monitor, etc.
- III. If it is the intention of the project trainees to utilize nitrous oxide or work on patients under nitrous oxide, then the project must apply for a modification to their application.

A copy of the administrative rules for nitrous oxide OARs 818-026-0000 through 818-026-0130 was supplied to the NPAIHB.

On November 30, 2017, OHA received a memo from NPAIHB stating: "After further review of the Oregon Dental Practices Act, we agree that our DHATs are not, and will not be authorized to administer Nitrous Oxide, or work on patients that have received Nitrous Oxide from someone who has a valid Nitrous Oxide permit."

NPAIHB failed to inform the project sites of the directives issued by OHA. The DHAT trainees at both pilot sites provided services to patients who were under the use of nitrous oxide.

Corrective Action: On February 28, 2018, OHA informed both the NPAIHB and clinic sites verbally of the concerns discovered in the oral interviews with the NARA clinicians. A commitment to cease procedures that are not allowed under the approved application was obtained from both the NPAIHB and the pilot site. On April 3, 2018, NPAIHB entered into a signed Stipulated Agreement agreeing that in lieu of OHA issuing a Notice of Suspension to the project, the NPAIHB will prohibit DHAT trainees from treating patients who are receiving nitrous oxide.

Required Next Steps: NPAIHB will develop written standing operating procedures (SOPs) and reference resources for use by each pilot project site. OHA will require the project to conduct training sessions at each pilot project site for compliance with required SOP and associated materials. Training sessions must be completed at each pilot site by August 1, 2018. Dates and attendees of the training sessions must be supplied to OHA.

- 3. Practicing Outside the Scope of Approved Practice:** Review of the chart records indicate that on three separate occasions the trainee completed extractions or attempted to complete extractions, which are outside of the trainees approved scope of practice as outlined in the Community Health Aide Programs Board (CHAP) Standards and approved application:

As stated in the approved application under CHAP Standard 2.30.610, in addition to the requirement that extractions must be completed by DHAT trainees in the event of a medical emergency, DHAT trainees are authorized to complete uncomplicated extractions with prior evaluation of the x-ray and consultation when appropriate for proximity to the mandibular canal; proximity to the maxillary sinus, root fractures or dilacerations; multiple roots; a well-defined periodontal ligament space; and enough

clinical crown to luxate the tooth.

Project trainees are only authorized to complete simple uncomplicated extractions. In two of these instances, the procedure became surgical in nature in order to complete the procedure.

- A. In the first instance, the trainee attempted to extract tooth #20 with no clinical crown above the gingival level. Radiographs demonstrate that the tooth had no clinical crown. Chart notes state that the trainee was unable to extract the tooth and required intervention by the supervising dentist. The dentist was required to cut a flap in order to extract the tooth.
- B. In the second instance, the trainee extracted teeth #15 and #16. Chart notes state that after the teeth were extracted by the DHAT trainee, buccal bone was attached to the extracted teeth. The supervising dentist was required to take over the procedure and used a bone file to reshape the bone in the extraction site and suture the area.
- C. In the third instance, the trainee extracted teeth #18 and #19. Tooth #18 had no clinical crown. The two remaining roots of #18 were embedded in the soft tissue. Both radiographs and intra-oral images demonstrate that the tooth had no clinical crown. Chart notes state that the trainee was successfully able to extract the teeth.

OHA is concerned that the DHAT trainee was authorized to complete procedures that fell outside of their scope of practice according to the approved project application. DHAT trainees do not have the scope of practice to cut soft tissue or resolve extractions that become surgical in nature. The NPAIHB has stated on several occasions that the DHAT trainees are taught the limitations of their scope of practice and are aware of those limitations. Of particular concern is that the DHAT trainee at the NARA site has been practicing for over 8 years.

There is considerable concern that the project's intention is to have the DHAT trainee complete extraction procedures under general supervision. Had the DHAT trainee been authorized to complete these procedures under general supervision, with no dentist on-site, the DHAT trainee would have lacked the necessary skills to complete the procedure. This would have resulted in undo pain for the patient and would have necessitated a referral to a dentist to complete the procedure.

Corrective Action: On April 2, 2018, NPAIHB entered into a signed Stipulated Agreement agreeing that in lieu of OHA issuing a Notice of Suspension to the project, the NPAIHB must only allow a DHAT trainee to perform extractions under the following conditions:

1. All extractions must be performed under the indirect supervision of the DHAT trainee's supervising dentist. Indirect supervision is defined under ORS 679.010 as supervision requiring that a dentist authorize the procedures and that a dentist be on the premises while the procedures are performed.

2. For primary and permanent tooth extractions, the DHAT trainee will first receive and document authorization from the supervising dentist.
3. For primary teeth, the trainee may perform non-surgical extractions on teeth that exhibit some degree of mobility. The trainee will not extract a tooth if it is unerupted, impacted, fractured or decayed to the gum line, or needs to be sectioned for removal.
4. For permanent teeth, the trainee may perform non-surgical extractions of periodontally diseased teeth with evidence of bone loss and +2 degree of mobility. The trainee will not extract a tooth if it is unerupted, impacted, fractured or decayed to the gum line, or needs to be sectioned for removal.
5. Document all information related to extractions as specified above along with the criteria required for the project evaluation which include a recent radiograph of the tooth to be extracted, a pre-operative intra-oral image of the tooth to be extracted, and a post-operative image of the extracted tooth.

Required Next Steps: The project is required to clarify the scope of practice concerns around intra-oral suturing. The DHAT trainee indicated in their interview during the site visit that they are specifically taught that intra-oral suturing is outside of their scope of authorized practice. This was confirmed in statements by the supervising dentist. Each stated that DHAT's are not taught suturing in the training program and are prohibited from suturing. This is of concern as NPAIHB contradicts the statements of both the trainee and supervising dentist. NPAIHB provided information to OHA stating that DHAT's are in fact authorized to perform suturing and are taught this as part of their training. Clarification as to the contradicting statements is required.

NPAIHB will develop written standing operating procedures (SOPs) and reference resources for use by each pilot project site. OHA will require the project to conduct training sessions at each pilot project site for compliance with required SOP and associated materials. Training sessions must be completed at each pilot site by August 1, 2018. Dates and attendees of the training sessions must be supplied to OHA.

4. **Informed Consent:** The project failed to obtain written informed consent for services by the trainee on the date of service, as required in OAR 333-010-0440 and OAR 123-456-7890, on multiple occasions in charts provided for review – including treatment of 3 minors. On four occasions, the signed consent to be treated by a trainee was obtained after the initial date of service. On two occasions, the printed patient name is not listed on the signed informed consent form. On one occasion, informed consent to be treated by the trainee was absent entirely. Overall, only 74% of the 23 charts reviewed in the randomized sample had a signed form consenting to treatment by the DHAT trainee on the initial date of service.

Additionally, an approved oral surgery consent form is required for all extractions. Of the 9 charts reviewed for which an oral surgery consent form is required, only 1 chart had a signed oral surgery consent form that matches the form approved for the pilot project. For the remaining charts, 7 charts included a different oral surgery consent form. Written consent for oral surgery is missing entirely for one chart.

Corrective Action: On April 3, 2018, NPAIHB entered into a signed Stipulated Agreement agreeing that in lieu of OHA issuing a Notice of Suspension to the project, the NPAIHB must ensure that all required consent forms are completed and placed in charts prior to services being performed.

Required Next Steps: NPAIHB will develop written standing operating procedures (SOPs) and reference resources for use by each pilot project site. OHA will require the project to conduct training sessions at each pilot project site for compliance with required SOP and associated materials. Training sessions must be completed at each pilot site by August 1, 2018. Dates and attendees of the training sessions must be supplied to OHA.

- 5. Non-Adherence to Approved Evaluation & Monitoring Plan:** Based on review of the 23 submitted charts, the project is not in compliance with Appendix C intra-oral image and radiographic collection requirements of the approved Evaluation and Monitoring Plan.

In the 23 charts submitted, there were 42 unique procedures identified that required a pre- and post-operative intraoral image. Of these, 12 procedures (29%) were missing a pre-operative and/or post-operative intraoral image. Additionally, restoration procedures require an intraoral image of the tooth prep, which was missing in 5 of the 31 identified procedures requiring a prep image. Adequate patient safety and procedure quality cannot be determined without proper image documentation.

Corrective Action: On April 3, 2018, NPAIHB entered into a signed Stipulated Agreement agreeing that in lieu of OHA issuing a Notice of Suspension to the project, the NPAIHB will adhere to their approved Evaluation and Monitoring Plan.

Required Next Steps: NPAIHB will develop written standing operating procedures (SOPs) and reference resources for use by each pilot project site. OHA will require the project to conduct training sessions at each pilot project site for compliance with required SOP and associated materials. Training sessions must be completed at each pilot site by August 1, 2018. Dates and attendees of the training sessions must be supplied to OHA.

- 6. Failure to Submit Required Information to OHA as Required:** As part of the site visit, the project was required to submit a randomized sample of charts to OHA by February 27, 2018 based upon quarterly data submitted in the Detailed Data Report. Upon review, it was determined that a significant portion of these charts were incomplete and were missing significant components required for review and assessment of quality. These include pre-operative intra-oral images, prep intra-oral images, post-operative intra-oral images, pre-operative radiographs and informed consent forms.

Reviewers were unable to adequately assess several of these charts as required for evaluation of patient safety. Of the 24 charts requested, 63% were missing one or more element. OHA further requested the missing components of the charts and received most of the required materials on March 16, 2018. Project managers indicated on that

date that one chart number had been included in the Detailed Data Report in error, and was not a patient seen by the trainee.

Corrective Action: On April 3, 2018, NPAIHB entered into a signed Stipulated Agreement agreeing that in lieu of OHA issuing a Notice of Suspension to the project, the NPAIHB will adhere to their approved Evaluation and Monitoring Plan.

Required Next Steps: NPAIHB will develop written standing operating procedures (SOPs) and reference resources for use by each pilot project site. OHA will require the project to conduct training sessions at each pilot project site for compliance with required SOP and associated materials. Training sessions must be completed at each pilot site by August 1, 2018. Dates and attendees of the training sessions must be supplied to OHA.

- 7. Detailed Data:** The project is required to submit a full and complete detailed data report (DDR) to OHA quarterly. Upon review of the DDR and comparison of the chart records, numerous procedures were omitted on the detailed data report. Instructions for submission of the DDR indicate that every service provided by the trainee must be included as a separate entry. Stratified random samples are selected from the information contained in the DDR, so accuracy of the DDR is critical to the required evaluation by OHA.

Based upon the submitted DDR, there were an expected 41 unique procedures (defined by ADA CDT codes) completed by the trainee on 23 unique patients. After review, there were 102 unique procedures identified as being completed by the trainee. Of the 23 charts reviewed, only 35% were accurately represented in the DDR. The procedures omitted in the DDR include one completed extraction, as well as many preventive and restorative services. This is an indication of severe data validity issues in the detailed data reports as submitted. Without a complete data set in the DDR, conclusions cannot be drawn as to the representative nature of the charts submitted. It is unknown how many other procedures have been completed by the trainee that were not included on the DDR for charts not selected in the randomized sample.

Corrective Action: On April 3, 2018, NPAIHB entered into a signed Stipulated Agreement agreeing that in lieu of OHA issuing a Notice of Suspension to the project, the NPAIHB will adhere to their approved Evaluation and Monitoring Plan.

Required Next Steps: NPAIHB will develop written standing operating procedures (SOPs) and reference resources for use by each pilot project site. OHA will require the project to conduct training sessions at each pilot project site for compliance with required SOP and associated materials. Training sessions must be completed at each pilot site by August 1, 2018. Dates and attendees of the training sessions must be supplied to OHA.

The next detailed data report is due to OHA by April 30, 2018 and must include every procedure completed by the trainee.

- 8. Failure to Document:** The pilot site has failed to maintain accurate patient records in accordance with OAR 818-012-0070. Examples include incorrectly recording treatment

rendered, incorrectly coding for one procedure when a different procedure was performed, and not recording patient weight when administering analgesics to minors.

Additionally, in one instance, the trainee completed an extraction that was coded as D7210, which falls outside the scope of DHAT practice. D7210 is defined as surgical removal of erupted tooth requiring elevation of mucoperiosteal flap and removal of bone and/or section of tooth. Project managers indicated that this was coded in error, which indicates a failure to accurately document patient treatment.

Required Next Steps: NPAIHB will develop written standing operating procedures (SOPs) and reference resources for use by each pilot project site. OHA will require the project to conduct training sessions at each pilot project site for compliance with required SOP and associated materials. Training sessions must be completed at each pilot site by August 1, 2018. Dates and attendees of the training sessions must be supplied to OHA.

9. **Advisory Committee:** The project failed to meet with their own advisory committee in the two years since approval of the dental pilot project. The approved application includes details of the project assembling an Advisory Committee of their own and meeting regularly. The project has not met once in two years since the approval of the project in February 2016.

Required Next Steps: OHA will require the project adhere to their approved application. OHA will require that the NPAIHB conduct quarterly meetings with their own Advisory Committee. The NPAIHB will submit dates and attendees of these meetings in their quarterly progress report to OHA.

10. **Project Management:** There is considerable concern that the NPAIHB is failing to adequately communicate clinical concerns with the project sites. Supervising dentists at each pilot site have indicated frustration with a lack of communication on issues which are highly relevant and time sensitive. Concerns remain that the NPAIHB does not have a clinical dental subject matter expertise in the project manager role. There remains ambiguity and inconsistencies regarding clinical questions and concerns raised by both OHA and the Advisory Committee around extractions, nitrous and suturing. Several statements received by OHA from the project have contradicted each other and have caused concern regarding patient safety and the provision of quality care.

Corrective Action: On April 3, 2018, NPAIHB entered into a signed Stipulated Agreement agreeing that in lieu of OHA issuing a Notice of Suspension to the project, the NPAIHB will hire or contract for an Oregon-licensed dentist actively practicing in the State of Oregon, to provide clinical technical expertise and project oversight by **June 21, 2018**.

RESPONSE REQUIRED

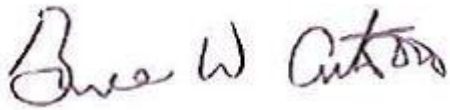
The project will respond to all concerns outlined above that are not addressed in the Stipulated Agreement. OHA will conduct a follow-up site visit to the NARA pilot site within

the next 6 months to assure that the corrective actions outlined above have been performed.

The Northwest Portland Area Indian Health Board must respond to any findings or requests for clarification by **Wednesday, May 16, 2018**.

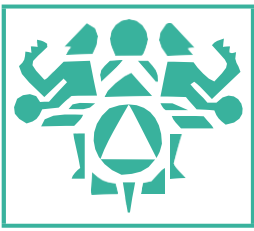
A full report of findings will be issued by OHA by August 1, 2018.

Sincerely,

A handwritten signature in black ink that reads "Bruce W. Austin". The signature is written in a cursive style with a large initial "B" and a stylized "W".

Bruce Austin, DMD
Statewide Dental Director

CC: Dental Pilot Project Advisory Committee #100



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Skokomish Tribe
Snoqualmie Tribe
Spokane Tribe
Squaxin Island Tribe
Stillaguamish Tribe
Suquamish Tribe
Swinomish Tribe
Tulalip Tribe
Umatilla Tribe
Upper Skagit Tribe
Warm Springs Tribe
Yakama Nation

March 22, 2018

Bruce Austin, State Dental Director
Oregon Health Authority
800 NE Oregon St.
Portland, OR 97232

Dear Dr. Austin,

On behalf of the clinicians participating and advising Pilot Project #100, I am sending you a follow up letter and proposed language regarding extractions that our dental therapists are allowed to do.

It is the intent of pilot project #100 to establish a protocol on simple extractions that allows dental therapists to utilize this authorized part of their scope to the greatest extent possible for the benefit of the patients they serve.

In order to graduate from the Alaska Dental Therapy Education Program, students must show satisfactory performance under general supervision of a dentist of "uncomplicated extractions of primary and permanent teeth" (CHAP 2.30.610 (b)(3)(c)) Their training does not limit them to extractions with a certain defined mobility, root structure, cavitation or any other clinical parameter.

It is in the supervision section of CHAP that introduced the language requiring a determination of "medical emergency" by the dentist after consult with the dental therapist in order to perform an uncomplicated extraction on permanent teeth. Taking into consideration the experience of practicing dentists and DHATs in Alaska, the expertise of our site clinicians, and the conversations held with OHA and the OHA Advisory Committee, there seems to be consensus that this language should be revised to keep in the consultation requirements, and eliminate the determination of medical emergency.

OHA has asked the project to enhance this language by adding further clinical parameters. We have drafted the attached language which:

1. **Clearly states the process of consultation between the dental therapist and supervising dentist.**
2. **Gives examples of clinical considerations in the decision-making process.** The reason we feel so strongly about not picking one or two parameters to define what should be extracted is that there needs to be a comprehensive assessment of the whole tooth and patient. Looking at the tooth using only one parameter does not give you all the information the dentist needs to make a judgment on whether the extraction is appropriate for the DHAT. For example, if mobility were the only parameter, it may give some indication of ease of extraction, but you would still have to assess other parameters to make a sound judgment. Some further examples that we talked about during the meeting included root count or shape, root length, bone loss or density. Each one of these should be considered, but not as the *only* way to tell if the tooth is a good candidate for extraction by the DHAT. By assessing extractions with one or two clinical parameters is both limiting to the providers who are trying to make the best decision with their patient, and also not the standard of care utilized by dentists doing the same extraction.

-continued

3. Clearly states extractions that will not be performed by a dental therapist

We ask OHA to also consider this language in the context of our requirements for patient safety for any irreversible procedure in the dental therapist scope. This includes:

1. Direct supervision during the preceptorship in which the dentist evaluates the ability of the dental therapist in all areas, including extractions. All evaluations of dental therapists work is submitted to OHA.
2. A practice agreement between the dental therapist and the supervising dentist which can limit any procedure for any reason, including extraction limitations and supervision levels required.
3. The chart reviews performed by the supervising dentist weekly, external dentist quarterly, and OHA at least yearly. All chart review data from supervising dentist and external dentist is turned into OHA quarterly.
4. The requirement that all supervising dentists are licensed in the state of Oregon, decisions and consequences about those decisions concerning extractions are made under that license.

Finally, although our original modification was only concerning the supervision requirements for extractions of permanent teeth, we understand that the scope of this conversation has been expanded to consider primary teeth.

The extraction of primary teeth has been completed by dental therapists throughout the world. Primary teeth have been extracted extensively in Alaska without noted negative post-operative outcome. Primary teeth are often small, short rooted and/or lacking roots, are typically not surrounded by dense bone, and are considered relatively easy teeth to remove. If the dental therapist believes there is an objective finding is unusual (ankylosis, minimal remaining tooth structure, etc.), they may consult with a dentist to see guidance on proceeding with treatment or referral. Children tend to be less sedentary in the dental chair than adults. An unnecessary mandatory consultation prior to an extraction may increase anxiety in the child as they spend additional time in the dental chair. A routine removal may become a more traumatic experience for the child if significant delay occurs while attaining a consultation.

Thank you for your consideration of our extensive work on this issue. We truly believe this language will result in the best outcomes for the patients and providers.

Sincerely,



Christina Peters, Project Director
Native Dental Therapy Initiative
Northwest Portland Area Indian Health Board

Prior to simple extraction of permanent teeth, the dental therapist should document objective findings in the dental record that reflect an extraction is indicated.

Examples of extractions that are not performed by a dental therapist.

1. Extraction of supernumerary, supplementary or malformed teeth
2. Extraction for lack of arch space, as part of an orthodontic treatment plan
3. Pre-prosthetic extraction in the absence of tooth specific disease
4. Extraction of bony or soft tissue impacted teeth
5. Prophylactic extractions (eg: wisdom teeth without caries).
6. Esthetic concerns

Examples of such findings that may warrant extractions include, but are not limited to:

1. Severe cavitation
2. Fractured or cracked teeth
3. Inadequate restorative ferrule
4. Spontaneous pain
5. Thermal testing where sensation lingers
6. No response to pulp vitality testing
7. Pain to percussion and/or palpation
8. Visible exposure of tooth pulp
9. Presence of suppuration, fistula, sinus tracts
10. Radiographic bone loss around teeth and/or significant probing depths
11. Extensive tooth mobility

The tooth objective findings thus should indicate why an extraction is indicated. Example of diagnosis that may be derived from the above list that warrant an extraction may include, but are not limited to:

1. Symptomatic Irreversible Pulpitis
2. Asymptomatic Irreversible Pulpitis
3. Pulpal Necrosis
4. Previously endodontically treated teeth
5. Previously initiated endodontic therapy

Apical Diagnosis may include:

1. Normal Periapex in the presence of pulpal pathology
2. Symptomatic Apical Periodontitis
3. Asymptomatic Apical Periodontists
4. Chronic Apical Abscess
5. Acute Apical Abscess
6. Condensing Osteitis

The dental therapist will ensure they have a radiograph of all permanent teeth planned for extraction. The dental therapist will consult with a dentist prior to extraction, and the dentist will make the determination if the tooth meets the criteria for extraction by a dental therapist. The dental therapist will make note of any specific instructions or orders from their supervising and/or consulting dentist.



March 28, 2018

Joe Finkbonner
Northwest Portland Area Indian Health Board
2121 SW Broadway STE 300
Portland, OR 97201

Dear Mr. Finkbonner,

The Oregon Health Authority (OHA) has been in the process of reviewing the project modification request submitted by the Northwest Portland Area Indian Health Board (NPAIHB) on January 2, 2018 and revised modifications submitted on January 26, 2018. Discrepancies have been found between the modification requests and what is actually occurring in the clinics as observed during the site visit on February 26, 2018. OHA is unable to make a final determination on all of the modification requests at this time.

OHA has **approved** modifications to the project on the following items only:

1. **Certification/Recertification:** DHAT trainees, as part of the approved Dental Pilot Project #100, are not required to obtain certification by the Community Health Aide Program Certification Board (CHAPCB). Project sponsors will require that the Dental Health Aide Therapist (DHAT) trainees are “certifiable” under the same standards of the CHAPCB. At this time, there are no National Board Dental Therapy Examinations that exist under the Joint Commission on National Dental Examinations (JCNDE); clinical board exam offered by the Western Regional Examining Board (WREB) for Dental Therapy, or legislation authorized which allow dental therapist to operate in Oregon outside of the approved Dental Pilot Project. There are no requirements in the Dental Pilot Project Oregon Administrative Rules 333-010-0400-333-010-0470 which require licensure, passage of an examination or certification in order to participate in the approved Dental Pilot Project as a trainee.
2. **Continuing Education:** A DHAT trainee, as part of the approved Dental Pilot Project #100, is required to complete continuing education requirements that are the equivalent of the requirements for Expanded Practice Permit Dental Hygienists as outlined in Oregon Administrative Rules OAR 818-021-0070. “An Expanded Practice Permit Dental Hygienist shall complete a total of 36 hours of continuing education every two years. Continuing education (C.E.) must be directly related to clinical patient care or the practice of dental public health.” DHAT trainees will submit evidence of completion of CE requirements by submitting a Continuing Education log available from the Oregon Board of Dentistry directly to the OHA Dental Pilot Project Program. The two-year period will begin at the completion date of the DHAT trainee’s preceptorship.

OHA has **denied** modifications to the project on the following items, but will reconsider the requests if the items are revised and resubmitted for OHA review:

1. **CDT Code Update:** OHA received the CDT Code Update document on March 9, 2018. The code D4341, periodontal scaling and root planing – four or more teeth per quadrant, has raised confusion. This is in conflict with the information received at the site visit on February 26, 2018 and practice agreement for Mr. Steward. The practice agreement outlines parameters under “Prophy” which allow for “toothbrush, hand scaling, ultrasonic or piezoelectric cleaning and rubber cup polishing of the coronal/exposed surfaces of teeth.” This conflicts with the scope of practice as outlined in CHAP Standards and Procedures 2.30.230. The project has also requested the addition of codes which are no longer in use by the ADA CDT 2018 codes.

Please modify the CDT Code Update and resubmit to OHA for review.

2. **Extractions:** On February 22, 2018, the project has requested the following modification “to remove the reference to CHAPCB Standards and Procedures section 230.610 (a) requiring "Pulpal therapy or extraction of adult teeth can be performed by a dental health aide therapist only after consultation with a licensed dentist who determines that the procedure is a medical emergency that cannot be resolved with palliative treatment."

OHA has **denied** the project’s request for modification as stated.

In review of the proposed modification, OHA consulted with both project dentist representatives, Advisory Committee representatives as well as conducted research on the authorized scope of practice for dental therapy.

The project stated that quantifiable criteria for extraction by a DHAT trainee includes severe cavitation, cracked or broken teeth, pain, temperature sensitivity, visible pulp, drainage or sinus tracts, bone loss, mobility, irreversible pulpitis, failed root canal treatment and apical pathology.

The above stated reasons are a list of potential reasons for extraction but do not constitute quantifiable criteria as requested by OHA and the DPP #100 Advisory Committee.

Existing standards for dental therapy scope of practice in other states, with legislatively authorized dental therapy, require similar criteria which include non-surgical extraction of periodontally diseased permanent teeth; +3 mobility; indirect supervision; dental therapists may not extract a tooth if it is unerupted, impacted or requires sectioning for removal.

On February 26, 2018, OHA in conjunction with members of the DPP #100 Advisory Committee conducted their first site visit to the NARA Dental Clinic Site in Portland Oregon. It was reported that on two separate occasions the DHAT trainee was unable to complete extractions; each of these extractions became surgical extractions which are outside of the scope of practice of a dental therapist and required the supervising dentist to take over and complete the procedure. This represents 25% of the dental extractions that the DHAT trainee had completed at the time of the site visit.

OHA will approve a modification to the project around extractions with the following criteria:

- 1) All extractions will be performed under the indirect supervision of the trainee's dentist. Indirect supervision is defined under ORS 679.010 as supervision requiring that a dentist authorize the procedures and that a dentist be on the premises while the procedures are performed.
- 2) For primary and permanent tooth extractions, the DHAT will first receive and document authorization from the supervising dentist.
- 3) For primary teeth, the trainee may perform non-surgical extractions on teeth that exhibit some degree of mobility. The trainee will not extract a tooth if it is unerupted, impacted, fractured or decayed to the gumline, or needs to be sectioned for removal.
- 4) For permanent teeth, the trainee may perform non-surgical extractions of periodontally diseased teeth with evidence of bone loss and +2 degree of mobility. The trainee will not extract a tooth if it is unerupted, impacted, fractured or decayed to the gumline, or needs to be sectioned for removal.

The above criteria for extractions must be identified in chart along with the criteria required for the project evaluation which include a recent radiograph of the tooth to be extracted, a pre-operative intra-oral image of the tooth to be extracted and a post-operative image of the extracted tooth.

OHA will approve a modification to the project around pulpal therapy with the following requirements:

- 1) The trainee may perform pulpotomies on primary teeth, under general supervision.
 - 2) The trainee is not authorized to perform pulpotomies on permanent teeth.
3. **Practice Agreement/Standing Orders:** The practice agreement received by OHA on February 22, 2018, conflicts with the CDT Code Update document submitted to OHA on March 9, 2018.
- 1) The following language omits supervision requirements "If in the event a new supervising dentist is assigned, each procedure listed in this Practice Agreement must successfully be demonstrated once to the new supervising dentist for a minimum of 80 hours."
 - 2) The number of hours and supervision requirements have been omitted in the following language "_____ has successfully completed his/her preceptorship achieving the minimum number of hours and successfully demonstrated competency in each of the procedures listed in this practice agreement."
 - 3) Supervision requirements on the form must be updated to reflect the language outlined above regarding extraction criteria.
 - 4) Extraction criteria, as outlined above, must be indicated on the form.

Please modify the form and resubmit to OHA for review.

Amended Application: OHA is requesting that NPAIHB revise and resubmit the original pilot project application. Since the original approval of the dental pilot project on February 8, 2016,

substantive changes to the project have been made or requested by NPAIHB which necessitates that the original approved application be amended to reflect the reality of current project.

The application needs to be updated with prior approved modification requests (i.e. NARA sites), as well as the current approved modifications outlined above and clarification language submitted to OHA. All documents, processes, language changes, etc. must be included in the amended application or revised appendix. Memorandum of Agreements for both CTCLUSI and Coquille expire March 31, 2018; please supply copies of an updated MOA for both pilot project sites. **Pending modification requests should not be included in the amended application until approved.**

Please submit two copies of the amended application to OHA:

1. Copy One will contain the original language with tracked changes. It must be clear what is being removed and what it is being replaced with.
2. Copy Two will be a clean version of the application with all tracked changes accepted. Amended or modified language must contain an asterisk and italicize the language to indicate to a reader that this language was modified. The asterisk will point to a citation with the date of modification in the footnotes of the page containing the modified language.

Example: *The application was updated to reflect new procedures.**

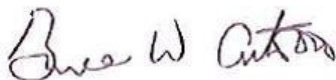
*Italicized language updated on March 13, 2018.

3. All appendixes, addendums, etc. must be placed into one document with a table of contents.

Please submit the amended application by April 11, 2018 by COB 5pm. OHA will review the amended application and corresponding appendix for completeness and accuracy within 21 days of receipt by our office.

Modification to the project cannot take effect until the stipulation agreement is signed by the both the project sponsor and the state dental director.

Sincerely,



Bruce Austin



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Nooksack Tribe
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Port Gamble S'Klallam Tribe
Puyallup Tribe
Quileute Tribe
Quinalt Tribe
Samish Indian Nation
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Siletz Tribe
Skokomish Tribe
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Swinomish Tribe
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Umatilla Tribe
Upper Skagit Tribe
Warm Springs Tribe
Yakama Nation

April 11, 2018

Dr. Bruce Austin, Statewide Dental Director
Oregon Health Authority
800 NE Oregon St.
Portland, OR 97232

Dear Dr. Austin,

In response to the letter dated March 28, 2018, we are submitting information to finalize the pending elements of the January 2, 2018 modification request:

1. A revised CDT Code Update. OHA has indicated that 4341 is in conflict with CHAP standards and Ben Steward's Practice Agreement. This code was from the original CDT list was turned in with the Evaluation and Monitoring Plan based on codes that some Alaska clinicians have aligned with the scope of practice outlined in the CHAP standards. However, the clinicians at our sites have indicated that they don't expect to use this code, so it has been removed. The codes we found that are no longer in use—0260, 0290, 1203, 1204, -- are all codes from our original code list. The codes referenced above have been removed. If there are other codes you were referring to in your letter, please let us know. Attached is a Revised Appendix E.

2. New language regarding extractions and pulp potomies. OHA has directed Pilot Project #100 to use new parameters for allowable extractions and pulp potomies. On March 15, 2018, Dr. Austin, a member of the advisory committee, and all of the project dentists met to discuss extractions by DHATs in the project. The project dentists were disappointed to see that more of the group's discussion was not reflected by the new parameters. We hope that the project dentists will still be able to participate in an ongoing discussion about the appropriate extraction parameters for DHATs in Oregon. We remain committed to patient safety and creating extraction parameters in collaboration with the OHA that will not interfere with patient care, and will allow the dentists or DHATs to safely work at the top of their scope and to use the dental team in the most effective manner.

The project dentists were also concerned about the small sample size (8 charts) used to limit supervision for all DHATs in the project related to extractions. The DHAT was working under direct supervision as part of his preceptorship, and did exactly as he was supposed to do in the event of the two extractions that he could not finish: he consulted with the supervising dentist who finished the procedures.

2121 SW Broadway, Suite 300 · Portland, OR 97201
19201 L Street NW, Suite 420 · Washington, DC 20036
Main Office: (503) 228-4185 · Fax: (228) 228-8182 · www.npaihb.org

It is the case that even an experience dentists sometimes needs to stop a procedure and refer a patient to a specialist. We hope that this restriction can be reexamined as more data from the project sites become available over time.

At this time we are submitting the extraction and pulpotomy modification language we have agreed to in Stipulated Agreement #8827695 and request that this language be revisited after the next NARA site visit. Our project dentists hope that this is a temporary measure and that it can also be revisited as we refine the scope of practice and supervision of this new provider to best serve our communities. Attached is Revised Extraction and Pulpotomy Modifications and Revised Appendix C to Evaluation and Monitoring Plan.

3. Revised Practice Agreement. Attached is a revised Practice Agreement Template with the changes requested for OHA review.

4. Amended Application. Attached is our amended application in both formats requested and appendices. We have kept our Evaluation and Monitoring Plan and appendices as a separate document.

If you have any questions or concerns, please do not hesitate to contact me.

Sincerely,



Joe Finkbonner, RPh, MHA
Executive Director
Northwest Portland Area Indian Health Board

Dental Pilot Projects Program

Dental Pilot Project #100
Advisory Committee Meeting

April 23, 2018

The logo for the Oregon Health Authority, featuring the word "Oregon" in a smaller font above the word "Health" in a large, serif font, with "Authority" in a smaller font below "Health".

Oregon
Health
Authority

Oral Health Program
Public Health Division

Dental Pilot Project DPP #100

Public Meeting

- Ten minute public comment period at conclusion of meeting
- Sign-Up sheet

Dental Pilot Project DPP #100

- Role of the Oregon Health Authority
 - The Oregon Health Authority (OHA) is responsible for reviewing and approving dental 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. 2011 Oregon Laws, Chapter 716.
- Purpose of site visits

Dental Pilot Project DPP #100

- Non-compliance with approved application
- Failed site visit
- OHA and NPAIHB signed Stipulated Agreement in lieu of suspending the project

Dental Pilot Project DPP #100

- STIPULATED AGREEMENT
- NPAIHB agrees that OHA has grounds to suspend the project
- NPAIHB agrees to corrective actions outlined in the agreement.
- OHA will conduct site visits:
 - OHA will conduct site visit to CTCLUSI on May 22, 2018.
 - OHA will conduct site visit back to the NARA on August 20, 2018.

Dental Pilot Project DPP #100

SITE VISIT FINDINGS: NITROUS OXIDE

FINDINGS: DHAT trainees at the pilot sites provided services to patients who were under the use of nitrous oxide. Nitrous oxide was administered by the supervising dentist under direct supervision.

- Project was notified if it is the intention of the project trainees to utilize nitrous oxide or work on patients under nitrous oxide, then the project must apply for a modification to their application.
- Project did not wish to modify their application around nitrous.
- DHAT trainees worked on patients under nitrous oxide, outside of the approved scope of practice in the approved pilot project's application.
- Dentists at both pilot sites indicated they were unaware of directives issued by OHA to the project sponsor

Dental Pilot Project DPP #100

SITE VISIT FINDINGS: NITROUS OXIDE

CORRECTIVE ACTION: NPAIHB signed Stipulated Agreement

- The Parties agree that OHA has adequate grounds to issue a Notice of Proposed Suspension (Notice) to NPAIHB.
- Agreement states that the in lieu of OHA issuing such a Notice the parties agree that NPAIHB must: “Prohibit DHAT trainees from treating patients who are receiving nitrous oxide.”

Dental Pilot Project DPP #100

SITE VISIT FINDINGS: NITROUS OXIDE

REQUIRED NEXT STEPS: NPAIHB will develop written standard operating procedures

- Project will conduct training sessions by August 1, 2018 at each pilot project site.
- OHA will conduct site visits:
 - OHA will conduct site visit to CTCLUSI on May 22, 2018.
 - OHA will conduct site visit back to the NARA site August 20, 2018.

QUESTIONS: Why isn't the NPAIHB allowing nitrous oxide to be included as part of the DHAT approved scope of practice?

Dental Pilot Project DPP #100

SITE VISIT FINDINGS: EXTRACTIONS

FINDINGS: Review of the chart records indicate that on three separate occasions the trainee completed extractions or attempted to complete extractions, which are outside of the trainees approved scope of practice

1. Approved application requires extractions are completed only if a medical emergency.
 - None of the extractions met the criteria of a medical emergency
2. If a medical emergency, trainees are authorized to complete uncomplicated extractions.
3. Two extractions became surgical in nature and should not have been authorized for extraction by the DHAT trainee

Dental Pilot Project DPP #100

SITE VISIT FINDINGS: EXTRACTIONS

FINDINGS: Notes from the Preceptorship Document

Extraction: Tooth #20

[Trainee] was unable to complete the extraction and asked for help - tooth was fragile and needed a full thickness envelope flap on mesial for adequate visibility for ext. I was able to elevate a flap and extract the tooth.

Marked **Acceptable** on Preceptorship Form

Extraction: #15 and #16

After ext #14, #15 - buccal plate and inter dental bone attached to teeth. Advised pt of this, implants/ RPD are not being considered so no further tx recommended. After pt was discharged debriefed with DHAT about rotation of tooth after engaging forceps, use of less buccal forces and more rotation may have a better chance of removing teeth with no bone - also advised possibility of thin buccal plate which may have been unavoidable.

Marked **Acceptable** on Preceptorship Form

Dental Pilot Project DPP #100

SITE VISIT FINDINGS: EXTRACTIONS

FINDINGS: Procedures occurred during DHAT trainee preceptorship

- **Experienced DHAT Preceptorship:** The DHAT is expected to perform each procedure 4 times, work independently each time and in compliance with the established standards for review of each aspect of the procedure.
- Experienced DHAT trainees complete an 80-hour preceptorship to demonstrate competency.
- CHAP Sec. 2.30.600. Dental Health Aide Therapist Training and Education Requirements. The preceptorship should encompass all competencies required of a dental health aide therapist outlined in section 2.30.610(b)(1), (2) and (3) [DHAT supervision and competencies; competencies], and students should demonstrate each procedure or service independently to the satisfaction of the preceptor dentist.

Dental Pilot Project DPP #100

SITE VISIT FINDINGS: EXTRACTIONS

FINDINGS:

- All extractions were marked “Acceptable” by supervising dentist

Extraction (Primary or Permanent) Acceptable:

-All required documents are signed and reviewed; tooth is removed as atraumatically as possible; no damage to adjacent teeth or structures; airway is protected; post-op instructions are provided verbally and in writing to patient; tissues are disposed of in accordance with clinic policy; no assistance is required from supervising dentist.

Extraction (Primary or Permanent) Unacceptable:

-Any irreversible damage to adjacent teeth, wrong tooth extracted, documents not signed, airway unprotected, or two of any other listed requirements.

- “no damage to adjacent teeth or structures” “no assistance required from supervising dentist” “all required documents are signed and reviewed”

Dental Pilot Project DPP #100

SITE VISIT FINDINGS: EXTRACTIONS

FINDINGS:

1. Concerns that the project intended to have extractions completed after the preceptorship under general supervision. (Dentist not on premises)
2. DHAT trainees do not have the scope of practice to resolve extractions that become surgical in nature (cannot cut soft tissue, cannot cut bone and according to DHAT trainee they cannot suture.)
3. Concerns that DHAT trainee at NARA site is experienced
4. Concerns about patient safety, what would have happened if DHAT had been operating off site under general supervision?

Dental Pilot Project DPP #100

SITE VISIT FINDINGS: EXTRACTIONS

CORRECTIVE ACTION: NPAIHB signed Stipulated Agreement. Agreement states that in lieu of OHA issuing such a Notice the parties agree that NPAIHB must: Only allow a DHAT trainee to perform extractions under the following conditions

1. All extractions must be under indirect supervision.
2. Trainee must first receive authorization from their supervising dentist for both primary and permanent extractions.
3. Primary teeth must exhibit some degree of mobility. Trainee will not extract teeth that are unerupted, impacted, fractured or decayed to the gum line or need to be sectioned for removal.

Dental Pilot Project DPP #100

SITE VISIT FINDINGS: EXTRACTIONS

CORRECTIVE ACTION:

4. For permanent teeth, the trainee may perform non-surgical extractions of periodontally diseased teeth with evidence of bone loss and +2 degree of mobility. The trainee will not extract a tooth if it is unerupted, impacted, fractured or decayed to the gum line, or needs to be sectioned for removal.
5. Document all information related to extractions as specified above along with the criteria required for the project evaluation which include a recent radiograph of the tooth to be extracted, a pre-operative intra-oral image of the tooth to be extracted, and a post-operative image of the extracted tooth

Dental Pilot Project DPP #100

SITE VISIT FINDINGS: EXTRACTIONS

REQUIRED NEXT STEPS: NPAIHB will develop written standard operating procedures

- Project will conduct training sessions by August 1, 2018 at each pilot project site.
- Project will clarify scope of practice around suturing.
- OHA will conduct site visits for compliance.

QUESTIONS: The DHAT trainee they are specifically taught that intra-oral suturing is outside of their scope of authorized practice. This was confirmed in statements by the supervising dentist. Each stated that DHAT's are not taught suturing in the training program and are prohibited from suturing. NPAIHB provided information to OHA stating that DHAT's are in fact authorized to perform suturing and are taught this as part of their training. Clarification as to the contradicting statements is required.

Dental Pilot Project DPP #100

SITE VISIT FINDINGS: INFORMED CONSENT

FINDINGS: Project failed to obtain written informed consent for services by the trainee on the date of service

- On 4 occasions, informed consent was obtained after the date of service
- On 2 occasions, informed consent there was no patients name on the form
- On 1 occasion, informed consent was absent entirely.

- Consent was missing for treatment of three minors.

- In all, 26% of the charts were missing informed consent for treatment by the DHAT.

- Written consent for oral surgery is missing entirely for one chart.

Dental Pilot Project DPP #100

SITE VISIT FINDINGS: INFORMED CONSENT

CORRECTIVE ACTION: NPAIHB signed Stipulated Agreement

- The Parties agree that OHA has adequate grounds to issue a Notice of Proposed Suspension (Notice) to NPAIHB.
- Agreement states that the in lieu of OHA issuing such a Notice the parties agree that NPAIHB must: “Ensure that all required consent forms are completed and placed in charts prior to services being performed.”

Dental Pilot Project DPP #100

SITE VISIT FINDINGS: INFORMED CONSENT

REQUIRED NEXT STEPS: NPAIHB will develop written standard operating procedures

- Project will conduct training sessions by August 1, 2018 at each pilot project site.
- OHA will conduct site visits:
 - OHA will conduct site visit to CTCLUSI on May 22, 2018.
 - OHA will conduct site visit back to the NARA site August 20, 2018.

Dental Pilot Project DPP #100

SITE VISIT FINDINGS: EVALUATION & MONITORING PLAN

FINDINGS: Based on review of the 23 submitted charts, the project is not in compliance with Appendix C intra-oral image and radiographic collection requirements of the approved Evaluation and Monitoring Plan.

Appendix C: “This purpose of this document is to provide guidance for the records necessary for irreversible procedures completed by dental therapists. This is to be used by dental therapists during direct, indirect, and external supervision while working in association with the Northwest Portland Area Indian Health Board.”

- 23 charts submitted; Of these 42 unique procedures identified that require a pre-operative intra-oral image and post-operative intra-oral image.
- Of these 29% (12 procedures) are missing either the pre-op or post-op image
- Restorative procedures require a tooth prep image, this is missing in 16% of the restorative procedures
- Adequate patient safety and procedure quality cannot be determined without proper image documentation

Dental Pilot Project DPP #100

SITE VISIT FINDINGS: EVALUATION & MONITORING PLAN

CORRECTIVE ACTION: NPAIHB signed Stipulated Agreement

- The Parties agree that OHA has adequate grounds to issue a Notice of Proposed Suspension (Notice) to NPAIHB.
- Agreement states that the in lieu of OHA issuing such a Notice the parties agree that NPAIHB must: “the NPAIHB will adhere to their approved Evaluation and Monitoring Plan.”

Dental Pilot Project DPP #100

SITE VISIT FINDINGS: EVALUATION & MONITORING PLAN

REQUIRED NEXT STEPS: NPAIHB will develop written standard operating procedures

- Project will conduct training sessions by August 1, 2018 at each pilot project site.
- OHA will conduct site visits:
 - OHA will conduct site visit to CTCLUSI on May 22, 2018.
 - OHA will conduct site visit back to the NARA site August 20, 2018.

Dental Pilot Project DPP #100

SITE VISIT FINDINGS: FAILURE TO SUBMIT

FINDINGS: Project failed to submit complete charts to OHA for review as part of the site visit

- The project was required to submit a randomized sample of charts to OHA by February 27, 2018 based upon quarterly data submitted in the Detailed Data Report
- 24 charts requested; 63% of these were missing one or more element
- Reviewers were unable to adequately assess several of these charts as required for evaluation of patient safety
- OHA further requested the missing components of the charts and received most of the required materials on March 16, 2018, after reviewers had conducted chart reviews

Dental Pilot Project DPP #100

SITE VISIT FINDINGS: FAILURE TO SUBMIT

FINDINGS:

- Project managers indicated on that one chart number had been included in the Detailed Data Report in error, and was not a patient seen by the trainee.

Dental Pilot Project DPP #100

SITE VISIT FINDINGS: FAILURE TO SUBMIT

CORRECTIVE ACTION: NPAIHB signed Stipulated Agreement

- The Parties agree that OHA has adequate grounds to issue a Notice of Proposed Suspension (Notice) to NPAIHB.
- Agreement states that the in lieu of OHA issuing such a Notice the parties agree that NPAIHB must: “the NPAIHB will adhere to their approved Evaluation and Monitoring Plan.”

Dental Pilot Project DPP #100

SITE VISIT FINDINGS: FAILURE TO SUBMIT

REQUIRED NEXT STEPS: NPAIHB will develop written standard operating procedures

- Project will conduct training sessions by August 1, 2018 at each pilot project site.
- OHA will conduct site visits:
 - OHA will conduct site visit to CTCLUSI on May 22, 2018.
 - OHA will conduct site visit back to the NARA site August 20, 2018.

Dental Pilot Project DPP #100

SITE VISIT FINDINGS: DETAILED DATA REPORT

FINDINGS: The project is not submitting all of the data to OHA.

- The project is required to submit a full and complete detailed data report (DDR) to OHA quarterly. Upon review of the DDR and comparison of the chart records, numerous procedures were omitted on the detailed data report.
- Instructions for submission of the DDR indicate that every service provided by the trainee must be included as a separate entry.
- Stratified random samples are selected from the information contained in the DDR, so accuracy of the DDR is critical to the required evaluation by OHA.

Dental Pilot Project DPP #100

SITE VISIT FINDINGS: DETAILED DATA REPORT

FINDINGS:

- Based upon the submitted DDR, there were an expected 41 unique procedures (defined by ADA CDT codes) completed by the trainee on 23 unique patients.
- After review, there were 102 unique procedures identified as being completed by the trainee.
- Of the 23 charts reviewed, only 35% were accurately represented in the DDR.
- The procedures omitted in the DDR include one completed extraction, as well as many preventive and restorative services.

Dental Pilot Project DPP #100

SITE VISIT FINDINGS: DETAILED DATA REPORT

FINDINGS:

- This is an indication of severe data validity issues in the detailed data reports as submitted.
- Without a complete data set in the DDR, conclusions cannot be drawn as to the representative nature of the charts submitted.
- It is unknown how many other procedures have been completed by the trainee that were not included on the DDR for charts not selected in the randomized sample.

Dental Pilot Project DPP #100

SITE VISIT FINDINGS: DETAILED DATA REPORT

CORRECTIVE ACTION: NPAIHB signed Stipulated Agreement

- The Parties agree that OHA has adequate grounds to issue a Notice of Proposed Suspension (Notice) to NPAIHB.
- Agreement states that the in lieu of OHA issuing such a Notice the parties agree that NPAIHB must: “the NPAIHB will adhere to their approved Evaluation and Monitoring Plan.”

Dental Pilot Project DPP #100

SITE VISIT FINDINGS: FAILURE TO SUBMIT

REQUIRED NEXT STEPS: NPAIHB will develop written standard operating procedures

- Project will conduct training sessions by August 1, 2018 at each pilot project site.
- OHA will conduct site visits:
 - OHA will conduct site visit to CTCLUSI on May 22, 2018.
 - OHA will conduct site visit back to the NARA August 20, 2018.
- **The next detailed data report is due to OHA by April 30, 2018 and must include every procedure completed by the trainee.**

Dental Pilot Project DPP #100

SITE VISIT FINDINGS: FAILURE TO DOCUMENT

FINDINGS: The pilot site has failed to maintain accurate patient records in accordance with OAR 818-012-0070.

- Examples include incorrectly recording treatment rendered, incorrectly coding for one procedure when a different procedure was performed, and not recording patient weight when administering analgesics to minors.
- In one instance, the trainee completed an extraction that was coded as D7210, which falls outside the scope of DHAT practice. D7210 is defined as surgical removal of erupted tooth requiring elevation of mucoperiosteal flap and removal of bone and/or section of tooth. Project managers indicated that this was coded in error, which indicates a failure to accurately document patient treatment.

Dental Pilot Project DPP #100

SITE VISIT FINDINGS: FAILURE TO DOCUMENT

REQUIRED NEXT STEPS: NPAIHB will develop written standard operating procedures

- Project will conduct training sessions by August 1, 2018 at each pilot project site.
- OHA will conduct site visits:
 - OHA will conduct site visit to CTCLUSI on May 22, 2018.
 - OHA will conduct site visit back to the NARA site August 20, 2018.

Dental Pilot Project DPP #100

SITE VISIT FINDINGS: ADVISORY COMMITTEE

FINDINGS: The project failed to meet with their own advisory committee in the two years since approval of the dental pilot project.

- The approved application includes details of the project assembling an Advisory Committee of their own and meeting regularly.
- The project has not met once in two years since the approval of the project in February 2016.
- Project submitted list of individuals associated with their own Advisory Committee in advance of the site visit.

Dental Pilot Project DPP #100

SITE VISIT FINDINGS: ADVISORY COMMITTEE

REQUIRED NEXT STEPS:

- OHA will require the project adhere to their approved application.
- OHA will require that the NPAIHB conduct quarterly meetings with their own Advisory Committee.
- The NPAIHB will submit dates and attendees of these meetings in their quarterly progress report to OHA.

Dental Pilot Project DPP #100

SITE VISIT FINDINGS: PROJECT MANAGEMENT

FINDINGS:

- There is considerable concern that the NPAIHB is failing to adequately communicate clinical concerns with the project sites.
- Supervising dentists at each pilot site have indicated frustration with a lack of communication on issues which are highly relevant and time sensitive.
- Concerns remain that the NPAIHB does not have a clinical dental subject matter expertise in the project manager role.
- There remains ambiguity and inconsistencies regarding clinical questions and concerns raised by both OHA and the Advisory Committee around extractions, nitrous and suturing. Several statements received by OHA from the project have contradicted each other and have caused concern regarding patient safety and the provision of quality care.

Dental Pilot Project DPP #100

SITE VISIT FINDINGS: PROJECT MANAGEMENT

FINDINGS:

- On November 27, 2017, OHA issued a notice to NPAIHB requiring the project to cease providing planned extractions by dental health aide therapist (DHAT) trainees since it is outside of the scope of practice requirements as outlined in the approved application.
- NPAIHB failed to inform the project sites of the directives issued by OHA. DHAT trainees at the pilot project sites continued to perform planned extractions outside of the requirements that they be a medical emergency. Medical emergencies are defined under ORS 682.025 and OAR 141-120-0000.

Dental Pilot Project DPP #100

SITE VISIT FINDINGS: DETAILED DATA REPORT

CORRECTIVE ACTION: NPAIHB signed Stipulated Agreement

- The Parties agree that OHA has adequate grounds to issue a Notice of Proposed Suspension (Notice) to NPAIHB.
- Agreement states that the in lieu of OHA issuing such a Notice the parties agree that NPAIHB must: “NPAIHB will hire or contract for an Oregon-licensed **dentist** actively practicing in the State of Oregon, to provide clinical technical expertise and project oversight by June 21, 2018.

Dental Pilot Project DPP #100

SITE VISIT FINDINGS

- The project will respond to all concerns outlined above that are not addressed in the Stipulated Agreement.
- OHA will conduct a follow-up site visit to the NARA pilot site within 6 months.
- The Northwest Portland Area Indian Health Board must respond to any findings or requests for clarification by **Wednesday, May 16, 2018**.
- A full report of findings will be issued by OHA by August 1, 2018.

Dental Pilot Project DPP #100

PROJECT MODIFICATIONS

Dental Pilot Project DPP #100

PROJECT MODIFICATION

Certification/Recertification

- OHA approved the modification request to remove requirement for certification as outlined in the original approved application.
- NPAIHB will require that the DHAT trainees are “certifiable” under the same standards of the CHAPCB.
- At this time, there are no National Board Dental Therapy Examinations that exist under the Joint Commission on National Dental Examinations (JCNDE); clinical board exam offered by the Western Regional Examining Board (WREB) for Dental Therapy
- There are no requirements in the Dental Pilot Project Oregon Administrative Rules 333-010-0400-333-010-0470 which require licensure, passage of an examination or certification in order to participate in the approved Dental Pilot Project as a trainee.

Dental Pilot Project DPP #100

PROJECT MODIFICATION

Continuing Education:

- OHA approved the modification request to clarify CE requirements for the DHAT trainees. As part of the approved Dental Pilot Project #100. DHAT trainees are required to complete continuing education requirements that are the equivalent of the requirements for Expanded Practice Permit Dental Hygienists as outlined in Oregon Administrative Rules OAR 818-021-0070.
- A total of 36 hours of continuing education every two years
- The two-year period will begin at the completion date of the DHAT trainee's preceptorship.

Dental Pilot Project DPP #100

PROJECT MODIFICATION

CDT Code Update:

- OHA denied the modification request to update the allowable CDT codes.
- Project included CDT Code D4341, periodontal scaling and root planing
- Procedure is out of the scope of authorized practice for a DHAT
- Practice agreement outlines parameters under “Prophy” which allow for “toothbrush, hand scaling, ultrasonic or piezoelectric cleaning and rubber cup polishing of the coronal/exposed surfaces of teeth.”
- NPAIHB stated “Therapists can provide the prophylaxis portion of periodontal prevention, and address issues at or supragingivally. DHATs recognize cases beyond gingivitis and refer these patients for management by a dentist.”

Dental Pilot Project DPP #100

PROJECT MODIFICATION

Project request to remove requirement to bring Experienced DHAT from Alaska

“One year prior to the graduation of the trainees, a trained and experienced DHAT will come to the pilot site to begin offering services alongside the supervising dentist. When the trainee returns to his or her tribe to complete their 400 hour preceptorship with the supervising dentist, the experienced DHAT will continue to serve the community and work as part of the dental team. After the trainee has completed the preceptorship, the experienced DHAT, the supervising dentist, and the newly trained DHAT will work together for at least one year. “

- Experienced DHAT is referenced 61 times in the approved application and Evaluation & Monitoring Plan

Dental Pilot Project DPP #100

- Memorandum of Understanding (MOU) between the project sponsor (NPAIHB)
- CTCLUSI expired March 31, 2018 – revised MOU expiration date is June 30, 2018
- Coquille expired March 31, 2018 – revised MOU expiration date is June 30, 2018
- NARA expired March 31, 2018 – revised MOU expiration date is June 30, 2018

Dental Pilot Project DPP #100

COQUILLE SITE

- Coquille Dental Pilot Project site was approved as part of the original application
- 2 DHAT trainees are slated to graduate in June 2018 and return to Coquille
- Coquille has no operating dental clinic
- CTCLUSI site is also located in Coos Bay, they will also be receiving a second DHAT in June 2018.

Dental Pilot Project DPP #100

Preceptorship

- DHAT trainee graduated in June 2017
- Still under preceptorship at the CTCLUSI site

NARA site

- DHAT trainee will start year two in Alaska in September 2018

Other Trainees

- Will NPAIHB be sending any other individuals up to Alaska to train with the intention of returning to Oregon?

Dental Pilot Project DPP #100

Grant Expired:

- The W.K. Kellogg Foundation grant, in the amount of \$2,509,460, expired on March 31st, 2018

Dental Pilot Project DPP #100

Oregon Administrative Rules

- OHA will be opening OARs for Dental Pilot Projects
- Applications will be accepted from May 7, 2018 – May 23, 2018. Those selected to serve on the Committee will be notified on Wednesday, May 30, 2018.
- Announcement and the call for applications will be made next week.
- Interested parties, please send email to oral.health@state.or.us

Dental Pilot Project DPP #100

- Next Meeting: June 18, 2018 9am-4pm PSOB
- Site Visit: May 22, 2018 in Coos Bay
- Site Visit: Follow up site visit to NARA on August 20, 2018.

Dental Pilot Project DPP #100

PUBLIC COMMENT

- Please limit comments to two minutes per person.
- Sign Up sheet