CENTER FOR PREVENTION AND HEALTH PROMOTION
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Oregon Health Authority
Dental Pilot Project Program
Rules Advisory Committee

MINUTES

Date: July 9, 2018

Time: 9:00 am - 11:00 am

Location: Portland State Office Building, 800 NE Oregon St., Room 1 A, Portland, OR 97232

Attendees:

Committee Attendees: Quanita Anwar (phone), Todd Beck, Jennifer Clemens, Shannon English, Christina Peters(phone), Hai Pham, Laura McKeane, James McMahan (phone), Conor McNulty, Heather Simmons (phone), Emily Wineland

OHA Staff: Kelly Hansen, Sarah Kowalski, Mauri Mohler, Shannon O'Fallon

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All meetings are recorded and transcribed. ***** indicate portions of the meeting that were not audible in the recording.

Agenda Topic: Welcome and Introductions

Meeting began at 9:05 am. Committee Members and OHA Staff introduced themselves.

Beginning of Transcription:

Speaker: All right, so for those of you on the phone we're going go ahead and get started. This is the Dental Pilot Project Rules Advisory Committee and as a reminder this is being recorded so we're going go ahead and do, um, a quick round of introductions. We'll do the room first and then we'll get to individuals on the phone. My name is Sarah Kowalski. I am the policy project manager for the dental pilot project program. Go ahead.

Next Speaker: Uh, my name's Hai Pham. I'm a pediatric dentist with the Board of Dentistry.

Next Speaker: Connor McNulty ****.

Next Speaker: Laura McKeane, All Care CCO.

Next Speaker: Shannon English, **** Dental.

Next Speaker: Uh, Emily Wineland from NARA and I brought my daughter here. She was born a couple days after our first meeting so thank you for the flexibility.

Next Speaker: Thank you for coming.

Next Speaker: Uh, this is Shannon O'Fallon with the Oregon Department of Justice and I advise the Public Health Division.

Next Speaker: All right, and those on the phone, um, Dr. McMahan, I heard you, why don't you start?

Next Speaker: Thank you, yes, Jim McMahan, uh, representing the Oregon Dental Association.

Next Speaker: And then Christine, I heard you chime in.

Next Speaker: Hi, Christina Peters, Northwest **** Health Board.

Next Speaker: Okay, anybody else on the phone?

Next Speaker: ****.

Next Speaker: Okay, so let's start. Heather, I heard Heather.

Next Speaker: Yes, with Pacific Source.

Next Speaker: Okay. And there was somebody else?

Next Speaker: Yeah, Quanita ****, dental hygienist.

Next Speaker: Hi Quanita. All right, anybody else on the phone? Okay. All right, so, um, same kind of thing as last time, um, we have the huge packet of meeting minutes that you guys were sent out and you can, um, read through them. This is the meeting minutes from last time. If you have any changes or any questions about either this one or the time before please let me know. I haven't heard any feedback about that from anybody. Um, and then for, I think Emily, you're the only one that hasn't maybe been in our building before, um, the elevators are down the hall to the right and there's restrooms on the other side of that. And then that's where you'll go, like, around 10:00 and, um, Mauri can show you where to go. So, let's get the right packet here. What I did to make this a little bit easier for people that we had a request to incorporate some language, um, so you have, you have the, the rules with the, um, with the red line rules and then you have a separate document that it's just the excerpts from the Oregon Dental Practice Act. Um, and they are, we wouldn't incorporate all the language into the rules, we're just reference that so because of that I wanted to have a printed version for you to see what we were potentially talking about referencing but, um, we will get to that section here. And so today we're going go back from the very beginning starting at the top of Page 1 and then what, rather than read line by line by line because we've already done that, we can address sections where you, um, where you have issues with it, um, and then

Shannon will be taking a look kind of at all the legal pieces and the language and things like that and, and the next **** that we're here might look a little bit different just with some actual language changes, um, that are required. Um, you want to come here? Come on down. Okay. So, um, let's start at the very top under dental pilot projects purpose, um, there was a request to strike out that language and change the purpose sentence. Does anybody have issues with that? This whole section here? Um, under 2B, there was a request for, um, to have timeline for dental pilot projects approved that are already approved to cap time to come into compliance and that was still, um, there was a question outstanding about how long a project's needs to come into compliance or if there's really an actual need to have that if this is gonna happen in November. Christina, you had proposed that language. Do you have a particular timeframe that you had requested and that we haven't really gotten any feedback from you?

Next Speaker: Well yeah, you know, I mean, and **** may have talked a little bit about this here and I was thinking about, um, I was thinking six months would be a safe amount of time. I mean, um, it might not take projects that long to come into compliance but it, just, um, from my sort of looking at it will require a significant rewrite of the existing application and potentially some things in the evaluation and monitoring plan and then we'll probably have to rewrite our, our freshly made standard operating procedures, so just the manpower to do those three things, um, I thought six months would be a reasonable amount of time as a deadline.

Next Speaker: Sarah, can I speak to that?

Next Speaker: Yes.

Next Speaker: So this is Shannon O'Fallon, um, so I wouldn't think that these rules would require anyone to rewrite their application. They're already an approved project but I think to the extent that you have an existing project that, um, maybe doesn't have all the pieces in place that meet the new minimum standards than that's the piece where, you know, I can see an existing project may be needing a little bit if additional time and there are a couple ways to do that. I mean, I think, you know, you can't expect people to come into compliance with rules that aren't actually in effect so, I mean, it makes, if it's gonna take until November to get them filed and effective, you know, folks aren't gonna know exactly what the final rules are gonna look like until they get filed with the Secretary of State. Um, they can have a delayed effective date which maybe causes a, you know, which maybe isn't the best thing because then they wouldn't apply to the new applications.

Next Speaker: Mm hmm.

Next Speaker: But I think we could add language and this first section that says for existing projects, you know, they have, you know, X amount of time to come into compliance to the new standards once they're adopted and that's, you know, a common, um, provision that you see in the rules.

Next Speaker: Okay.

Next Speaker: Okay. All right, so let's move down to, uh, the definitions. Under, um, so these are, so we have the address, really what I want you all to do since, rather than going piece by piece by piece here, is there any issues with No. 1, adverse event? That was the definition that, um, did you, did you, the CDC, is that the CDC definition?

Next Speaker: No, that's what I wrote, this, this is Kelly Hansen, uh, this is based on our literature search of **** reported.

Next Speaker: All right. All right, and then, um –

Next Speaker: ****.

Next Speaker: Okay. Any concerns with that? Then the clinical, uh, evaluator, um, there weren't any issues highlighted **** anybody have any issues with that? So, um, jumping, so we have clinical phase complications, means a disease or injury that develops a treatment of an earlier disorder. Any questions, comments? No. That, that was an issue at the first meeting, we were having questions about that. All right, um, I'm going move down to, I'll just let you guys look through Page 2 here and ask if there's anything that you want to discuss and if not, we'll move on to Page 3.

Next Speaker: Question here, on the employment utilization site, um, so does all these, uh, locations that EPDH practice, um, so why is this necessary?

Next Speaker: On number, why, why is that language there?

Next Speaker: Yeah. So, can, is there any setting where **** provide by the **** to be broad and would it encompass everything?

Next Speaker: Um, I believe that was original language from, I'm not sure, I'd have to go back and check but it, I think it was just being very descriptive about where **** programs describes.

Next Speaker: No. 78, the, the, it's purple on mine, what, what did we leave that at?

Next Speaker: Oh, that one was just moved **** in, um, alphabetical order 'cause we added the term project dental director.

Next Speaker: Oh yeah, it's down. Yeah.

Next Speaker: So it still exists it's just moved.

Next Speaker: Yeah, exactly. It's a little, that's why it gets harder and harder when we're red lining everything. All right.

Next Speaker: Um, okay. So if we move over to Page 3 we can talk about that so it's now, um, No. 18. Um, we were having some questions about titling this at our first meeting.

Next Speaker: Yeah.

Next Speaker: Um, and there's also some language questions on here so it's project dental director means individual whose actively responsible for oversight of the dental pilot project and who is a dentist licensed in the State of Oregon. There was a, a, um, comment to include or an additional individual that was approved by the Authority so that in the event the, the, like, a dental hygienist could function in that role, um, there was different feedback on that, whether or not that should be, uh, allowed or not. Does anybody have any comments on that? The, um, individual approved by the Authority which is, it'd have to be somebody that would

function in that dental director type role. So it would have to be somebody that can already do the skills that are being, um, tested in the pilot.

Next Speaker: So at, at or above the skill level.

Next Speaker: Yeah. Yeah. So whether or not that would actually be a hygienist, I mean, somebody brought up what, what if there was a, a, I mean, they were trying to think of some scenarios of how that might, what that might look like and gives the, gives a little bit of flexibility there. Is there any concerns with that language?

Next Speaker: Well I think we, turning back to the last conversation, I think a lot of the discussion around this was with the intent is, um, the first pilot is **** challenges **** would be a licensed dentist would have the best ability to coordinate all the pieces of the whole oversight, everything happening in that. That would **** –

Next Speaker: Yeah, and that's why so, it is, it is initially with **** a dentist license in the State of Oregon, um, and then it would if somebody wanted to propose another person it would have to be approved.

Next Speaker: But that's written like it has to be **** –

Next Speaker: As written, yeah. As written it could be.

Next Speaker: Correct.

Next Speaker: 'Cause I think one of the concerns too was that, um, some of the IHS dentists are not licensed within the state that they're practicing in, so –

Next Speaker: Yeah.

Next Speaker: They would just have to –

Next Speaker: **** they are a licensed dentist.

Next Speaker: That is true so it does give some flexibility for, um, that's true. That is, that is a good point. Okay, so –

Next Speaker: This is Dr. McMahan, just making sure I understand. Have we stricken or dental hygiene in that, in that, in that Section 21?

Next Speaker: Um, we are on –

Next Speaker: 18.

Next Speaker: – 18.

Next Speaker: Oh, okay. I'm, I'm sorry. I was lookin' at 21, gotchya.

Next Speaker: Yeah, so, um –

Next Speaker: It does ****.

Next Speaker: Yeah, it would, I mean, really the purpose of the, the purpose in all likelihood it, the project would have to be, I mean, I'm just tryin' to think of scenarios that where a dentist wouldn't be involved and it would be, I mean, it's possible but really the intent is to have it be a dentist in that role.

Next Speaker: So why do we need that?

Next Speaker: I think it –

Next Speaker: Well –

Next Speaker: – **** due to Shannon's belief of if you're using a, a dentist who can be licensed but is not because of they work for DHS or the DA or potentially **** Washington.

Next Speaker: There are dentists at the dental school that are not licensed in Oregon.

Next Speaker: So it, it, it gives **** authority to **** so you're not boxed in to **** licensed.

Next Speaker: But again, it requires individual authority approval by the Authority.

Next Speaker: Yeah. Any questions about that?

Next Speaker: Um, okay so next –

Next Speaker: Can I just, so –

Next Speaker: Oh, sorry.

Next Speaker: This is Shannon O'Fallon, I would just say when it says an individual approved by the Authority, I mean that indicates to me it could be anybody so if you want to say, you know, if you wanna be specific and say you're talking about a dentist that might not be licensed in Oregon but is licensed somewhere else.

Next Speaker: So we could have some like, like, like **** –

Next Speaker: Dental provider –

Next Speaker: Something specific though that it's, that it is a dentist.

Next Speaker: Yeah.

Next Speaker: If that's what, if that's what –

Next Speaker: So maybe we, okay, come up with some language that it is a dentist.

Next Speaker: I just wanna, is the goal to and I, I like actually the change that you made to say or as approved by the Authority for, for two reasons. One, because it does allow, you know, for federal health programs or the VA or education programs to use dentists that might not be licensed in Oregon. But also it does, you know, allow projects that might fall within the

full scope of a hygienist to apply to the Authority for an exception to the rule based on that language.

Next Speaker: Okay, let me make a note.

Next Speaker: Um, and I guess just the other thing is, you know, there's, there's nothing I think in these rules that talk about, you know, how that approval is supposed to be sought or what the standards might be and so that –

Next Speaker: So being more specific.

Next Speaker: – a more **** might need to be addressed. Yeah.

Next Speaker: So if you were specific in saying that it is an individual who is a dentist not licensed would that give you what you were talking about? Or it still doesn't have enough?

Next Speaker: Um, well, I mean, again, I mean if the only basis upon which you're gonna approve or disapprove somebody is that they're, you know, is that they're licensed somewhere that maybe you don't need an authority approval staff if it's gonna, if it's gonna, if it's gonna require sort of something else and there's other criteria that you are going to, um, apply when someone says you approve this person I think that needs to be a rule.

Next Speaker: So the, in the, what the criteria is that we want somebody who is in Oregon, um, familiar with the Dental Practice Act in Oregon. Um, that was the first piece of that and I don't know if we can say resides because there are people that live in Washington, lots of people live in Washington so that, and are duly licensed in Oregon and Washington so that's, that's part of the reason we didn't say resides in Oregon. Um –

Next Speaker: Okay.

Next Speaker: We're leaving it to the discretion of the Authority though? I mean, I think we **** some of this is done in the spirit of, uh, **** itself. But dentists licensed in the State of Oregon, uh, or another dentist approved by the Authority would give flexibility to the Authority to understand but I think what our concern is if you've got, um, someone being appointed that has no frame of reference or context for Oregon delivery systems or what the issues are here administering it from the East Coast or, you know, something else that doesn't really apply to somebody –

Next Speaker: Yeah.

Next Speaker: Yeah.

Next Speaker: But I think, from my recollection, **** notes from our previous discussions the intent to have a dentist is, is the focal point on this.

Next Speaker: Yeah. Mm hmm.

Next Speaker: A licensed dentist.

Next Speaker: Okay.

Next Speaker: Which could be facility, which could be IHS, which could be, you know, there's some flexibility there.

Next Speaker: Are there, um, this is Shannon O'Fallon again, are, under the Dental Practices Act the, the, um, the dentist licensure statutes are there exemptions that allow someone to teach or, you know, practice at the VA or whatever without being licensed?

Next Speaker: **** licensed **** the state.

Next Speaker: Yes.

Next Speaker: Right?

Next Speaker: There is, yes, but it has to **** specific guidelines and there's some exceptions **** Mission Mercy, dentist from other, um, but you have to apply through the Board of Dentistry and then we have to vote as a board to approve those, um –

Next Speaker: Okay.

Next Speaker: – yeah.

Next Speaker: So you're approving an exemption is that what it is?

Next Speaker: Yes. My understanding, yes.

Next Speaker: Okay. So that might be another way to get at it, somebody that has been, well anyway, I ****.

Next Speaker: 'Cause they have to go through a background check.

Next Speaker: Right.

Next Speaker: Also.

Next Speaker: Right. Okay.

Next Speaker: So, you can leave it up to they have to approve, get some kind of, uh, exception through the Board of Dentistry, uh, so at least you know they're being vetted because there are people who have applied, uh, there for a licensure and, like, they've had serious issues in other states under their license and, like, do we really want this individual comin' to Oregon practicing dentistry, right?

Next Speaker: Right.

Next Speaker: Uh, so perhaps I think that might be wise to, you know, say, you know, with approval of the Board of Dentistry so at least you know they're getting vetted really well.

Next Speaker: Yeah. Right.

Next Speaker: Okay.

Next Speaker: 'Cause some of 'em have, could have insurance medical fraud or dental fraud things like that. That'll apply to things –

Next speaker: Mm hmm.

Next speaker: – like that so.

Next speaker: ****.

Next speaker: Yeah.

Next speaker: And I think at the end of the day, I think, you know, the dental director needs to be a dentist.

Next speaker: Agree.

Next speaker: Um, just because, yes, he can be a hygienist, he can't perform this acts but **** as a leader, uh, the head of that, uh, group needs to be a dentist because you go through all the extra training, you see the big picture and it's not just that little small campus thing. Um, you know, it's just like in a big research project, let's say at OHSU, I mean, those are led by, you know, physicians, right?

Next speaker: Right.

Next speaker: I was up there on Friday giving a talk with the governor and, you know, we had chief executive medical director, you know, his M.D. is not a, you know, nurse practitioner or PA leading these discussions. It, it's the M.D. who's very highly qualified.

Next speaker: Mm hmm.

Next speaker: So I, I think we should do the same here, uh, just so there's not so many, uh, grey area when it comes time, uh, to create these programs and to **** so.

Next speaker: Okay.

Next speaker: All right.

Next speaker: **** can I go back. Am I on mute? Can you hear me?

Next speaker: Oh, yes.

Next speaker: Yes.

Next speaker: We can hear you, yeah.

Next speaker: I just wanna go back to something, I think it was Dr. Pham said earlier about the approval of the project director by the dental project director by the Board of Dentistry, so are you suggesting making the **** those directors some, the help from the Oregon Health Authority are you giving that to the Board of Dentistry –

Next speaker: No.

Next speaker: – the, the Oregon –

Next speaker: We have –

Next speaker: – are you gonna **** the Authority of approving those providers, those –

Next Speaker: Christina, –

Next speaker: – dental ****.

Next speaker: – this is Sarah Kowalski. It would have to be a dentist that the Board of Dentistry would allow to be a dentist in Oregon. They're not approving the project dental director. They're just saying that this is the dentist that they would let work in Oregon. Does that make sense?

Next speaker: Uh, –

Next speaker: Just like a ****.

Next speaker: – yeah. No, it makes sense **** clarify that.

Next speaker: Yeah, okay. So, um, moving down here to, um, to moving on here and to the next, um, under sponsor, we have, um, the definition we added tribal organization or clinic. There was a request if there could be multiple sponsors and, um, in looking just at best practices about projects and having multiple sponsors is really challenging. You have an issue of who is in charge and then if there's an issue who's going be the final person who, final organization who is responsible for dealing with problems so the recommendation just from looking other best practices with projects is to have a single entity, um, and then you could have, um, I'm just looking at, like, the OHSU project right now. They have OHSU as the sponsor but they're working with Capitol. They're working, kind of, with other stakeholders or partners, I guess they're calling them. Um, any questions about that? Okay. Moving on here. Did any, any other questions on Page 3? Okay. So No. 4 is everything we've, we've already gone over everything here. Um, does anybody have any questions on Page 4?

Next speaker: I think I have one on the 3A, 3B, does it, uh, **** make sense to **** authority the ability to deny an application for other content reasons, like the model doesn't make clinical sense or applications to Oregon, um, is that something that'd be listed in the denial section. I just wanted maybe a little bit more clarity on that from our previous discussion.

Next speaker: So this is ****. I mean, this, this section right here is about not accepting new applications versus denial, –

Next speaker: Yeah.

Next speaker: – versus a basis for denying. Um, so, I mean, the things that you mentioned seemed to me to be sort of content related where you would review an application and say –

Next speaker: ****.

Next speaker: – you know, think it doesn't meet the standards, um, which is different then we're just not gonna accept the application. We're not gonna look at it because, you know, because of these reasons. So I think it's a little bit different.

Next speaker: Okay.

Next speaker: Okay. All right. So let's move on to Page 5. So anywhere, like, at the top of C on Page 5, anywhere, um, it just, it's just saying project dental director just to be really clear that you're, we're talking about, um, –

Next speaker: To go online for–

Next speaker: – the same person.

Next speaker: – ****.

Next speaker: – Yeah, exactly. Thank you. Um, so one of the areas that we need to flesh out a little bit more, and it might be something that we're gonna have to do a little more research on, is under G, um, standard operating policies and procedures shall consist of the following and then we have three, um, A, B and B, apparently, that should be C. Um, those need to be, um, a little bit more, sounds like need to be more prescriptive than what we have written out here so that's something that we can follow up on and, and research unless anybody wants to add anything to that language right now.

Next speaker: I think that, this is **** I found the goal is just to make sure that an applicant understands, you know, what it is that they need to provide and these general categories might not give enough for guidance for that.

Next speaker: Okay. Anybody have any other comments on Page 5? Okay. So, um, Page 6. Uh, the only changes on this are under F, just the language. Just ensure background checks are conducted on participating trainees that would be the project has to ensure that they're responsible for doing that, the project sponsor.

Next speaker: Do we need define, uh, the background checks on what's, what it entails or?

Next speaker: I don't, is that something that we would define would you say criminal background check or would you?

Next Speaker: Um, –

Next Speaker: I don't think so.

Next Speaker: Standard term ****.

Next Speaker: It's pretty standard. I mean, you could say criminal. What, where is it again?

Next Speaker: Um, –

Next Speaker: **** –

Next Speaker: – **** F.

Next Speaker: On Page 6.

Next Speaker: – background check.

Next Speaker: And does this, if they do this background check in the beginning, does this, are we asking for monthly OIG checks or is it, it's just this check here? I mean, do we need to do that?

Next Speaker: OIG.

Next Speaker: Like, we have to do monthly checks on every one of our providers?

Next Speaker: How.

Next Speaker: Oh, uh.

Next Speaker: To make sure that there's no fraud claims, nothing. That's why, I mean I don't –

Next Speaker: I, –

Next Speaker: – that's what **** –

Next Speaker: – I don't know.

Next Speaker: – IOHA to us. We have to do that monthly for all our providers are board members. Dentists, I mean the dentists DCOs do it too,

Next Speaker: What is the board of dentistry, the board of dentistry does it only when you apply for your license.

Next Speaker: Just that one time.

Next Speaker: Yeah.

Next Speaker: Initially you get a background check, yeah.

Next Speaker: It's a –

Next Speaker: **** be with –

Next Speaker: – initial check.

Next Speaker: – ****.

Next Speaker: Yeah, we don't redo background checks.

Next Speaker: Yeah. All ****.

Next Speaker: Dentistry unless –

Next Speaker: Unless there's –

Next Speaker: – something weird.

Next Speaker: – some allegation or something for us to do it.

Next Speaker: Um, is this language sufficient the way it's ****?

Next Speaker: I think you can add criminal background check 'cause that's what you're talking about.

Next Speaker: Would it be fair just to have the minimum background requirements 'cause there's a, there's only **** dental practice have to reference the state and national, state and nationwide criminal background checks and fitness determinations. That's a little **** clarify specifically what you're talking about.

Next Speaker: Yeah, though I don't know. I mean, I don't know if these projects are gonna be able to do fingerprint, FBI –

Next Speaker: I was gonna say that was one of the –

Next Speaker: – criminal background checks.

Next Speaker: So one of the things that, um, we had, that was, and we'll, we'll be getting to that in this next section here, was asking if we could include, um, state and nationwide criminal background checks, fitness determinations and actually have the Board of Dentistry do it, and they said they wouldn't do it.

Next Speaker: No, **** they can't do that.

Next Speaker: Yeah, they said the FBI told them they can't, which I believe them **** good. We'll move on from that. But, um, so we'll have to just, you're okay with that language or we can revisit if it **** needs to be.

Next Speaker: Yeah, they assume, they just, I mean, they're gonna, the projects gonna need to describe how they're gonna do a criminal background check and there ain't no third-party vendors that can do, you know, **** of nationwide check. It's not, you know, it's not gonna be up to the standards necessarily of an FBI fingerprint check but.

Next Speaker: So just, and if this has been covered I apologize, I'm still, I apologize for being late, um, it's with regards to the background checks did, is this stating that we just wanna ensure that there are background checks or the background checks are actually passed. I think there's a distinction there. It's like sterilize your monitor and stuff that we do. You have to monitor your sterilizers but they don't have to actually pass, so I think that someone should pass a background check. I think that should be, it should be worded that way.

Next Speaker: Which begs the question of what it means to pass a background check.

Next Speaker: Yeah.

Next Speaker: Uh, that's a good question. You know what I could ask 'cause I don't think I even know the answer to that, um, I, I know if something is **** on a background check for somebody who's applying for life ****, it's brought before the board on a case-by-case basis and we discuss it so.

Next Speaker: Yeah.

Next Speaker: Okay.

Next Speaker: I mean, you could, but you know, I mean, you could have someone that comes ****. Sorry, go ahead whoever's **** phone.

Next Speaker: And I don't know how other organizations do it but other organizations if you can't pass the back, the background check, you can't be employed by the ****. So **** be able to have somebody in our project specifically, um, that couldn't pass a background check. They can't work for the board. They can't work ****.

Next Speaker: I think what we're talking about here is right, that the project needs to explain what they're process is for a criminal background checks and it probably makes some sense to say something else about and they need to explain, you know, what would essentially disqualify someone from working in a project and you would think that anything is gonna show up on a criminal background check is going to, um, you know, have the potential to put, um, patients of the project, um, at risk, you know, including things related to fraud or violence, etc., would be things that would be disqualifying.

Next Speaker: Okay.

Next Speaker: I, I think you, we should be careful coming up with a specific list of –

Next Speaker: Yeah.

Next Speaker: – disqualifiers 'cause that boxes us into that.

Next Speaker: I agree.

Next Speaker: I'd much rather have, if it doesn't pass, meaning there's no red flags on a background check, whatever comes up on that background check, then it comes before whatever committee, person, persons, or entity is selecting these people, and they make the decision. I, I, that, that makes more sense to me than saying well, if you, you know, if, if you got two DUIs and you got this and this and this –

Next Speaker: Yeah. Right, uh –

Next Speaker: – right?

Next Speaker: – right. No, I wasn't suggesting that, but I think what, what we need to say is that they need to have criteria and they need to tell us what their criteria is for, essentially for, you know, disqualification.

Next Speaker: 'Cause again, it's the project getting this. Not ****.

Next Speaker: Mm hmm. Mm hmm.

Next Speaker: That's correct.

Next Speaker: Okay.

Next Speaker: And if you're processing **** then –

Next Speaker: Okay. Um, so the next thing that this is gonna **** this come up again, um, but very bottom, it says costs and there's a comment over there. Um, request that projects must demonstrate financial resources prior to final approval. What about, um, the scenario where, um, uh, kinda the chicken and the egg thing. You apply without having a grant or whatever on the, on the, well, you know, but the grant that you're going to apply for requires you first to have proof that, that project has to be approved. So, little bit of, um, there wasn't a lot of clarity, um, in the rules about this before. So, we were trying to, um, is it okay that they don't have, uh, maybe they identify what the resources will be, but they don't necessarily have them yet?

Next Speaker: So, it's a contingent total approval, continued –

Next Speaker: Mm hmm.

Next Speaker: Uh, approval.

Next Speaker: But the, yeah, but the final approval, um, this is more saying like, we wouldn't give them final approval until they have those resources and is this –

Next Speaker: So, final approval will be contingent upon receipt of grant funds.

Next Speaker: Um, and, you mean, I don't know if, and this, does anybody have, I mean, what is the feedback on this? Do we, I mean, we're, we're not giving, OHA doesn't provide grants. I mean, really, it's, it's the projects, it's up to the project to be able to find the resources to do the –

Next Speaker: Mm hmm.

Next Speaker: – projects. So, if they don't, you're gonna go through all these steps to do this without any, having any money. I mean, that's, seems kinda crazy that we even really have to say that. I mean, we don't have to say this. Um, but there was a request to put that in there, so does anybody – we can leave it out?

Next Speaker: Does make sense to save you guys time, you know.

Next Speaker: Yeah, just another step and **** –

Next Speaker: And, and sometimes there's an ongoing grant process.

Next Speaker: Yeah. Exactly.

Next Speaker: You know, for different phases of the project.

Next Speaker: Mm hmm.

Next Speaker: Yeah.

Next Speaker: So, you know, maybe **** –

Next Speaker: Your **** –

Next Speaker: **** is superfluous, like extra step –

Next Speaker: Yeah.

Next Speaker: – that we're getting –

Next Speaker: Mm hmm.

Next Speaker: – into making sure you have many when we're not, I mean, we're not funding you, so. Okay, does any, uh, is anybody okay if we just not require that? It wasn't required before. It's confusing I think for people. Um, okay. So, let's move down on Page 7, we have K. Um, these are the, do you wanna speak to anything here? Anybody have any questions about this section? The preliminary evaluation plan? So that the goal, or the, the way that it, the overall, they apply. **** structure. Thank you. It's, or it's Monday.

Next Speaker: Feels **** –

Next Speaker: It feels so Monday too. Um, the overall structure is that they apply, they have a preliminary evaluation plan, um, they receive provisional approval and they don't receive final approval 'til they provide a full fleshed out evaluation plan.

Next Speaker: Correct.

Next Speaker: Nothing?

Next Speaker: Yes.

Next Speaker: Okay. All right, so, any questions on Page 7?

Next Speaker: Yes. So, um –

Next Speaker: Okay.

Next Speaker: – and maybe Jim, is, is Jim on the call?

Next Speaker: Yes.

Next Speaker: Mm hmm.

Next Speaker: Yes, I am. Yeah, I, I was just kinda concerned. I don't see any reference or, about specifically how patient outcomes will be evaluated, that that should be addressed and how, how the **** intends to, uh, **** get, uh, obtain metrics on patient outcomes.

Next Speaker: There, um, I do believe in the, uh, later sections relating to the full evaluation plan, there are, um, patient outcomes and patient, and quality of care are, um, addressed there, but that does make sense to have a, uh –

Next Speaker: It should be in preliminary –

Next Speaker: – brief –

Next Speaker: – as well.

Next Speaker: – a, uh, a section with, like, initial metrics on.

Next Speaker: What clarity **** for that area ****.

Next Speaker: Yeah. I think that's a good point, Jim. I, I, yeah, I definitely think that, that that should be stated –

Next Speaker: So, that'll be in the, that'll be later on –

Next Speaker: We can add that in **** –

Next Speaker: – in, in the plan **** –

Next Speaker: – in No. 4 under K.

Next Speaker: Okay.

Next Speaker: Okay. Sounds great.

Next Speaker: So, uh, patient, I just wrote patient outcomes. Is that –

Next Speaker: Yeah, we'll, we'll find some language.

Next Speaker: – ****. Okay.

Next Speaker: Um –

Next Speaker: To flesh it out?

Next Speaker: That matches **** language.

Next Speaker: Okay.

Next Speaker: Okay, any other questions on Page 7, before we move on? Okay, Page 8. Um, everything in here we've already talked about, but, we're, we're just making it clear who's doing what with the language where it says authority. Um, any questions on Page 8?

Next Speaker: On No. 3, where reference to the individuals **** applications. No individuals contributed to or helped prepare application will be permitted to do a review.

Next Speaker: Yes.

Next Speaker: Is it possible to add where **** technical review, can they meet to evaluate the application?

Next Speaker: That is what that is.

Next Speaker: That is the technical ****.

Next Speaker: Yeah. And the committee shall at minimum include representation from the Board of Dentistry, School of Dentistry and professional associations. Based on our conversations the last time and, and to, to date, that seems to be one of the areas that has –

Next Speaker: So, we can invite individuals. We can't make people come.

Next Speaker: Mm hmm.

Next Speaker: So, and that's been, I mean, you know, from the various programs. Um, various stakeholders –

Next Speaker: **** include the invitations and representation ****. Board of Dentistry, School of Dentistry and professional associations?

Next Speaker: Okay. And there's, there's also language in SB738 that we can, that's not handy right here, but, um, that we, it's similar to that. So, I think that would be, we could look at that language. Let's see, ****. For, for the purposes of rule writing, actually. Is where **** in there.

Next Speaker: And so what's the wording going to be on that?

Next Speaker: Um, well, what does it say in 738? Like when they –

Next Speaker: How 'bout say shall invite. Not may invite.

Next Speaker: Oh, the parties shall seek the advice of appropriate professional societies and licensing boards before adopting rules under Subsection 2 it says.

Next Speaker: I'm sorry, did you say shall or may?

Next Speaker: Shall.

Next Speaker: Okay, good.

Next Speaker: Does –

Next Speaker: Two very important differences.

Next Speaker: – does that –

Next Speaker: But that's adopting rules, so.

Next Speaker: That's adopting rules, but would that language, if we change that language here to, um, sim, not the word, take out the rules language, but.

Next Speaker: Yeah.

Next Speaker: So, seek, seek advice, or –

Next Speaker: **** place in ****.

Next Speaker: Okay. I'll just say look at SB738.

Next Speaker: Professional **** societies.

Next Speaker: Okay. Um, okay, anything else on Page 8?

Next Speaker: Now, one second here.

Next Speaker: Uh, the notification for the **** intent, uh, it says 10 days. I think that's pretty short, especially on, uh, with everybody's busy schedule ****. I'd like to see at least 60 days –

Next Speaker: For public comment?

Next Speaker: Yeah.

Next Speaker: Yeah.

Next Speaker: What's standard for public comment?

Next Speaker: And we allow months for public comment and rule changes for the Board.

Next Speaker: Yep, only.

Next Speaker: So, on No. 5, notice to provisionally approve or deny will be provided to applicant posted for public comment for a period of 10, and you want 60 there?

Next Speaker: Mm hmm.

Next Speaker: That seems very long.

Next Speaker: No, it isn't.

Next Speaker: Hi, this is, this is Heather Simmons from Pacific Source. Um, that concerns me to put in extended periods of public comments here. I'm not quite sure I see the reason for that?

Next Speaker: Transparency.

Next Speaker: I think personally 10 business days is sufficient.

Next Speaker: What do we normally allow for rules? Isn't it 15?

Next Speaker: I don't even remember. Um –

Next Speaker: It's more than that. Um, I mean there's sort of a, a timeline that, then I, and I forget sort of what the minimum is for actual public comment like that. I thought it was like 45 for a total period, including notice of legislators.

Next Speaker: I'm okay with 45. I just want transparency like Dr. Beck said.

Next Speaker: Absolutely. It, I mean, when, even when we change a comma in a rule that substantially changes the meaning of a rule, um, we have, right now we're in the middle of a rules, uh, uh, change and I think we've allowed, what? Four months total for public comment, and we rarely get it.

Next Speaker: If it changes law, and this is just –

Next Speaker: I was gonna say, this is, it's just approval of –

Next Speaker: No, this is for rules.

Next Speaker: – an application.

Next Speaker: This is for rules. This is not law.

Next Speaker: Oh, this is for rules right here.

Next Speaker: This is not law. This is for rules.

Next Speaker: No.

Next Speaker: When we're changing a rule, if you're changing a law, the **** should be a lot higher than that.

Next Speaker: Right, but then **** –

Next Speaker: **** we're talking about a pilot project here and not a rule.

Next Speaker: Yeah. An application.

Next Speaker: So.

Next Speaker: In fact, there's no requirement –

Next Speaker: This is getting a little cumbersome.

Next Speaker: **** that public comment –

Next Speaker: Yeah.

Next Speaker: I mean, the, I mean they can –

Next Speaker: But you don't think –

Next Speaker: – strike public comment –

Next Speaker: No, well, wait a minute. Wait a minute. It –

Next Speaker: – altogether.

Next Speaker: – I totally disagree with that. If we, if we have something that, uh, potentially affects the citizens or Oregon, even if no one shows up, I think we are bound by duty to have a public comment period. We cannot, that, then that, that, that, then there's no transparency. You gotta at least give people the option to participate in this.

Next Speaker: So, what, so what **** –

Next Speaker: Well, there is a public comment period of 10 days.

Next Speaker: Ten days is not enough.

Next Speaker: I mean, I, I –

Next Speaker: Well, 60 days is too long.

Next Speaker: – I mean.

Next Speaker: This is Shannon. I, I'm, I'm not gonna debate the policy, but, you know, it's, it's not common for applications for something to go through a public comment period. I would say, so.

Next Speaker: But this isn't, this is an exception to this standard anyway, to have 10 days? To even have one?

Next Speaker: I mean, I'm not saying it's a bad thing. Right? I mean, transparency is good in allowing, you know, allowing for, you know, general feedback. It's a good thing, but as you say, but, but, you know, I guess I think when you say 60 days, then you're, for the, for the pilot project, you're really drawing things out and –

Next Speaker: Yeah.

Next Speaker: – um –

Next Speaker: But that's a –

Next Speaker: It's gotta be more than 10.

Next Speaker: 'Cause **** to move forward.

Next Speaker: Well, this isn't a **** –

Next Speaker: Uh, to Jim again, if we're, if we're gonna have the public comment period, in the, in the pace of life we life in today, 10 days is inadequate. It's, it's like, it's like not even having one, so we need to extend that. Sixty maybe is too much. Forty-five sounds reasonable, but, uh, it's not, uh, a big encumbrance to make it 45 days.

Next Speaker: I, I guess I disagree with that. I think 45 days is too long for an application process.

Next Speaker: Okay, well, we will have to look at maybe what else is happening. Um –

Next Speaker: You might look at other, other project programs –

Next Speaker: – even, even, um –

Next Speaker: – and in other places.

Next Speaker: Well, even our rulemaking process doesn't –

Next Speaker: That's what I was asking. In our normal rulemaking process –

Next Speaker: – our rulemaking process –

Next Speaker: – what is the ****.

Next Speaker: Now, in the first packet that you were given on the first day you were here, um, the timeline like for this is, um, between August 27th and the 31st, rulemaking documents are gonna be posted. Um, and then a notice, on September 1st, a notice appears in the Oregon Bulletin, um, and then –

Next Speaker: 22nd?

Next Speaker: – and the 22nd, public comment period closes. So –

Next Speaker: Mm hmm.

Next Speaker: – that's 22 days. And that's for rules. So.

Next Speaker: So if we could back up just a lit, little bit and look at this from a global perspective, we're talking about, we're not talking about little policy changes that may not affect people. We're talking about applying for a program where people that are being trained are working on patients in Oregon, possibly causing re, irreversible changes, maybe not damage, but changes to their dentition. I think that warrants more than 10 days. It may not be 60. I'll, I'll back off the 60, but it sure as hell warrants more than 10 days. This is not just an application to do anything. This is working on people. And I know I'm coming from a specific point of view, being the Board of Dentistry, but 10 days is not enough time to give people, to, to give general stakeholders time to weigh in. And I'm sorry if the process takes a while. This is important stuff. It takes a while.

Next Speaker: On that just, maybe from a, from a different perspective, I think the, uh, with the requirements and with what we change, trying to get as much information as, as, as

possible, having comment from the dental communities, um, around the State, especially any pilot who's talking about showing a need and showing a different, you know, potential model or provider structure or whatever else it is, I think 10, 10 **** days is extremely, uh, short amount of time in order to gather good feedback from those communities of saying, you know, this is something that we agree on or we think there is an issue here in this particular area. A lot of the confusion within the pilot process is to date has come from within the dental communities. You know, I think they didn't really know any of this was happening and didn't have an opportunity to talk about it, so.

Next Speaker: Mm hmm.

Next Speaker: I, I would agree that extending it way, far beyond the 10 days is sufficient whatever the termination is, 30, 45 days. Uh, I think that that minimum would be, you know, would be helpful for these purposes.

Next Speaker: So, there's the, so it sounds like the Dental Association, the Board of Dentistry and other sort of dental specific folks are gonna be invited to, to a technical review of the application, so. I mean, I think that that's significant as well, so that sort of input sounds like it's gonna be happening anyway.

Next Speaker: But even to circulate something for information and feedback, 10 business days is extremely short amount time –

Next Speaker: But the technical review group isn't, isn't bound by the 10 days. That's not how I read that.

Next Speaker: This is after the technical review.

Next Speaker: Right, this is the, this is open for public comment, right? That's what we're talking about?

Next Speaker: Yeah.

Next Speaker: Yeah.

Next Speaker: Yeah, so that's not the technical group. I, I agree –

Next Speaker: Yeah.

Next Speaker: Yeah.

Next Speaker: – with that. I think the technical group can probably sus things out in a couple of meetings –

Next Speaker: Okay, **** –

Next Speaker: That makes perfect sense.

Next Speaker: Oh, yeah.

Next Speaker: But, an opportunity to let other people weigh in, other stakeholders that may not even be in the dental community, that may just be concerned citizens, and, and we have not very many people show up to these meetings to, to talk to us. Our last public heating meeting lasted like 10 minutes, and so, but it, it gives the, it, it, it lets people know that we're being transparent and we're not trying to shove any program or anything on the citizens, that we're including them. And, and I think it's really important, the optics of it are important.

Next Speaker: Okay. Let's move on for now for that. Um, under the next, um, page, we're moving to Page 9. This is just all these little, um, pieces, um, uh, uh, this should be in red, but 2A, projects that receive provisional approval may not operate until final approval is receive from the Authority. That was just a clarity to make sure that that was understood. Any, any questions with that? Okay. Move on to Page 10. Um, really the area that we're gonna start talking, if we go down the minimum standards, spend some time on this. Um, so, comply, let's go to 1A. Comply with informed consent in accordance with, um, the, what will become the informed consent section later on in the rules. Um, let's move over to Page 11 because this is where it's gonna get a little ****. So, this is where, um, um, so, there was a request by the Board of Dentistry to add some language and reference applicable sections of the Oregon Dental Practice Act. Um, so if we read, so go to D. So, trainees participating in approved dental pilot projects are subject to applicable sections of the Oregon Dental Practice Act as though licensed by the Oregon Board of Dentistry. Is that acceptable language, Shannon? I don't know if that will work, but, um, trainees must comply with the listed applicable sections, might, I don't know it's redundant, but, um, the question, so, so we went through, and this is where this whole second big one we passed, I fleshed it out to the second piece of –

Next Speaker: This other document, en, uh, entitled excerpts from the Oregon Dental Practice Act.

Next Speaker: So, I don't know, um, if we wanna, not everything that you submitted is applicable, so some of the things just, we didn't put in here. Um, like the, uh, man, I, I don't need to go through all of them, but the ones that we thought were applicable, um, we put in here. Um, we can go through, so, um, No. 1 was the mandatory reporting of child abuse. No. 2, comply with the use of X-ray machines so, um, my question, and this is, this was kind of probably more of a question for you, is if we're referencing these sections in the Practice Act and they all say licensee, licensed, licensed to that person, um, are these enforceable the way that we're, the way that we have them here? So that the person has to follow the rules in, under those sections of the Practice Act? Does that make sense?

Next Speaker: Yeah. This is Shannon O'Fallon. I, it, it is, um, I mean, looking at the specifics of these rules, I think that there are some provisions in there that are maybe sort of problematic, and there's someplace where it talks about licensees and some places in the rules where it talks about dentists.

Next Speaker: Mm hmm.

Next Speaker: Um, and, you know, this particular rule is saying that these, that there are things the trainees had to do and some of these rules deal with recordkeeping and things like that, and keeping records for 7 years which seems like –

Next Speaker: Yeah.

Next Speaker: – a, an, you know, a standard that maybe you want to apply to the project but not to the trainees themselves. So, it's a little bit apples and oranges, and I'm not sure that it, that it is super clear and there might be, I mean, it might be better to take a look at the, um, Board of Dentistry rules and take the specific standards that you want to apply and just –

Next Speaker: Put 'em in here.

Next Speaker: – put 'em in here.

Next Speaker: Okay.

Next Speaker: Rather than reference?

Next Speaker: Yeah.

Next Speaker: Yeah.

Next Speaker: I think the intent was to keep it, um, uh, not static so that if they were, they're updated in case there were updates –

Next Speaker: Yeah, 'cause the rules –

Next Speaker: – so that would be **** for being, for referencing.

Next Speaker: – **** reference.

Next Speaker: Yeah.

Next Speaker: So.

Next Speaker: But that actually doesn't work because if you update your rules, then these rules are only gonna apply to the rule that was adopted at the time these rules were adopted.

Next Speaker: Well, not if –

Next Speaker: So, there, so there's no automatic **** –

Next Speaker: – what if the language is, you know, that, the, the idea was that the, the pilot project should adhere to, or whatever the legal word is, adhere to the current rules of, of the OBD in these sections. Wouldn't that then be a living, breathing document 'cause that's how we do it with the Board. That's how we do it for our licensees. So why would it be different with pilot projects?

Next Speaker: Um, it's a little different. I'm trying to see if I can figure out to, so for example, it's the case, um, if you adopt by reference, um, a document or a manual in your rules, um, you can't adopt it so that every time that, that manual or document is updated that then the current version applies for your rules. You have to actually update your rules and reference the new version of that thing in order for it to be enforceable. So it's the same thing here. Um, I mean your rules, when you revise them, are applying to the licensees that, that are governed by them.

Next Speaker: Correct.

Next Speaker: So it's not, it's sort of not the same issue, but you are updating your rules. Here, it's sort of a cross reference, so you would have to, they would have to update them again.

Next Speaker: Hmm. How do we do that?

Next Speaker: So, there's not a legal bridge in between, you're saying there's no legal bridge to reference?

Next Speaker: Right.

Next Speaker: Well, not one that's automatically updated. Um –

Next Speaker: 'Cause otherwise, you're not, you, you, your, your, the public and the people that have to comply with the dental pilot project rules sort of aren't getting an opportunity to weigh in on those changes before they happen. I mean, you would have to know that the Dental Board rules are being changed and that therefore, that was affecting the rules that you were subject to. So it sorta doesn't work that way.

Next Speaker: And public noticing to the exhaustive extent that we do it wouldn't, wouldn't, wouldn't, uh, satisfy that?

Next Speaker: No, probably not.

Next Speaker: So, the question is if they were gonna actually flesh out each of these sections, then what you'll have to do, um, is to go, the, I don't know if it, the ODA submitted this for the Board. I can't remember which of you did. You'll have to go and look at each of these sections and determine, what are you asking of the trainees? Under what –

Next Speaker: Okay, so –

Next Speaker: – standards **** –

Next Speaker: – if I, uh, and that makes sense. So, if I'm, if I'm following that, then, so, uh, Sharon, right?

Next Speaker: Shannon.

Next Speaker: Shannon. Sorry. Um, if, let's say with like prescription writing, or with the administration of certain anesthetics. Um, if we mirror, uh, for the pilot project what the Board of Dentistry has in its rules, and then the Board of Dentistry changes, which we do sometimes. We change, you know, rules. Uh, if we don't change the rule at the pilot project, then they're gonna be out of sync. Right?

Next Speaker: Mm hmm.

Next Speaker: And so, how do we trigger so we know, see for me, for a reference, ref, referring would make so much more sense if it could legally, if it, if it legally matched than having to remember, okay, we changed this rule. Well, we referenced it with this pilot project.

Now that's gotta change. So is there a way to automatically reference that so that we don't run into the problem of, well, we, now we don't, we're not allowing our licensees to use this medicine on a 6-year-old. We wanna make sure that's reflected with the pilot project. If we just have an automatic reference, that would automatically do it, but if not, how do we keep track of, uh, those changes and make sure that they get put everywhere they need to go if we don't have a, an automatic reference?

Next Speaker: I mean, I'm not saying that you can't do the reference. But, I just like, when I look at even the standards of practice, unprofessional conduct, it just isn't clear how some of these things apply to trainees. And so I think it's confusing, like there, and there are not just in this rule but in other rules, things about, you know, providing patient records to patients, or, you know, charting, charging fees to patients for records. Um, I mean, things about ordering, uh, you know, ordering drugs, use of, I mean, these, these trainees, I'm, I assume they don't have prescription authority.

Next Speaker: They don't.

Next Speaker: Um, I mean, there's just so many things in, in your rules that seem to apply to the dentists, and these trainees aren't dentists, that I just, I don't think that they match very well, which is why I guess I think it would be better to cherry pick a little bit from the –

Next Speaker: Okay.

Next Speaker: – from the Board of Dentistry rules.

Next Speaker: So maybe more of the standard of care or, well, we don't really have rules on that, but –

Next Speaker: Yeah.

Next Speaker: – maybe more like defining what, which it's very well defined in our rules, but unprofessional conduct, or that would be something I think that would apply directly to a trainee. Um, you know, you don't grope a patient. You don't –

Next Speaker: Sure.

Next Speaker: – you know, those –

Next Speaker: Right.

Next Speaker: – types of things.

Next Speaker: Right.

Next Speaker: Right.

Next Speaker: Which again, we don't, we don't, and in the EPA, we don't specifically say you can't touch someone here, say something or do, you know, it's, it's sort of a generalized thing because we don't wanna box ourselves in or out of anything. So, um, if I'm hearing you correctly, those types of issues, interactions with patients, but if they don't have any, they have no prescription writing authority, but they are gonna be delivering local anesthetics. So, we

need to have those rules apply, that would apply to local anesthetics, which is not just dentists. It's also dental hygienists. And that's where the whole licensee versus dentist language comes in –

Next Speaker: Yeah.

Next Speaker: – because some things in our EPA are specific for dentists.

Next Speaker: Right.

Next Speaker: Some are for all licensees and so –

Next Speaker: Right.

Next Speaker: – that's where that –

Next Speaker: Right.

Next Speaker: – gets a little confusing. So you would like more specificity rather than just pointing to the rules.

Next Speaker: Right, so, you know –

Next Speaker: Okay –

Next Speaker: – I mean, your rules say that it's unprofessional conduct to fail to maintain a minimum, at a minimum, a current BLS for healthcare provider certificate or its equivalent. Well, I don't know if that's a trainee requirement, so, again, you know, just, just saying you have to comply with these rules, or it's unprofessional conduct if you don't I think is gonna be, there's just, there's gonna be a disconnect there for some of these things.

Next Speaker: So, maybe what you can do is what you did for **** but then go through each of those sections, um, I'm looking like at unprofessional conduct and do kind of go through them, what would a, what would **** –

Next Speaker: Well, I would just copy everything that we think is unprofessional conduct. I mean –

Next Speaker: Well, that's what I'm asking you to do.

Next Speaker: Yeah. So, how is that different than ref, referencing the rule?

Next Speaker: Well, you could reference –

Next Speaker: Well –

Next Speaker: Yeah.

Next Speaker: – specific subsections maybe.

Next Speaker: Okay.

Next Speaker: I mean, if you think there are subsections –

Next Speaker: What would be helpful, and I'm happy to do the work, what will be helpful is if, could you, um, maybe make a list of the ones that you think that just don't apply that we need to scratch? That wouldn't apply specifically to this, um, so that we can have reference on where to, I mean, these are the ones we thought were important. That's why we threw 'em in, right?

Next Speaker: Right.

Next Speaker: And so, if we're getting pushback on, for, for legal reasons, it'd be helpful to know why so that we can maybe do a workaround. 'Cause we think these are really important from a protect-the-public point of view, which is the lens we look at, look through all the time.

Next Speaker: So the ones in here, in this language, in this –

Next Speaker: Yes.

Next Speaker: – section here, this is like the whole list that we were given, and then what we did from here is we went through and said okay these were the ones that we thought we could require that are actually in the, the, in the document here, um, that, you know, because they don't have prescription capabilities, they're not in, not doing IV lines, um, there's not, um, we can't ask the Board of Dentistry to do the fitness determinations and –

Next Speaker: Right.

Next Speaker: – um, there is no controlled substances, etc. So these, these are the ones here that you could then take – I mean, you could also go back and look at what you originally recommended in addition, but there, **** not **** prescriptions, so it would be, you don't have to do that, but, um –

Next Speaker: So, could I go back, uh, in the crossed-out sections, um, up at the top for E and, and G. Are those are the original language from the original ****.

Next Speaker: Um, well H wasn't, but – yeah, so E –

Next Speaker: Are those –

Next Speaker: – **** at the top of the page.

Next Speaker: – actually acceptable usage of a reference?

Next Speaker: Under the very top of Page 11. That, that was original ****, uh, for 19B. Um, where it says comply RLS 453.605 blah, blah, blah, related to the use of X-ray machines; that was original language, um, from the rules. So we just took that and infection control procedures; that was also original language.

Next Speaker: Yeah. I think the statutory references are okay, though. I have a question about whether or not these trainees would be able to use X-rays and, under any circumstances, so I would check with Radiation Protection Services because, you know –

Next Speaker: Well, that's –

Next Speaker: their rules –

Next Speaker: – part of the program, right? Teaching 'em –

Next Speaker: Yeah.

Next Speaker: – how to take radiographs?

Next Speaker: Yeah.

Next Speaker: You have to, yeah. You cannot practice –

Next Speaker: Okay.

Next Speaker: You can't practice ****.

Next Speaker: I just **** that so I'm ****.

Next Speaker: Yeah. I was thinking, um, dental radiographs.

Next Speaker: Yeah.

Next Speaker: Mm hmm.

Next Speaker: Um –

Next Speaker: And I looked at, I looked at those statutes and I didn't see anything in there that, um, sort of raised the same concerns, and like, you know, this prohibition against using the behavior management technique hand over mouth, you're just referring to that subsection of 0010? I don't have any problem with that. Um, it's just these other rule references are, I think are too broad given the content of what is in the Board of Dentistry rules.

Next Speaker: So for example under 5, under 5 there, with the hand over mouth, um, we could take, you, you could go into, um, unacceptable patient care, which is, go back to Page 2 on this excerpts document. So you could go through, um, um, under 81801200010, unacceptable patient care on the excerpts document on Page 2.

Next Speaker: ****.

Next Speaker: Okay.

Next Speaker: And so you could go through all of these and then –

Next Speaker: And you could just cite to –

Next Speaker: – cite which ones are applicable kinda like I did here with this hand over mouth, um, which was No. 11 on, under unacceptable patient care, but you could pull out all of the ones that you – if that's what you're asking.

Next Speaker: Mm hmm.

Next Speaker: Okay.

Next Speaker: Does that make sense? Do you have any – I mean, we can go through, if you want, put all of them in there and we can go through and determine what is appropriate. But like to your point about record keeping and some of those other pieces that might not be applicable.

Next Speaker: Well, I guess what I'm struggling with is we're trying to make these rules applicable for **** current pilots ***** consideration, uh, **** trainees but **** one in particular. I don't know how, how to hook up this other than to reference a dental practice **** sections that are applicable if we need to dial down further into **** do you think there's some ways to get more **** language that would make it as applicable as possible and broad as possible but not, uh, bringing up the necessary language that I think would be complicated for ****. I don't think anybody wants to complicate it or make it more burdensome, uh, down the line in terms of, uh, uh, reviewing applications or evaluation plans that, that, uh, we don't know what they will look like.

Next Speaker: Okay. Well it's a project, so.

Next Speaker: Would anybody be opposed to, um, Dr. Pham and I, um, taking these suggestions, uh, and running them by our AAG to see how we might make this simpler or, you know, she looks at everything through the Board's perspective as far as legally doing things. Is any, would anyone have an opposition to us doing that, to asking Laurie for an opinion on how we might make this language better? I don't want to overstep toes or anything, I just wanted to make sure –

Next Speaker: No. I know Laurie. I like Laurie.

Next Speaker: – okay. I like Laurie too.

Next Speaker: Yeah Laurie. Okay, all right, so, um, for now we will move on from this section because we, it's still too, a little bit to determine, so on the top of Page 12, um, who's on the phone, is somebody sayin' somethin'?

Next Speaker: You know are you looking **** from the minimum standards section?

Next Speaker: We're on Page 12.

Next Speaker: Um, okay, you're still on minimum standards?

Next Speaker: Yeah. It's the whole thing is minimum standards. Yeah. It's, um, yeah,

Next Speaker: We're, we're just movin' on from the, uh, rules section **** reference section.

Next Speaker: All right.

Next Speaker: Um, okay, so, okay. Any questions, um, on this page? Any comments? We're on Page 12. Okay? We're gonna move on to Page 13. Um, so what we did here, um, in the last, uh, we're on 9, on the top of Page 13. The stricken language says report serious adverse events to the Authority the date they occur. Took that language out and looked at the language, um, that was referenced, um, in the, in the dental practice actively. This is where this is. Um, shall report to the Authority incidents which result in any untoward medical occurrence that is life-threatening, requires hospitalization, results in disability or permanent damage, requires medical or surgical intervention or result in death that occur in the provision of care by the trainee. Anybody have any?

Next Speaker: Hi, this is Heather.

Next Speaker: Hi Heather.

Next Speaker: Um, would, would, given that the trainee is working under the, um, licensure and guidance of the dentist or the hygienist, whoever it might be, and of course the project dental director, would it, is it appropriate for the trainee to turn in this document or would it be the dental director?

Next Speaker: It would, the project would turn this document to the Authority. The dental director that they're working under or supervisor is also respon, like, uh, held to account by the Board of Dentistry, so they have their own reporting procedures. This is to make sure that us as the Oregon Health Authority.

Next Speaker: Are you, are you referencing A, 9A where it says the trainee?

Next Speaker: Yeah. I'm just, it, from my, yeah, I would just think that the trainee wouldn't actually be the one submitting this document.

Next Speaker: So, so, who should be submitting the document?

Next Speaker: The project.

Next Speaker: The project, should we say the project.

Next Speaker: Yeah.

Next Speaker: Well if it's related to these ad, adverse events then it probably should be the supervising license professional.

Next Speaker: Yeah. That project dental director. That makes sense.

Next Speaker: Supervising however it's referenced in the, the definition, so the supervising dentist or supervisor or how, I'd have to go back and look at the exact language but.

Next Speaker: That does make sense.

Next Speaker: Does anybody have any questions about that?

Next Speaker: So, this is Shannon. My only question is, you know, we define an adverse event and I didn't do a search. I don't know if adverse events are supposed to be reported elsewhere, but you know, we're using this oth, other language here untoward medical occurrence. I don't understand what untoward means, but, um, in this instance, but I'm just wondering why we're using adverse events but here we're using sort of different language.

Next Speaker: So, do you wanna explain that a little bit? 'Cause, 'cause adverse events.

Next Speaker: So it's adverse events and complications and then, um, –

Next Speaker: Serious.

Next Speaker: – serious like hospitalizations, like, so you have these distinctions between ****.

Next Speaker: The idea was to, to, to encourage projects to track adverse events so that they can make sure that the, the patients are receiving quality care throughout the project. Uh, this **** important, the, the purpose of this section is to report truly, truly serious problems, um, that they don't it, it becomes an overly burdensome reporting if they have to report every time there is an adverse event.

Next Speaker: Okay.

Next Speaker: It feels like they're the same sort of thing.

Next Speaker: Those are not out of course within, you know, those are com, not common, but they occur in the normal course of treatment sometimes. Um, so it's, it's we don't, that's why we wanted to have that distinction. Um, I think the purpose of defining adverse events and complications, um, and I don't know if it actually made it into the final version of the evaluation section but was to, uh, make it clear that they should be tracked for evaluation, so they are ****.

Next Speaker: So, I think it's the same as we do at the dental school. Yeah, they're different levels. We call them unwanted events or, um, so it's someone –

Next Speaker: Everybody has their own little.

Next Speaker: – is prepping, someone preps the wrong tooth or they do the wrong surface or they leave decay or they go into the nerve and they shouldn't have and there's a complication that's, that's fixable but not life-threatening so it deviates from what the plan was, then we don't report that to the Board. I mean that, that stays within the school because there was no malpractice done but there's training to be had from that. Right? We want to make sure that the, the student, once they graduate to become a dentist or hygienist that they don't do that as much. And so, we have a way of reporting that at the school level where we, where I teach at the school. I think that's what we're talking about. Things that are sub, they, they don't reach the threshold of being life-threatening or irreversible or, you know, they're a learning experience versus things that are, you know, you gave somebody an injection even if you, you know, most, most unwanted, I mean, I think most, even most deaths in dental offices,

um, are not intended, right? It's, it's well-intended treatment that goes bad. That rises to a different level than I prepped the wrong surface.

Next Speaker: Right.

Next Speaker: We need to make sure that we know what **** versus distal is.

Next Speaker: Could we take out the word untoward?

Next Speaker: The, see the language part I'm good with anything. But, I'm, I'm not a lawyer so I don't know what fits best with that.

Next Speaker: Because it's, I mean we're talking about any medical occurrence that is life-threatening blah, blah, blah and that, that occurs **** care by the trainee, so it seems to me we don't want anyone thinking about well was it untoward or not ****.

Next Speaker: Oh. Okay.

Next Speaker: Oh yeah.

Next Speaker: **** inappropriate or inconvenient. I mean I would think that any life-threatening thing that happens like as the result of the, the dental care you want to be reported whether –

Next Speaker: It's inconvenient or not.

Next Speaker: – inconvenient. **** we think, hope it would be unexpected.

Next Speaker: So we're talking about the language that rises to the level of reporting.

Next Speaker: Yeah.

Next Speaker: So untoward is too soft for that.

Next Speaker: Yeah.

Next Speaker: I just don't know what it adds and I think it adds, it adds confusion and I don't think it helps.

Next Speaker: Okay.

Next Speaker: And just saying straight up, you have to result, you have to report an incident which results.

Next Speaker: Mm hmm.

Next Speaker: Which, well anyway, an, an incident where somebody is, you know, where it's a life-threatening ****.

Next Speaker: So, how do we make sure to them that these sub important events that have to do with how someone's adequately being trained get reported? Because that can't be left out. That to me is untoward.

Next Speaker: Yeah, so they'll need to be reported.

Next Speaker: That'll be quarterly.

Next Speaker: Quarterly monitored.

Next Speaker: Sure, sure, **** get it somewhere.

Next Speaker: And I, I –

Next Speaker: **** their index section is No. 10.

Next Speaker: Yeah.

Next Speaker: **** quality monitoring data, do we need to have a subsection indicating that adverse events and complications ****.

Next Speaker: And I just wrote in my notes over **** said that something like project shall submit a process for outlining and reporting adverse events and complications. Kinda, just speaking to –

Next Speaker: Perfect.

Next Speaker: – maybe, like, how they do it at OHSU.

Next Speaker: Okay.

Next Speaker: Yeah.

Next Speaker: – or in dental hygiene, whatever.

Next Speaker: So ****.

Next Speaker: **** process.

Next Speaker: –24 hours.

Next Speaker: Right, and –

Next Speaker: Yeah, they don't need to go to –

Next Speaker: But it would be, like, yeah, if you went and numbed up the wrong side.

Next Speaker: Right.

Next Speaker: That's, I think that people, well people do that all the time. Are you kidding? I've done it before, I mean, I, I was given bad instructions, actually.

Next Speaker: I wasn't. I just screwed up.

Next Speaker: I was told to do something, I just listened and didn't look, you know, but, um, **** happens. Okay, so I think that we can flush out some language under 10.

Next Speaker: Yeah.

Next Speaker: Um, to, to your point to make that a little clear, um, and projects are doing that now, by the way, but I think it's good to have it clear about what expectations are.

Next Speaker: **** what definitions.

Next Speaker: Yeah.

Next Speaker: Okay.

Next Speaker: Yeah. Exactly. Um, okay, so moving down to, um, informed consent on Page 13, um, we talked a lot last time –

Next Speaker: ****?

Next Speaker: Oh, yes?

Next Speaker: Um –

Next Speaker: Hello?

Next Speaker: Can you hear me?

Next Speaker: Yes.

Next Speaker: Uh, kinda.

Next Speaker: You can? Okay so before we move on to No. 10, um, or from No. 10, can we add to No. 10 after submit detailed quarterly data in a format required by the Authority and as detailed in the approved evaluation and monitoring plan?

Next Speaker: Can you say that again?

Next Speaker: I don't understand.

Next Speaker: I don't understand why.

Next Speaker: Well, **** 10 it says submit detailed quarterly monitoring data in a format requested by the Authority and then just after that add the words and as detailed in the approved evaluation and monitoring plan. This goes back to my earlier comments about making sure that requests of the project have a process, um, shows a process and that process is to add those things to the evaluation and monitoring plan so that there's a, there's a start date and there's clear instructions for what those are and what, what the expectations are.

Next Speaker: Okay, okay. Do you have any questions about that?

Next Speaker: I mean, the purpose of this section is for the monitoring by the Authority not by, not for –

Next Speaker: Their –

Next Speaker: – the, the evaluations **** of the project themselves. Um –

Next Speaker: This is how we get the data from the project so that we can do our part, right?

Next Speaker: But then are you pulling the data or is the project pulling the data? Because if the project is pulling the data then in, in the format requested by the Authority that should go through the, that should be part of the evaluation and monitoring plan. You know, so that –

Next Speaker: **** the, using that in their evaluation monitoring plan but they're not required to.

Next Speaker: But, I –

Next Speaker: This specific injury Heather. I think, I mean, I recall this too, we were talking about the importance of, um, being transparent, up front, um, and building and to evaluation plans, um, the types of information and reports that the Authority is gonna wanna see so that programs can be collecting this information all along rather than trying to scramble and produce it later. Um, so I'm not sure why there can't be more transparent or referred to, I mean, I would think that if the Authority is gonna be requesting information on a quarterly basis that should be known ahead of time.

Next Speaker: Okay.

Next Speaker: But –

Next Speaker: No, there's a different, I'm, I'm sorry, I, I, maybe I'm confused and I don't understand. I apologize. We're talking about transparency. We're talking about being transparent to all stakeholders and we're talking about evaluating something, um, well, who are we being transparent to if we're trying to, if **** wants to evaluate something. What, where, I don't understand where there's not transparency there. Why does there need to be transparency there?

Next Speaker: All I'm saying is that the project, the, there should be a description of what is gonna be monitored quarterly.

Next Speaker: I –

Next Speaker: So that the project can gather that on an ongoing basis and prepare that.

Next Speaker: But, but that is such –

Next Speaker: It shouldn't be a surprise to them.

Next Speaker: It's too broad to put in a rule because every project is so specific. OHSU, um, has a detailed data report that's much, much, much smaller than the other project which has hundreds of lines of, of data points and **** because of the –

Next Speaker: I don't think we can get overly specific here, uh, without locking ourselves in.

Next Speaker: Well I think –

Next Speaker: Well it's –

Next Speaker: – what we can do potentially is say that the details will be, you know, in accordance with the evaluation plan.

Next Speaker: Well, but that's not –

Next Speaker: For each project –

Next Speaker: But the purpose here is not, is, it's separate from the evaluation.

Next Speaker: There's two things happening. You've go the projects doing their evaluation on their own and OHA is responsible for completely separate evaluation of the data.

Next Speaker: And, and one reason is to keep it open in case there is something comes up dur, during the course of the project that requires the Authority to, uh, look into something further if something is not, comes up that's not expected. I don't wanna be boxed in.

Next Speaker: So the way you're –

Next Speaker: No, I understand that. But why, why would the Authority not, you said they have a, you know, a detailed evaluation, you know, requirement with multiple components. Why would that not be shared with projects from the beginning?

Next Speaker: It, it should be.

Next Speaker: They're, we're not saying –

Next Speaker: Yeah, so that's the point –

Next Speaker: It is.

Next Speaker: – I'm making.

Next Speaker: 'Cause that's set forth earlier. What is to be shared.

Next Speaker: So this quarterly monitoring –

Next Speaker: Maybe that –

Next Speaker: – **** is that information?

Next Speaker: Maybe that, that will be shared with the project in advance, that makes sense. I just don't, I, I want to push back from saying that it, it automatically becomes part of the evaluation monitoring plan. Or is somehow tied to the evaluation monitoring plan which is –

Next Speaker: 'Cause they're two separate.

Next Speaker: – it's something designed and run by the project themselves.

Next Speaker: Yeah, that's fine. I, just my whole point here is that we, I think it's fair for everyone to know in advance what sort of data will be requested of them.

Next Speaker: Can you put in at least some sort of broad category?

Next Speaker: Yeah, we can put in categories.

Next Speaker: Yeah.

Next Speaker: Because the Authority should be able to request any and all the information. Correct? At any time?

Next Speaker: Okay.

Next Speaker: So this is, **** um, I, I guess my purpose is that, you know, there should be some written document for the project to go back to reference for any new requests. Like, I recognize and as our project has gone through many times with Oregon Health Authority, they receive something from us. They read it and they're, like, this is great but it would've been better with X change. So there needs to be some sort of process for the project and the Authority to go through for those types of requests so that the project has some ability to ask questions, some ability to get the instruction that they need in order to properly use the, the, you know, take the data, um, format request by the Authority so that, you know, the Authority can get what it's asking for so the project can deliver that and I think that, and so that there is a start date to any new requests. So, you know, for example, if you want the detailed data report and the first time you ask for it you did not include color of tooth. But then you're, like, oh gosh, it would've been really helpful to have color of tooth, and I'm just makin' stuff up here. Um, you know, so that from this date forward you would be required to provide this but you don't necessarily need to go backwards in time. Um, also helpful for when you're, you have a site visit and they say why didn't you do this thing? It's, like, well, because there's nothing in writing that told us to do this thing and it would just be helpful for there to be more things in writing for requests from the site, um, and for there to be a process so that the site can get the information that they need. So from my perspective from working **** project we want to give the Authority what they want. But we also, we also need the time and the ability to, to deliver that and we'd like it to be more of a collaborative process. And to your point, Dr. Beck, I think that was your voice I heard, yeah, the Authority can come in any time and say give us all of your records today right now and I think the rules already allow for that. I'm talking about things that need to be produced on a regular basis for the Authority. I'd like there to be some, um, process that those are approved by the Authority.

Next Speaker: Christina, this is Sara. What about a guidance document for approved projects? Would we be able to do something like that? Like, an outline?

Next Speaker: What'd you mean?

Next Speaker: For, like, each project could have a, um, like this is what we need from you. These are the elements that we'll need.

Next Speaker: So would that be another section where we say the Authority shall develop a guidance document outlining ongoing ****.

Next Speaker: I wouldn't put that in.

Next Speaker: And the reason why, the reason why I thought of, you know, as detailed and **** evaluation and monitoring plan, you know, our quarterly report requirements and other things like that are all, are all built into that evaluation and monitoring plan. So from my perspective it makes sense if this is a question related to monitoring data that it be built into the evaluation monitoring plan then we don't have to create something new. We don't have to create a new process. There's already processes for updating the evaluation and monitoring plan and it also re, reduces the number of guiding documents. I think the last thing that we want is there, for there to be ten documents or that **** project directors have to be wrangling into the standard operating procedures, um, you know, because for example, a detailed quarterly monitoring data will require some change to our standard operating just because it requires the project staff to do something to get that data for the Oregon Health Authority. So every, you know, this one in particular just has ramifications on the project so I think it's important and totally appropriate to add it to the evaluation monitoring plan.

Next Speaker: I just don't wanna require that.

Next Speaker: Let's, um, let's move on –

Next Speaker: Okay.

Next Speaker: – from this and, and we're gonna go down to dental pilot project informed consent, um, we're on the bottom of Page 13. Um, so this, so last time there's lots of language, fi we move over to Page, um, 14, this still goes into the informed consent, um, pieces and what we did is took the language that already exists in the Dental Practice Act and put it, um, under 4, what, this is confusing. 4 –

Next Speaker: 4 little a, big A.

Next Speaker: – big A and big B and then that, it basically says the same thing just in a, just in a more familiar way for dental people that are familiar with the Dental Practice Act. Um, on the top of Page 14 it does go over to 15 and talks about, um, PARQ, um, and then, um, so let's, so let's go through this, um, and on 14 just, does anybody have any questions? And then there is a question on Page 15 and we'll get to, um, it's hard when you're looking at two different ****.

Next Speaker: And that also was there anything on the beginning **** informed consent section back on Page 13.

Next Speaker: So we changed one thing on 3, on the bottom of Page 13, is we inserted the words at a minimum, um –

Next Speaker: Just so projects are not boxed in by that language.

Next Speaker: So projects can have more language on there but at the, at the minimum they need to have this there. And then if we look over to Page 15, still on informed consent D, informed consent for treatment must be obtained in writing for select procedures as required by the Authority and such consent must be included and documented in the patient's record. Um, so there is different, different procedures where you might verbally do, you know, I don't know, I'm trying to think verbally you might do sealants and document it in the chart, um, where extractions you may decide, um, so I did verify with the Board of Dentistry you are actually not required to have written informed consent signature for extractions. So, and I talked to Teresa Hanes about that so she, and I went, I couldn't find it either. The written informed consent is required under anesthesia for, um, I don't know if it's even Nitrous, I think it's more **** sedation, whatever. Um, so the reason we included the language in her for select procedures as required by the Authority would be to determine with probably the Technical Review Board that reviews the applications, what procedures would we want the, the project to have, trainees have, you know, if it's extractions or any other procedures. Does that make sense? It's a little bit, is that enough? Do I need to, we need to specify here any more?

Next Speaker: Well, you're in, I don't know how you're gonna specify what procedures would require written informed consent.

Next Speaker: Would they, would that be, that's where we need guidance document in general, I guess. Um, but would that be something we'd have to identify in approval?

Next Speaker: Yeah, could we do that there, there? If it's under scope of practice and we know they're doing these, you know, 15 procedures and we want them to have written informed consent for these two, or whatever, can we do that in the approval letter? Would that be **** that?

Next Speaker: If you request written informed, written informed consent, and I remember how this conversation was last time and I think the example I gave was that I overkill in my office so I have written four things that aren't actually required.

Next Speaker: Mm hmm.

Next Speaker: Um, but the only thing we require written for from a Board perspective is IV anesthesia or deep moderate or general anesthesia.

Next Speaker: Right.

Next Speaker: And not for Nitrous or anything below. Not for ****. They have to be in the chart but not written with, with a signature unless we're treating a minor which is a different issue. And so, um, I don't think that if I'm correct that the scope of any of these pilot projects would be including a trainee administering IV anesthesia or a deep moderate sedation orally.

Next Speaker: Right.

Next Speaker: I, I, I think that –

Next Speaker: No.

Next Speaker: – I don't think that would happen so I don't know that we need to necessarily require at a minimum anything that is a written informed consent. But it just has to be **** or equivalent in the chart.

Next Speaker: Well, we're requiring them to do written informed consent to see if the trainee and that is back, um –

Next Speaker: Wait –

Next Speaker: And that's okay with the same –

Next Speaker: So we've got two things here.

Next Speaker: Okay.

Next Speaker: We've got the trainee, ****.

Next Speaker: Mm hmm.

Next Speaker: And then the procedures. So we've got two, two pieces to this.

Next Speaker: Okay. Okay.

Next Speaker: So, um, back on Page 13, top of, uh, Informed Consent No., No. 1, um, give written consent to be treated by the dental pilot project trainee and gives informed consent for treatment by the trainee.

Next Speaker: Okay.

Next Speaker: So written, for sure, we have. So are you comfortable with following what would be standard practices **** under the Dental Practice Act for treatment? So that would mean that you would not have written, you would not have written consent. The way that we have it here is it gives the Authority flexibility in requiring consent for certain procedures like extractions.

Next Speaker: I, I like the idea since this is a trainee to have that consent to know that, you know, this is what they can or cannot do and these are the procedures. So I like having that clarification there versus you know, a licensed dentist, you know, it's a little bit different in EPA but I think the training tech program the dental students, I mean, we have to sign everything.

Next Speaker: Yeah, yeah.

Next Speaker: Because it's in training?

Next Speaker: Correct.

Next Speaker: Because it's the training program.

Next Speaker: Okay.

Next Speaker: So there is, that's true, there are written consents and signed consents. 'Cause we have to sign off on all their work.

Next Speaker: Yeah.

Next Speaker: So it's a little bit –

Next Speaker: Okay.

Next Speaker: – a little bit different. But, yeah.

Next Speaker: So the way its written here, um, is we would have, um, I'm just trying to think like how, how we would do –

Next Speaker: I just don't know why, I mean, I think if you want, if what you wanna do and it's your policy call about requiring written informed consent that shouldn't change depending on the pilot project. So I think you just need to say in rule which procedures require informed consent. Just, you know, prior approval by the Authority is just, I think, an unneeded extra stuff.

Next Speaker: Okay. So let's talk about what procedures we'd require informed consent. Right now we're requiring it for oral surgery, um, on the second pilot project. The first pilot project, um, is doing written informed consent for ITRs. Would we have required that? Probably not but their IRB process through OHSU would require them to do that. So these are, this needs to be flushed out.

Next Speaker: Well one of the things –

Next Speaker: Maybe we can –

Next Speaker: – that I think is, is good as far as, as a training procedure is it, it forces the individual, the healthcare provider to, I mean if they're doing it correctly, to sit down and have a conversation with the patient. I mean, I can after the fact write **** in my chart if I'm dishonest and say I had a conversation but it, if I have to get a signature they had at least, the patient at least had to have read that and presumably I had a conversation with them answering their questions and engaging with them. So from a training perspective I, I see nothing wrong with, in fact I like the idea of having, of going above what the standard is and having for all procedures maybe, you know, we talked about too a couple meetings ago about, um, do we, do we have to **** for every single, you know, if we have a treatment plan listed with five things to do on someone. Do we inform consent them each time they come in? There was a discussion about that so there's, there's, there's a, uh, uh, a written informed consent at the beginning unless the treatment plan changes you really don't need to do another informed consent over fillings, um, crowns, that type of thing. Once we start getting into more invasive things like endo, extractions, um, uh, statement, well endo and extractions then I, I think informed consent –

Next Speaker: Would you say –

Next Speaker: – written informed consent.

Next Speaker: – irreversible procedures?

Next Speaker: Well that would all –

Next Speaker: That's all –

Next Speaker: That's everything, right?

Next Speaker: Well, ****.

Next Speaker: That's sealants too.

Next Speaker: Well, that's a good point, uh –

Next Speaker: That's, that's, therein lies the thing. Are you gonna get written informed consent for somebody coming in and having a ****? Or having an X-ray? So that's why we need to be specific here.

Next Speaker: Yeah.

Next Speaker: 'Cause that's onerous on the project to get, I mean, you know what I mean? Like to come in and have to sign –

Next Speaker: Right.

Next Speaker: – for, for an exam.

Next Speaker: Right.

Next Speaker: For a fill, I, you know what I mean. So that's, I think that that's –

Next Speaker: Well, it is onerous but if you think back to school that's exactly how it's done.

Next Speaker: Right, but if it –

Next Speaker: But these aren't provided in school settings. So –

Next Speaker: Yeah.

Next Speaker: No but they're being trained.

Next Speaker: Right.

Next Speaker: They're being trained.

Next Speaker: Exactly.

Next Speaker: And so if we're going to, if they're gonna be trained in the standards that we're training our dentists and hygienists that, that's where I'm coming from is why would we not apply the same standards for training?

Next Speaker: If it's for preventative care like sealants and **** varnish, you know, we're really trying to get a ton of kids especially in to be seen and so it's actually just gonna kind of clog up the workflow. **** reversible procedure, irreversible procedure I totally understand having informed consent. You know, as for each, each visit.

Next Speaker: So you could say irreversible procedures, like, if we're just thinking about this, are sealants considered irreversible?

Next Speaker: I'd say so because let's say we have –

Next Speaker: They're very hard to get out.

Next Speaker: Yes 'cause you have to cut out the burr and two, if you don't do it correctly you ****, right?

Next Speaker: Yeah, underneath them it's masked and you don't find out until way later.

Next Speaker: But I would wanna make sure that –

Next Speaker: But should we have a dentist or someone trained to make sure there's no decay before someone slaps a sealant on?

Next Speaker: No, we're, no.

Next Speaker: We're getting very descriptive now.

Next Speaker: That's, yeah, that, and that goes, I'm just saying no because of all the EDPHs that are out there doing sealants and sealant programs and they don't, they don't need a dentist goin' in there and doin' that.

Next Speaker: Okay, yeah.

Next Speaker: And it would be quicker for me to just do it myself than go in and check it.

Next Speaker: Yeah.

Next Speaker: Check to see if it needs to be done and that kinda defeats the purpose of having this provider.

Next Speaker: No, right, exactly, and that's the whole, I mean, yeah, you're just creating barriers which is –

Next Speaker: And I think we need to include new skills in that.

Next Speaker: What'd you mean?

Next Speaker: So I mean, if you're saying that the sealant being irreversible. Well if it's say a hygienist who's being trained. They already do sealants so they wouldn't need to sign a consent –

Next Speaker: Oh, I see what you're saying –

Next Speaker: – for sealants 'cause they're part of –

Next Speaker: So –

Next Speaker: That they're already licensed.

Next Speaker: – they're licensed.

Next Speaker: So it's project dependent.

Next Speaker: Mm hmm.

Next Speaker: Okay. All right, so we need to think about this.

Next Speaker: Mm hmm.

Next Speaker: A lot. I mean, **** okay. Um, so I'm just gonna make a note here, um –

Next Speaker: So is the question on the table still what need to be written versus what just needs to be –

Next Speaker: Mm hmm.

Next Speaker: Yeah.

Next Speaker: – vocalized or written in the chart, right?

Next Speaker: Yeah.

Next Speaker: What needs to be signed versus in the chart?

Next Speaker: Right.

Next Speaker: Okay.

Next Speaker: I mean, and, and I kinda like the idea of, you know, just kinda what is standard or care for extractions, Nitrous, you know, would be kind of the two procedures that we're looking at that are, that are being done by current projects and probably –

Next Speaker: Mm hmm.

Next Speaker: – future projects that would, 'cause they're, they're not going to, I don't know, they're not gonna be prescribing, um, like an anti-anxiety medication that would be from the dentist so they wouldn't have to have that consent.

Next Speaker: Right.

Next Speaker: **** right.

Next Speaker: So –

Next Speaker: Okay, we will, um, go back –

Next Speaker: And they're not doing root canals.

Next Speaker: – **** this and flush it out because it's not –

Next Speaker: **** times.

Next Speaker: No, they're doing ****.

Next Speaker: **** simple.

Next Speaker: **** question is, is that –

Next Speaker: That's I have, no, I haven't done –

Next Speaker: ****.

Next Speaker: – it in 20 years.

Next Speaker: Yeah.

Next Speaker: That can go wrong really fast too though, right? A, a simple **** the pulpae **** floor and then all of a sudden this kid gets an abscess, and the person training doesn't recognize that, you know, come a week, 2 weeks they're **** big abscess or it's in a lot of pain ****.

Next Speaker: Which is why they're under, um, under supervision. So they're not doing, I mean, yeah, okay.

Next Speaker: And keeping in mind too that informed consent, whether it's in a written or –

Next Speaker: Mm hmm.

Next Speaker: – a verbal form, and documented, that's honestly more to protect the provider than it is, I mean, let's be honest here, than it is to –

Next Speaker: Yeah, yeah.

Next Speaker: – protect the patient. You want the patients to know what's going on **** but I do that to cover my butt.

Next Speaker: Sure.

Next Speaker: You know, and so, I think anything we can do to make the programs better for themselves, I think that's also very helpful.

Next Speaker: All right, so, um, we will continue that conver-, I mean, I will go do some research and figure out how we're going –

Next Speaker: Yea.

Next Speaker: – fun. Okay, so, now I'm still Page 15, um, so, we included, um, language here, and I believe that G, should have been red, I don't know why it's not red but –

Next Speaker: **** purple?

Next Speaker: Mine's purple, I don't know. Um, G was this new, a process for regular evaluation of project activities across the lifecycle of the project for continuous quality improvement purposes. Any changes in project activities must be approved by the Authority. So, this is pilot, this is under this pilot project evaluation and monitoring by the sponsor. So, this is what the project is doing. So, their process for continual quality improvement, like, do you have anything, I mean, you're, you, you found –

Next Speaker: This is, this comes from CDC language for best practices at program evaluation. Um, just to have that, that ongoing, the idea that evaluation plan is a living document, that's fine **** that intervals. Any questions?

Next Speaker: So, when you say regular evaluation, are you putting a timeframe on that, like –

Next Speaker: That's **** project.

Next Speaker: Okay.

Next Speaker: 'Cause that's highly specific.

Next Speaker: Yeah, okay.

Next Speaker: I believe –

Next Speaker: **** on, so –

Next Speaker: Yeah.

Next Speaker: And changes in project activities, you're not like talking about scope of practice or anything like that.

Next Speaker: Like project evaluation activities –

Next Speaker: Okay.

Next Speaker: – is what I was meant there ****.

Next Speaker: Should we say that?

Next Speaker: Yeah.

Next Speaker: That doesn't really go here, right?

Next Speaker: I just wanted to make clear that they, they should re-evaluate their evaluation plan regularly, make sure it's working, it's undergoing the, it's working correctly for the purpose. Um, if they want to make any changes they can't just do it without notifying the Authority. That was –

Next Speaker: Yeah.

Next Speaker: This is changes to the scope of action, activities –

Next Speaker: Mm hmm.

Next Speaker: – this is changes to the evaluation, the plan in particular. So, I don't know the correct language to put in there legally to say that it has to be notified and approved by the Authority, but the evaluation plans had, by necessity change over the lifecycle of the project.

Next Speaker: Okay.

Next Speaker: I think it needs to be a new, like it would be a Subsection 3 and it would say –

Next Speaker: Okay.

Next Speaker: – if the, if the sponsor, you know, is making any substantive changes to this evaluation and monitoring plan needs to submit those to the Authority –

Next Speaker: Okay.

Next Speaker: – if they were approved before they can make the changes.

Next Speaker: All right, so we'll make that a whole new section. Okay, so let's move on to the top of Page 16. Um, we still have under, we still have ****, so under Patient Safety, No. 4, um, we have changed this language. It's still a little confusing. Um, it did say employment utilization site compliance. Now we have site compliance with evaluation plan. Is that still ready? Anybody have any questions about that?

Next Speaker: What, what is meant by site com-, site compliance in the evaluation plan? Does that mean they're doing they're evalu-, they're complying with their own evaluation plan?

Next Speaker: They're collecting their data at each site.

Next Speaker: It's sort of a check that, that since the, in the hierarchy of a project the sponsors are the ones that actually interact with the OHAs. We need to make sure that they're actually getting the correct information back to the sites and the sites are doing what the sponsors say they're doing.

Next Speaker: So –

Next Speaker: That's my understanding anyway.

Next Speaker: – when, when the submission of the evaluation plan on time consistently be proof that they're complying with their evaluation plan?

Next Speaker: No.

Next Speaker: No?

Next Speaker: No, I mean, this is, um –

Next Speaker: We're talking about data, right? Doesn't the evaluation plan include data?

Next Speaker: Mm hmm.

Next Speaker: Yeah.

Next Speaker: ****.

Next Speaker: This section could go, this line could go under –

Next Speaker: ****.

Next Speaker: – or it could go under, um, under site –

Next Speaker: Yeah.

Next Speaker: – visit –

Next Speaker: Yeah.

Next Speaker: – because that's where you would –

Next Speaker: ****.

Next Speaker: – and, and that, yeah, I don't think that makes sense in here anyway, but putting it under, uh, oh, under the site ****.

Next Speaker: Which we already –

Next Speaker: We go by that, oh, it's down here in the next section.

Next Speaker: Yeah.

Next Speaker: But so, down under, so if we're under, um, we're still on Page 16, so, under 2B, site visits shall include but are not limited to two, determination that adequate patient safeguards are being utilized, and then B, validation of the project is complying with the approved or amended application. So, if we go back up to the top of 16, that you can strike the language site compliance of evaluation plan because the purpose of B, the validation, the evaluation plan is part –

Next Speaker: ****.

Next Speaker: – of the application part of that.

Next Speaker: Yeah.

Next Speaker: So why would you, it's kind of redundant.

Next Speaker: Mm hmm.

Next Speaker: Yeah.

Next Speaker: So, let's just strike it, it's confusing and redundant.

Next Speaker: Okay. Um, and then under C, um, at bottom of Page 16, **** reviews of patient records to evaluate patient safety, training competency, quality of care, minimum standard of care, and compliance with the approved or amended application. Anybody, this is like the actual chart reviews that OHA requests, um, a certain percentage of charts from the project, and then, um, individuals on the advisory committee that are –

Next Speaker: Providers of that service.

Next Speaker: Yeah, you have to be able to, like you have to be right, you have to be a dentist.

Next Speaker: **** providers **** practice **** project.

Next Speaker: Yeah. So, does this sentence make sense the way that it's written? Is there any, any questions with it, anything missing? Okay. All right. Okay, so move to 7, Page 17. Um, okay, so this is where we asked, um –

Next Speaker: So this is the, any requests for patient records would give, be given 14 days notice to –

Next Speaker: So they have –

Next Speaker: **** –

Next Speaker: – 14 days to collect 'em.

Next Speaker: – get them together. Um –

Next Speaker: We're giving 90 days notice of a scheduled site visit, so 90 days out, 3 months, whatever, we'll say hey, we're coming to **** um, and that is sufficient time, just to, I mean, that's what we do in practice, so it's not, that's what we do now. We, we do the, that, because we know if you're scheduled, you know, 6 months out we wouldn't surprise you. There is a provision in here, um, unless there are concerns about patient or training safety, we would then say hey, we're coming, and we'd just come.

Next Speaker: Okay.

Next Speaker: So, um, that's under –

Next Speaker: That was C.

Next Speaker: – yeah, the, I guess it's what, it's hard to read these since there are all these people. Um, and then we have the, all these steps in here and –

Next Speaker: And that, none of that's changed ****.

Next Speaker: – yeah, and all of that is exactly the same, um, from last time. Anybody have any questions on that before we move down to project modification? We're still on Page 17.

Next Speaker: **** this is Christina Peters, can you hear me?

Next Speaker: Uh, yep, I can. I didn't –

Next Speaker: Hi.

Next Speaker: Hi.

Next Speaker: The **** and the, not to continue to be a broken record, but, um, No. 4, um, requests the records, I'm sorry, um, information and documents in a manner requested by the Authority or within the timeframe requested by the Authority, I think there are special circumstances where you might want something because you're concerned about patient safety and that's totally fine, but I think that if there are regular reports and documents that you're requesting from the sites that there should be language, um, tying it back to the approved evaluation and monitoring plan. I just think it's really hard for the site to hit a moving target, and it would be for any pilot project going forward, um, I think it would be really helpful to have some process whereby if the Authority is gonna make requests that there be some process and some timeframes for that request to go into, um, effect, and some ability for the project to have a dialogue with the Authority about how to best present that information.

Next Speaker: So, you're on No. 4, failure of a sponsor or anyone involved with an approved –

Next Speaker: Right.

Next Speaker: – project to cooperate.

Next Speaker: Yeah, yeah, because I think that if you add the language on the second sentence, failure to cooperate included but is not limited to say or to provide information or documents in a manner requested by the Authority, I think you should add, in accordance with the approved evaluation and monitoring plan.

Next Speaker: So, so **** -

Next Speaker: Um, or within the request of the Authority. This just goes back to my earlier comment about, you know, not putting the sites or any project in a, in a situation where they, they, um, are subject to re-, like regular requests that are in a constant state of changing. There should be some process, um, for the site to protect them from arbitrary –

Next Speaker: This –

Next Speaker: – ****.

Next Speaker: Well then, so –

Next Speaker: But I think you, if you terminate the project dates on 'em.

Next Speaker: So the, the, I think one of the reasons why they have, we have language in here stating that a project doesn't want to give us charts. Um, that's not in your evaluation and monitoring plan. There's nothing in there that says anything about charts, but if, if, if a project **** I'm not giving you Chart No. whatever, that, that, that we ask for, that wouldn't make sense the way that you're saying it, if you included the language that you're recommending.

Next Speaker: Hi, this is Heather. Uh, I completely agree with Christina on this, and, I mean, with the chart re-, charts you mentioned about in the section that we just discussed that you'll be requesting charts.

Next Speaker: But what if you didn't give 'em to us. This No. 4 is, is saying OHA –

Next Speaker: No, I don't, I don't disagree that there should be a clause in here that if, you know, that's similar to this, but like Christina is saying, I think that these, this information and reports should be spelled out clearly, um, I'm just referencing it as OHA's monitoring plan for the project, they should know what it is, um, and this is just sort of speaking very generally about any information. So, I think from my perspective, uh, I'd like to see these periodic routine reporting deliverables spelled out and known to projects at the beginning, and then referred here in this paragraph, especially since, you know, you know, given the risk that's here.

Next Speaker: This is Todd Beck. Um, I, I think, I, I hear what you're saying, and, and that does make sense if we're talking about routine reporting, but this clause, if I'm understanding it correctly, speaks to a little more dire situation where the Authority has requested something and the project, for whatever reason, has not provided it, and there's a real urgent reason for that. I think there needs to be a clause that says the Authority can go in and get what they need if, and there's no time restrictions on it. There's, there's no, we don't have to give warning, and I don't mean we, I'm not on the Authority, but the, I, I'm sort of mixing in my job on the Board. If we have something that is sig-, that is egregious and we're concerned about it, we'll show up on the dentist's doorstep with an investigator and demand right now to have things. So, I think there has to be a provision that allows the Authority, um, uh, if something is egregious or there's a noncompliance issue, there's not gonna be any warning to the program. We want, the Authority will want the stuff and will want it right away, and I think that's, I don't think this provision will be invoked very often, but I think it needs to be there so that if we're not, if, I keep saying we, I'm sorry, if the Authority is not given the information that they've requested, that they have a venue to get that. I think that's really important to leave that in there.

Next Speaker: Well I –

Next Speaker: I –

Next Speaker: I think that this is, I'm not sure where the Bullet Point No. 3 went in this section, but this bul-, this Subsection 4 is a little bit separate the way I'm reading it from when the Authority responds to issues.

Next Speaker: And this is Christina. Todd, I agree with you, if there is an issue where the Authority, uh, feels that there, somebody is in danger, they should absolutely have the authority to show up that day, demand information, whatever they need, um, but you could, and I'm not a lawyer and I would ask any lawyer in the room, um, but you could, if the language in here doesn't specify, it's not specific to charts or emergency situations, it really just says any information or documents **** requested by the Authority. I mean, they can walk in and say we want all of the reports on peach scented bunny paper, and if we didn't comply with that, we could, based on the open nature of this, this language, have to do that or be out of compliance.

Next Speaker: I think that's **** but, uh, I, I think we should just leave it the way it is. Um, 'cause I, I think **** like you get pulled over by a police officer it's license and registration. You don't give that information, you get a ticket, you know?

Next Speaker: Well, I don't think –

Next Speaker: It's **** –

Next Speaker: I don't this is ****.

Next Speaker: – rules and I feel like you guys want certain exceptions, uh, for whatever reasons I don't understand, but I think rules are rules, and you, they're made to be followed, and I think we're here to protect the public and the patients that are in the chair, and I understand that this is an important topic, but just because we want something doesn't mean we should. At the end of the day, we need to protect these patients, um, and so I think we need to be very careful here what we're doing.

Next Speaker: Okay, anybody have anything else to add to that?

Next Speaker: Yes.

Next Speaker: Go ahead.

Next Speaker: I appreciate that we're not, I mean, having, giving the project, um, some sort of written process perhaps to provide regular quarterly reports does not put the public in danger, and it's not an exception. I think that any project and anybody who's **** a project would appreciate not having a moving target when they're, when they are, um, when they're, uh, making plans for the resources within their projects, you know, and for a real concrete example, we were asked for a detailed data report last year, and, you know, if you go through our site visit reports, the first time we did that it was terrible. It was terrible because all of our requests for information from the Authority were not responded to, and it was several because we didn't, we didn't really understand what was being asked of us, and so, and then the next time we went through the process we had a lot more access to the information that we needed, it was a little bit better, but it still needed more, like it still needed more time, and once the Authority got the better, the better report they were like oh, actually it would be even more better if you did this other thing, and so, I just want there to be some process for asking for regular things. I'm not talking about emergencies, I'm not talking about when they believe that

somebody's in danger. I'm just talking about regular reports and if you're gonna, if you're going to have language, **** language in here that says that you're gonna, you're gonna, uh, suspend or terminate a project if you're not getting what, if you're not getting an information or document, I think it should be specific if you're talking about **** in situations ,and I think, or you should exempt things like regular reports, but I do feel very strongly that it needs some process for requiring regular reports from the, from the projects.

Next Speaker: I'm just, maybe I'm being altruistic here, but going through this revised process and clarifying this as much, I think any project coming into it now has more clarity than there has been, so I would hope that that would kind of take care of this from the onset, not looking back at, at what issues had occurred specific to one project, we're talking about the umbrella for all, I mean, as I look at this, there's much more clarity now –

Next Speaker: In the specific reports that were requested?

Next Speaker: – ****. I'm sorry?

Next Speaker: The specific reports that are requested of the programs, so, what's clear to you now?

Next Speaker: Well, being included in, in all of their evaluation criteria –

Next Speaker: Yeah, I know that some things –

Next Speaker: – **** evaluation **** –

Next Speaker: – have changed –

Next Speaker: – insight on that.

Next Speaker: – as we've been going along and people have had to stay way past regular working hours to make it happen, so, I know that it definitely has been an issue in our clinic, um.

Next Speaker: So, are you okay with the first, the, so it says two sentences here, failure of a sponsor or anyone involved with an approved project to cooperate with a request for records, interviews, or a site visit, is ground for the Authority to suspend or terminate a project. That's the first sentence –

Next Speaker: Oh.

Next Speaker: – and in the second sentence –

Next Speaker: What about a corrective action plan? The language has been very extreme for such a vague sentence.

Next Speaker: It says grounds for it, it doesn't say it will happen. It says grounds for it, and I, this is Todd by the way. It says ground for it, and we have the same type of wording when it comes to dealing with licensees, um, rarely do we ever take a license or take away anybody's ability to make a living, but we have to have the in-, we have to have the authority to do that should it be necessary, and that's what grounds for means.

Next Speaker: Okay, so we do need to stop here because we need to do, um, uh, well, is there anybody in the room that would like to do public comment? No, okay, anybody on the phone that would like to do a public comment? Okay, um, so, we, my question, so no comment, no public comment? Okay, Shannon?

Next Speaker: Mm hmm.

Next Speaker: This section about failure of a sponsor and cooperation and that kind of stuff, would it better be to be moved, move this whole section into the suspension or termination of a project? Would that be better fit there?

Next Speaker: Yeah, it probably goes there, and, you know, then you'll see that, I mean, if the Authority were to take that step right there would be a notice, there would be an opportunity for hearing, and so I think that, you know, provides sort of a check on the con-, you know, the concern about ****.

Next Speaker: It would trigger due process, just like –

Next Speaker: Like OHA ****.

Next Speaker: – administrative law does, right?

Next Speaker: ****.

Next Speaker: Right, and if, you know, and if the Authority said well we asked for records on, what was it, pink bunny scented paper or whatever, um, and they didn't give it to us, you know, they gave it to us on white paper, first of all I would advise them not to take that action, um, but you know, an administrative law judge would –

Next Speaker: Probably slap that down.

Next Speaker: – probably slap that down.

Next Speaker: Okay. So, and our, so we have some more stuff to do, yay, and we are going to, um, be meeting on –

Next Speaker: The 23rd.

Next Speaker: – the 23rd.

Next Speaker: **** a legal question, if you don't mind. So, if the Authority should shut down a program, I just want to know if it works like it does, 'cause this is under the **** of administrative law, correct?

Next Speaker: Right.

Next Speaker: So, if the Authority should shut a program down for whatever reason, um, that program can go to an ALJ and say, and get a stay until the hearing, correct? So they could be back in business until the hearing? 'Cause that's the way dentists do it, and I'm just wondering if it's the same process?

Next Speaker: Right, so unless it was an emergency suspension because of, you know, some kind of imminent threat to public health and safety where the project would get shut down before they get a hearing.

Next Speaker: Okay.

Next Speaker: Um, normally how it works is you issue a notice that would say we intend to suspend or terminate the project –

Next Speaker: ****.

Next Speaker: – you have the right to request a hearing, and during the he-, during that sort of hearing process they can continue to operate.

Next Speaker: Okay, okay.

Next Speaker: Yeah.

Next Speaker: Okay.

Next Speaker: Yeah.

Next Speaker: Okay, thanks.

Next Speaker: Okay, so we are gonna conclude the meeting. Thank you all, see you in 2 weeks.

Next Speaker: Thank you.

Next Speaker: Okay, bye-bye.

Kowalski Sarah E

From: Kowalski Sarah E
Sent: Tuesday, July 10, 2018 9:36 AM
To: Christina Peters; Conor McNulty (cmcnulty@oregondental.org); Schwarz Eli; Emily Wineland ; Hai Pham; Heather Simmons ; James McMahan; Jennifer Clemens (jenclem76 @msn.com); Laura McKeane ; Quanita Anwar; Shannon English; Todd Beck
Cc: Austin Bruce W; Wilcox Cate S; Hansen Kelly; UMPHLETT Amy M; HALL Brittany A
Subject: Dental Pilot Project: Rules Advisory Committee: RAC Comments and Feedback
Attachments: DRAFT - Amended Dental Pilot Project - OAR - Redline - 7-5-2018 - Final.pdf

Importance: High

Thank you for those of you who were able to make it to yesterdays RAC meeting. We have one scheduled meeting remaining on the calendar on July 23rd.
In order to make the most efficient use of our scheduled time, if you have any comments or feedback, please submit them by COB **Monday July 16, 2018.**

All comments must be shared with <u>all individuals</u> on the RAC and will be part of the public record.

Please reply all to this message when submitting comments. Please be respectful and courteous of others and please be brief and succinct.
When commenting, please submit comments within the body of an email and please do not attach documents. Please use
the most recent iteration of the amended rules which we reviewed yesterday. (See attached)

Comment Format Example:
In reference to page #1: Dental Pilot Projects: Purpose: #3 a. Comment: This is where I would write a comment.

Thank You,
Sarah

Sarah Kowalski, RDH, MS
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Kowalski Sarah E

From: Heather Simmons <Heather.Simmons@pacificsource.com>
Sent: Tuesday, July 10, 2018 3:32 PM
To: Kowalski Sarah E; Christina Peters; Conor McNulty (cmcnulty@oregondental.org); Schwarz Eli; Emily Wineland ; Hai Pham; James McMahan; Jennifer Clemens (jenclem76 @msn.com); Laura McKeane ; Quanita Anwar; Shannon English; Todd Beck
Cc: Austin Bruce W; Wilcox Cate S; Hansen Kelly; UMPHLETT Amy M; HALL Brittany A
Subject: RE: Dental Pilot Project: Rules Advisory Committee: RAC Comments and Feedback

Good Afternoon Sarah and Committee Members,

I appreciate this additional opportunity to provide comment and revision suggestions.

My suggestions stem from a belief that future project sponsors need to be able to fully understand what is expected of them (for example, the types and frequency of data reporting). At the same time, clear expectations should not unreasonably limit OHA from acquiring data and information necessary to fulfill OHA's oversight responsibilities. I don't see how we can expect project sponsors to agree to future reporting of data without knowledge of what those elements might be and without the ability to evaluate their systems capabilities to collect and report this information. Project Sponsors should be given the opportunity to know what reporting deliverables may be required and to integrate such requirements into their Project Monitoring and Evaluation Plans. Towards these ends, here are my revision suggestions.

In reference to page 13, consider revising Section Dental Pilot Projects: Minimum Standards; Subsection 10 to read:
"(10) Submit detailed quarterly monitoring data, in the requested format, in accordance with the Authority's Pilot Project Monitoring and Evaluation description [Pilot Project Monitoring and Evaluation by Authority]."

In reference to page 15, consider revising Section Dental Pilot Projects: Pilot Project Monitoring and Evaluation by Sponsor to include new subsection (I) to read:
"(I) The Evaluation Plan must include a detailed description of the methodology and data sources to be used for collecting and reporting those data elements required as part of the Authority's Pilot Project Monitoring and Evaluation plan."

In reference to page 16, consider revising Section Dental Pilot Projects: Pilot Project Monitoring and Evaluation by Authority; subsection 1 (d) to read:
"(d) Quarterly submitted data as described in the Authority's Pilot Project Monitoring and Evaluation description and 333-010-XXXX [Minimum Standards]."

In reference to page 16, consider revising Section Dental Pilot Projects: Pilot Project Monitoring and Evaluation by Authority to include a new section 2 (move the current section 2 to section 3 and so on):
" (2) The Authority shall provide to Sponsor a detailed description of the measurement, data collection, and reporting requirements reasonably anticipated as necessary for the Authority to conduct evaluation and monitoring activities, including the Program Evaluation. To ensure the Sponsor is capable of providing reporting requirements to the Authority, the Authority's Pilot Project Monitoring and Evaluation description shall be incorporated into the Sponsor's final Project Evaluation and Monitoring Plan.

In reference to page 17, Section Dental Pilot Projects: Pilot Project Monitoring and Evaluation by Authority; Subsection (4) "Failure of a sponsor or anyone involved to…", this doesn't make sense (in my opinion) to be included here. Rather, why not move it to the section that discusses suspension and termination? Please consider striking and moving from page 17 to page 19; Section Dental Pilot Projects Suspension or Termination of Project under a new Subsection between the current (1) and (2) to a revised read of:

"(2?) In accordance with this Section, 333-010-XXXX Dental Pilot Projects: Suspension or Termination of Project, providing the Authority has communicated the concerns or areas of non-compliance that require remedy to the Sponsor, and the Authority has made available a reasonable corrective action period to cure deficiencies, and the Sponsor has failed to satisfactorily remedy the concerns and achieve compliance with requirements within 333-010-XXXX, the Authority may suspend or terminate a pilot project for the following reasons:

(a) Failure by a sponsor or anyone involved with an approved pilot project to cooperate, within requested timeframes, with the Authority's records requests, document reviews, site visits, interviews, and other investigatory activities related to serious concerns or suspected violations, and

(b) Failure by a sponsor to provide those data elements in accordance with the Authority's Pilot Project Monitoring and Evaluation description.

Kowalski Sarah E

From: Todd Beck <toddbeck@mac.com>
Sent: Monday, July 16, 2018 11:36 AM
To: Kowalski Sarah E
Cc: Christina Peters; Conor McNulty; Schwarz Eli; Emily Wineland; Hai Pham; Heather Simmons; James McMahan; Jennifer Clemens (jenclem76@msn.com); Laura McKeane; Quanita Anwar; Shannon English; Austin Bruce W; Wilcox Cate S; Hansen Kelly; UMPHLETT Amy M; HALL Brittany A
Subject: Re: Dental Pilot Project: Rules Advisory Committee: RAC Comments and Feedback

Importance: High

Hello all. Please find my comments below:

In reference to Page #6: Dental Polit Projects: Application Procedure 5(D) f:

> Background checks: I would be happy to speak about how the OBD handles positive background results; who evaluates and how decisions are made. I think its very important that the governing body (OHA) and NOT the projects have this oversight.

In reference to Page #8: Dental Pilot Projects Application Review Process #3:

> Evaluation of patient outcomes: this was a big problem with #100. Maybe we can look at #200 application and see what Dr. Schwartz put down and use that as the standard.

In reference to Page #13: Dental Pilot Projects: Informed Consent: 2(a):

> Patients should receive information about the trainee's education and training: there should be an explanation of the role and statute of the trainee, are they licensed, what level of education and training do they have, how long have they been treating patients, how is the trainee being supervised.

There is no rule to reference here, just my suggestion:

> Record keeping and compliance with DPA: I would say that the trainee should "ensure" that the clinic they are working in is in compliance with all rules and regs. The actual responsibility would lie with the supervising dentist… their license is on the line.

There is no rule to reference here, just my suggestion:

> The Advisory Board for a project shall be consulted on all aspects of a project ongoing. The Board shall have the authority to terminate a project, independent of the OHA. This should be codified in RULES.

There is no rule to reference here: just my suggestion:

There should be a Technical Board reviewing all project applications for compliance and this Board would be required to sign off on an application before a projects gets a green light. This would be independent of the OHA.

If any of this is unclear or if I am off base, I will be happy to discuss next Monday.

Have a great week everyone!
Todd

Todd L. Beck, DMD
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Kowalski Sarah E

From: Conor McNulty <cmcnulty@oregondental.org>
Sent: Monday, July 16, 2018 4:21 PM
To: Kowalski Sarah E
Cc: Christina Peters; Schwarz Eli; Emily Wineland; Hai Pham; Heather Simmons; James McMahan; Jennifer Clemens (jenclem76@msn.com); Laura McKeane; Quanita Anwar; Shannon English; Austin Bruce W; Wilcox Cate S; Hansen Kelly; UMPHLETT Amy M; HALL Brittany A; Todd Beck (toddbeck@mac.com)
Subject: Pilot Program Rules Advisory Committee - ODA Comments

Sarah and fellow committee members:

Thank you for the opportunity to provide further comment on the proposed rules. Please see below for our suggested changes and comments.

1. In reference to Page #1: Dental Pilot Projects: Purpose #1.

Comment: The purpose of the pilot projects is to **explore** methods which will improve access to oral health care….

Suggested revision:
The purpose of the Dental Pilot Projects are to explore innovative methods designed to improve access to oral health care, reduce oral health disparities, and improve the oral health of Oregon's vulnerable and underserved populations.

2. In reference to Page #1: Dental Pilot Projects: Purpose #3.

Comment: Existing projects should not be given more than 3 months to come into compliance with these rules. These rules are developed to ensure patient safety, project integrity and proper oversight.

3. In reference to Page #3: Dental Pilot Projects: Definitions #18.

Comment: Project Dental Director should be required to be a dentist. Preference is an individual who is licensed in Oregon, but they should at minimum be licensed in the United States. Remove language giving the Authority room to approve a non-dentist.

Suggested revisions:
(18) "Project Dental Director " – means an individual who is actively responsible for oversight of the dental pilot project and who is a dentist legally practicing in ~~licensed in~~ the State of Oregon. ~~The Authority or an individual approved by the Authority.~~

4. In reference to Page #3: Dental Pilot Projects: Definitions #21.

Comment: Supervisor must be a dentist only. SB 738 clearly states that the pilot projects can only be operated under the general supervision of a dentist licensed under ORS chapter 679.

Suggested revision:
(21) "Supervisor" means a person designated by the project sponsor who already possesses the skills to be taught the trainees and is licensed in Oregon to practice dentistry. ~~or dental hygiene.~~

5. In reference to Page #6: Dental Pilot Projects: Application Procedure 5 (D) f:

Comment: Agree with Dr. Beck's comments.

6. In reference to Page #6: Dental Pilot Projects: Application Procedure 5 (k):
Comment: include patient outcomes evaluation criteria in preliminary evaluation plan requirements.

Suggested language: (iv) how the project sponsor will monitor and evaluate patient outcomes

7. In reference to Page # 8: Dental Pilot Projects Application Review Process #3:

Comment: Add that the Authority will convene a technical review committee to evaluate the application and advise the Authority on whether to approve the application. Representatives from Professional Associations, the Board of Dentistry and the School dentistry shall be invited to participate. No one on the technical review committee shall have a financial interest in the project.

8. In reference to Page # 8: Dental Pilot Projects Application Review Process #5:

Comment: 10 business days is wholly inadequate for a public comment period. Pilot Projects are potentially creating a new type of provider, outside of a licensing process, otherwise without public input. If this is meant to be a true public notification for public engagement 30 days is minimum, but 45-60 would be ideal.

Suggested revision: Once the Authority project staff completes an application review, a Notice of Intent to provisionally approve or deny an application will be provided to the applicant. The and the Notice and application will be posted for public comment for a period of ~~10~~ 45 business days. The Notice will be sent to interested parties.

9. In reference to Page # 11: Dental Pilot Projects Minimum Standards

Comment: Trainees should need to comply with RPS standards for x-ray machines

10. In reference to Page # 11: Dental Pilot Projects Minimum Standards (d): DPA references

Comment: We encourage DPA references as previously requested and will be happy to share additional language.

11. In reference to Page # 12 (9) : Dental Pilot Projects Minimum Standards- Incidents reported to the OHA should also be reported to the Board of Dentistry. (Either directly, or OHA should report to BOD)

12. In reference to Page # 13: Dental Pilot Projects: Informed Consent: 2(a):

Comment: Patients should receive information about the trainee's education and training. Echo Dr. Beck's comments.

Suggested Revision: An explanation of the role and statute of the trainee, whether the trainee is licensed or unlicensed, the education and training of the trainee, and the availability of the trainee's supervisor for consultation.

13. In reference to Page # 16: Dental Pilot Projects: Pilot Project Evaluation and Monitoring by Authority 1(a)

Comment: Add reference to a project advisory committee under 1(a)

Add: the Authority shall convene an advisory committee, made up an interdisciplinary team members, representing licensing boards, professional associations who will advise the authority. The advisory committee shall advise OHA on any action taken in relation to the pilot project.

14. In reference to Page # 17: Dental Pilot Projects: Project Modification: 2(b)

Comment: Site changes should not be considered a minor modification. Any future sites should be included in the original application.

15. In reference to Page # 18: Dental Pilot Projects: Discontinuation or Completion of a Project 4(b)

Comment: The Authority, as a state agency, should **not** be advocating for the change of existing licensure laws. The report should be limited to the nature and outcome of the pilot project.

Suggested language: remove 4(b)

16. In reference to Page #19: Dental Pilot Projects: Suspension or Termination of Project # 2(a)

Comment: Concerned with the subjective nature of OHA deciding when to work with a project and when to terminate. Rules should be drafted clearly and concisely where when a project doesn't meet the established criteria, OHA simply terminates project. Advisory committee referenced earlier can help advise OHA when needed.
Suggested Language: remove 2(a)

Conor McNulty, CAE
Executive Director
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Kowalski Sarah E

From: JENNIFER CLEMENS <jenclem76@msn.com>
Sent: Monday, July 16, 2018 8:22 PM
To: Conor McNulty
Cc: Kowalski Sarah E; Christina Peters; Schwarz Eli; Emily Wineland; Hai Pham; Heather Simmons; James McMahan; Laura McKeane; Quanita Anwar; Shannon English; Austin Bruce W; Wilcox Cate S; Hansen Kelly; UMPHLETT Amy M; HALL Brittany A; Todd Beck (toddbeck@mac.com)
Subject: Re: Pilot Program Rules Advisory Committee

Thank you to the Committee for all of the thoughtful comments.

I'd like to add a comment around Conor's point #14. I think there should be some flexibility to add sites which are not included in the original application. It would be reasonable to have to go through an approval process prior to adding sites, but excluding the option entirely limits the pilot project and prevents it from taking advantage of opportunities that arise after the application is submitted.

Regarding the public comment period: is there a precedent for previous (non-dental) pilot projects? It would be nice to be consistent with how it has been done previously by other programs. An extended comment period makes sense, but deciding between 30, 45, or 60 days seems arbitrary and I'd like to see some evidence for why a particular decision is made.

Jennifer Clemens, DMD, MPH

Sent from my iPad

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 purpose of Dental Pilot Projects are to improve access to oral health care, reduce oral health disparities, and improve the oral health of Oregon's vulnerable and underserved populations.

(2) These rules establish the requirements of Dental Pilot Project applications; the process for reviewing applications; approval or denial of applications; minimum standards for approved projects; evaluation and monitoring of Dental Pilot Projects; suspension or termination of an approved Dental Pilot Project; and discontinuation or closure of a project.

(3) These rules apply to:

(a) Applications for dental pilot projects received on or after December 1, 2018; and

(b) Dental pilot projects approved before or after December 1, 2018.

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

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 the State of Oregon or another state, who is responsible for conducting a clinical evaluation of an approved dental pilot project; who is

unaffiliated with the project; and who has no financial or commercial interest in the project's outcome.

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

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

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

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

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

(6) “Complications” means a disease or injury that develops during or after the treatment of an earlier disorder.

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

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

(9) "Employment/utilization site" means an Authority approved site for use during the employment/utilization phase that provides care to vulnerable populations that evidence-based studies have shown have the highest disease rates and the least access to dental care. An employment utilization site includes any location where dental health care services are provided by a project’s trainees.

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

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

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

(13) “Project” means a Dental Pilot Project approved by the Authority.

(14) "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.

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

(a) Licensed in the State of Oregon; or

(b) That is exempt from state licensure under ORS 679.020 or 679.025.

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

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

(18) "Sponsor" means an entity that is a non-profit educational institution, professional dental organization, community hospital or clinic, coordinated care organization or dental care organization, tribal organization or clinic that:

(a) Submits a dental pilot project application; and

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

(19) "Standard operating procedures" means the written documented processes that describe the project's regularly recurring operations to ensure that the operations are carried out correctly and consistently and in accordance with these rules.

(20) "Supervisor" means an individual, certified or licensed in the State of Oregon to practice dentistry or dental hygiene, designated by the sponsor to oversee trainees at each approved employment/utilization site, with the skills necessary to teach trainees the scope of practice outlined in the approved project.

(21) "These rules" means OAR 333-010-XXXX through 333-010-XXXX.

(22) "Trainee" means an individual who is part of an existing category of dental personnel; a new category of dental personnel; or a category of previously untrained dental personnel who has agreed to participate in a project and will be taught the scope of practice identified by the project.

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

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

333-010-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 determines:

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

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

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

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

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

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

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

(D) Develop new categories of dental personnel.

(b) Sponsor information:

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

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

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

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

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

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

(c) Instructor and Supervisor information:

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

(B) Instructor-to-trainee ratio;

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

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

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

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

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

(B) The skills trainees are to learn;

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

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

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

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

(e) Trainees:

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

(B) The number of proposed trainees;

(C) The proposed scope of practice for trainees;

(D) Information regarding the background check process for participants to determine compliance with OAR 333-010-XXXX [Minimum Standards].

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

(g) Employment/utilization sites:

(A) A list of all employment/utilization sites the proposed project intends to use; and

(B) Documentation that shows that each site listed meets the definition of an employment/utilization site.

(h) Costs:

(A) The average cost of preparing a trainee, including but not limited to the costs related to instruction, instructional materials and equipment, space for conducting didactic and clinical phases, and other pertinent costs;

(B) The estimated cost of care provided in the project; the likely cost of this care if performed by the trainees of the project; and the cost for provision of this care by current providers.

(C) A budget narrative that lists costs associated with key project areas, including but not limited to:

(i) Personnel and fringe benefits for project director, project dental director, instructors, and staff associated with the project;

(ii) Contractors and consultants to the project;

(iii) Materials and supplies used in the clinical, didactic, and employment/utilization phases of the project;

(iv) Equipment and other capital costs associated with the project; and

(v) Travel required for implementing and monitoring the project.

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

(j) A preliminary evaluation plan that includes, but is not limited to:

(A) How the project sponsor will monitor and evaluate the project;

(B) A description of the key project activities and their intended effects;

(C) How the project sponsor intends to use the evaluation results for program improvement and decision making; and

(D) A description of intended patient outcomes and metrics.

(k) An identified clinical evaluator who will conduct the clinical evaluation of the project in accordance with the evaluation plan.

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

333-010-XXXX
Dental Pilot Projects: Application Review Process

(1) The Authority 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, then the Authority shall notify the applicant of the information that is missing and shall allow the applicant 30 business days to submit the missing information.

(b) If an applicant does not submit the missing information within the timeframe specified in the notice, then the application shall be rejected as incomplete. An applicant whose application is rejected as incomplete may reapply at any time.

(2) An application deemed complete will continue through a review process.

(3) The Authority may have individuals outside the Authority, including representatives of appropriate professional societies and licensing boards, review applications, but no individual who has contributed to or helped prepare an application will be permitted to conduct a review.

(4) The Authority may request additional information from an applicant during the review process.

(5) Once the Authority completes an application review, a Notice of Intent to provisionally approve or deny an application will be provided to the applicant. The Notice will be sent to interested parties and will be posted for public comment for a period of 30 calendar days, along with a link to the application and other materials submitted by the applicant.

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

333-010-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 [Application Review Process], the Authority 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 approval of an application; or

(b) A denial of the application.

(2) If the application is provisionally approved, the project sponsor must comply with the requirements in OAR 333-010-XXXX [Provisional Approval; Final Approval] before it can receive final approval. Projects that receive provisional approval may not operate until final approval is received from the Authority.

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

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

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

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

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

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

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

(1) A project sponsor that has been provisionally approved must, within 90 calendar days of provisional project approval, submit the following to the Authority for approval:

(a) A detailed evaluation and monitoring plan that meets the requirements in OAR 333-010-XXXX. [Pilot Project Evaluation and Monitoring by Sponsor].

(b) Written standard operating policies and procedures for the project that ensure compliance with 333-010-XXXX Minimum Standards. Standard operating policies and procedures shall include, but are not limited to:

(A) Clinical policies and procedures that describe the steps required for implementation of the project at each site;

(B) Administrative policies and procedures that describe protocols;

(C) Administrative protocols for mandatory record keeping;

(D) Data collection policies and procedure protocols that:

(i) Require data capture and data entry, including identification of the staff positions or other individuals responsible for these activities;

(ii) Define policies for protection and security of patient data;

(E) The protocol for orientating supervisors to their roles and responsibilities; and

(F) The process for ensuring that potential problems and root causes for deviations and non-conformances are identified, possible consequences assessed, actions to prevent recurrence considered, and corrective actions are taken if necessary.

(2) The Authority will review the documentation required in section (1) of this rule and notify the project sponsor if the plan and policies and procedures are acceptable. The Authority may request additional information and may request that the project sponsor revise the plan or policies and procedures to meet the requirements in these rules.

(3) Once the Authority has received an acceptable plan and policies and procedures, it will notify the project sponsor that the project has been approved along with the plan and policies and procedures. The final approval letter shall include:

(a) The permitted scope of the project;

(b) Any conditions the Authority deems are necessary to protect patient safety;

(c) Procedures for which the project will be required to obtain written informed consent for treatment under OAR 333-010-XXXX Informed Consent; and

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

(4) The Authority shall notify the Oregon Board of Dentistry when a project is approved.

333-010-XXXX
Dental Pilot Projects: Minimum Standards

An approved dental pilot project shall:

(1) Provide for patient safety as follows:

(a) Comply with informed consent in accordance with OAR 333-010-XXXX. [Informed Consent];

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) Date and description of examination and diagnosis;

(c) An entry that informed consent has been obtained in accordance with OAR 333-010-XXXX. [Informed Consent];

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

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

(f) Health history; and

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

(4) Have a sufficient number and distribution of qualified clinical and non-clinical instructors to meet project objectives, as identified in the approved application.

(5) Provide instruction to trainees following the training program outlined in the approved application by the Authority.

(6) Assure that trainees achieve a minimal level of competence before they are permitted to enter the employment/utilization phase. The sponsor must provide notice to the Authority within 14 calendar 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;

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

(c) Information regarding the trainee's responsibilities and limitations under Oregon Laws 2011, chapter 716 and these rules; and

(d) A disclaimer that there is no assurance of a future change in law or regulations that will allow them to practice without a license outside an approved dental pilot project.

(e) Trainee monitoring records shall be provided to the Authority.

(7) Comply with the requirements of the Dental Pilot Projects statute, Oregon Laws 2011, chapter 716; these rules; and the approved application including, but not limited to, the evaluation and monitoring plan.

(8) Evaluate quality of care, access, cost, workforce, and efficacy in accordance with the evaluation and monitoring plan approved by the Authority and as described in OAR 333-010-XXXX. [Pilot Project Evaluation and Monitoring by Sponsor]

(9) Within 24 hours of any incident involving a patient in the care of a trainee which results in any medical occurrence that is life-threatening, requires hospitalization, results in disability or permanent damage, requires medical or surgical intervention or results in death, the sponsor must ensure that a detailed written report, along with the patient's complete dental records, is submitted to the Authority by the supervising dentist.

(10) Submit detailed quarterly monitoring reports in a format prescribed by the Authority that include but are not limited to the following categories for the previous quarter:

(a) Accomplishments or highlights.

(b) Challenges faced and continuous quality improvement activities.

(c) Updated project timeline.

(d) Data Reports.

(A) A comprehensive breakdown of each of the data points the project is capturing in its approved evaluation and monitoring plan.

(B) Case-level data generated by the clinical evaluator.

(C) Number and type of any adverse event or complication that occurred during the reporting period.

(11) Follow written standard operating policies and procedures approved by OHA as outlined in 333-010-XXXX Provisional Approval; Final Approval.

(12) Use templates and follow guidelines for the submission of documents and other reporting requirements as prescribed by the Authority.

(13) Provide care only at Authority approved employment/utilization sites.

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

333-010-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:

(a) Is provided written information about the dental pilot project and who will be providing treatment;

(b) Gives written consent to be treated by the dental pilot project trainee; and

(c) Gives informed consent for treatment by the trainee.

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

(a) An explanation of the role and status of the trainee, whether the trainee is licensed or unlicensed, the education and training of the trainee and the availability of the trainee's supervisor for consultation;

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

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

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

"I _____[name of patient or person acting on patient's behalf] have 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 the procedure.

(A) Informed consent means the consent to a procedure obtained by:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(7) A process for ongoing quarterly monitoring in accordance with 333-010-XXXX [Minimum Standards.]

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

333-010-XXXX
Dental Pilot Projects: Authority Responsibilities

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

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

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

(c) Reviewing the quarterly reports submitted by the project as described in 333-010-XXXX [Minimum Standards.]

(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;

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

(D) Reviews of patient records to monitor for patient safety, trainee competency, quality of care, minimum standard of care and compliance with the approved or amended application.

(b) An interdisciplinary team composed of representatives of the dental boards, professional organizations, or other state regulatory bodies may be invited by the Authority 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 90 calendar days prior to the date of the site visit;

(d) Plans to interview trainees, supervisors, and patients or to review patient records shall be made in advance through the project director;

(e) An unannounced site visit may be conducted by program staff if program staff have concerns about patient or trainee safety;

(f) The Authority will provide the project sponsor with at least 14 business days to submit to the Authority required patient records, data or other documents as required for the site visit; and

(g) Following a site visit the Authority will:

(A) Within 60 business days, issue a written preliminary report to the sponsor of findings of the site visit, any deficiencies that were found, and provide the sponsor with the opportunity to submit a plan of corrective action;

(i) A signed plan of correction must be received by the Authority within 30 calendar days from the date the preliminary report of findings was provided to the project sponsor;

(ii) The Authority shall determine if the written plan of correction is acceptable no later than 30 calendar days after receipt. If the plan of correction is not acceptable to the Authority, the Authority shall notify the project sponsor in writing and request that the plan of correction be modified and resubmitted no later than 10 calendar days from the date the letter of non-acceptance was mailed to the project sponsor;

(iii) The project sponsor shall correct all deficiencies within 30 calendar days from the date of correction provided by the Authority, unless an extension of time is requested from the Authority. A request for such an extension shall be submitted in writing and must accompany the plan of correction.

(iv) If the project sponsor does not come into compliance by the date of correction reflected on the approved plan of correction, the Authority may propose to suspend or terminate the project as defined under [OAR 333-010-XXXX Dental Pilot Projects: Suspension or Termination of Project.]

(B) Within 90 business days of receipt of a plan of correction, issue a final report to the sponsor; and

(C) If there are no corrections needed, the Authority will issue a final report within 180 business days.

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

333-010-XXXX
Dental Pilot Projects: Project Modifications

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

(2) Minor modifications may 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; and

(c) Changes in project staff or instructors.

(3) Any modification to a project that is not a minor modification is not permitted and requires. the project sponsor to 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 calendar days prior to discontinuation. Notification must include a closing report that includes, but is not limited to:

(a) The reasons for discontinuation as a pilot project;

(b) A summary of pilot project activities including the number of persons who entered the employment/utilization phase; and

(c) A description of the plan to inform trainees of the project's discontinuation and that they are precluded from performing the skills authorized under the pilot project after discontinuation unless the provider type has been legalized by the State of Oregon.

(2) The project must obtain written acknowledgement from trainees regarding notification of the project's discontinuation and preclusion from performing skills authorized under the pilot project after discontinuation, unless the provider type has been legalized and the trainee has met necessary licensure requirements.

(3) Project completion. A project sponsor must provide a full report of findings to the Authority within 180 business days of the completion of the project in a format prescribed by the Authority.

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

333-010-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) Failure of a sponsor or anyone involved with an approved pilot project to cooperate with a reasonable request for records, interviews or a site visit is grounds for the Authority to suspend or terminate a project. Failure to cooperate includes, but is not limited to, failure to provide information or documents in a manner requested by the Authority or within the timeframe requested by the Authority.

(3) If the Authority determines that a dental pilot project is in violation of 2011 Oregon Laws, chapter 716 or these rules, the Authority may:

(a) Require the sponsor to implement an approved corrective action plan in accordance with 333-010- XXXX Dental Pilot Projects: Authority Responsibilities; or

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

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

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

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

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

CENTER FOR PREVENTION AND HEALTH PROMOTION
Oral Health Program
Kate Brown, Governor

Oregon Health Authority

800 NE Oregon St, Ste 370
Portland, Oregon 97232-2186
Office: 971-673-1563
Cell: 509-413-9318
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healthoregon.org/dpp

Quarterly Progress Reporting Requirements

All Dental Pilot Projects must submit **quarterly** progress reports throughout the duration of the project period. The report lengths and content vary depending on the pilot project. Such reports range from a brief summary to an exhaustive compilation of the project results.

The purpose of the quarterly progress reports is to update the OHA on the status of the Dental Pilot Project towards meeting the projects stated objectives as outlined in the approved Dental Pilot Project Application and the approved Evaluation & Monitoring Plan.

Initial progress reports will place emphasis on reporting activities. As the project progresses you will be reporting specific accomplishments. For example, describe major activities; significant results, major findings, developments, or conclusions (both positive and negative) and key outcomes or other achievements. Include a discussion of stated goals both met and not met. Provide information on specific program goals and their current status whether in-progress, completed etc. Address the progress made with reference to planned activities and milestones both achieved and delayed. Provide reasons and explanations for delays or changes and corrective action plans.

The Dental Pilot Project Program allows authorized organizations to test, demonstrate and evaluate new or expanded roles for oral healthcare professionals before changes in licensing laws are made by the Oregon State Legislature. The intent of the project is to prove quality of care provided, trainee competency and patient safety in addition to the larger goals of access to care, cost effectiveness and the efficacy of introducing a new workforce model.

Instructions: The following information should be submitted as part of the Dental Pilot Project Program quarterly reporting requirements as outlined in OAR 333-010-0435. If a category is not applicable, indicate N/A in that section.

1. Quarterly progress reports are public documents.

2. Patient confidentiality is a priority. Documents should not contain information that will identify any patient.

3. Follow submission instructions indicated under each heading, (i.e. Submit a summary of the Accomplishments/Highlights. Attachment: Label Attachment, AH.)

4. Quarterly Progress reports are **DUE** to the Oregon Health Authority on the following dates:

February 1, 2018	**May 1, 2018**	**August 1, 2018**	**November 1, 2018**
February 1, 2019	**May 1, 2019**	**August 1, 2019**	**November 1, 2019**

5. Complete Page 3, “Cover Sheet” and utilize as the cover sheet as page one for each quarterly progress reporting submission.

6. Follow submission instructions as outlined on Page 3 of this document.

COVER SHEET
DENTAL PILOT PROJECT PROGRAM

QUARTERLY REPORTING PERIOD DUE DATE:
[Check One Box Only: Double-Click Box, Under Default Value Change to Checked]

☐ February 1, 2018	☐ May 1, 2018	☐ August 1, 2018	☐ November 1, 2018
☐ February 1, 2019	☐ May 1, 2019	☐ August 1, 2019	☐ November 1, 2019

Quarters follow standard quarter reporting periods, i.e. January 1-March 31

Project Name & ID Number:	
Indicate Date Span of Reporting Period (e.g., Q4: 10/1/2016-12/31/2016):	
Primary Contact Name and Title:	
Telephone:	
Email Address:	
Individual Completing Form:	
Submission Date:	

Send completed Quarterly Report and attachments in **one email**. Each page of an attachment must be labeled per the submission instructions, ie. LL1 in upper right hand corner. **Send each attachment in two formats: word format and pdf format.**

Email to: bruce.w.austin@state.or.us

Contact Information:

Bruce Austin, DMD
Statewide Dental Director
Statewide Dental Director
OREGON HEALTH AUTHORITY
HPA, HSD, PHD
Office of the Chief Medical Officer
Office: 503-551-5905
Fax: 971-673.0231

On a Quarterly basis, please update the Oregon Health Authority, Dental Pilot Project Program, on the following:

1. Accomplishments/Highlights.

Provide a description of project accomplishments. This includes any activity that has been successfully achieved or should be noted, regardless of whether it is large or small.
Attach in PDF Format.

Submit a summary of the **Accomplishments/Highlights**.
Attachment: Label Attachment, AH.

2. Lessons Learned/Challenges.

Provide a description of lessons learned and program challenges. This includes any activity that has been a challenge to the project and should be noted, regardless of whether it is large or small. Describe how you will use this information for project improvements, if applicable.
Attach in PDF Format.

Submit a summary of the **Lessons Learned/Challenges**.
Attachment: Label Attachment, LLCH.

3. Timeline.

Provide an update to the timeline since the last quarterly progress report.
Attach in PDF Format.

Submit a copy of the **Timeline**
Attachment: Label Attachment, TL.

4. Data.

Provide an update to the data submitted since the last quarterly progress report. This should include a comprehensive breakdown of each of the data points the project is capturing as indicated in the Dental Pilot Projects approved Dental Pilot Project Application and approved Evaluation & Monitoring Plan.

Data should demonstrate the quality of care provided, trainee competency and patient safety in addition to the larger goals of access to care, cost effectiveness and the efficacy of introducing a new workforce model.

Patient confidentiality is a priority and is not to be disclosed. Documents should not contain information that will identify any patient. Patient demographics must comply with REAL-D standards for the collection of data on race, ethnicity, preferred spoken or signed and preferred written language and disability status. See Oregon Administrative Rules 943-070-0000 through 943-070-0070.
Follow submission dates as outlined.

Dates of Service	Data Due Date
01/01/2018 – 3/31/2018 (Quarter 1 2018)	5/1/2018
4/1/2018 – 6/30/2018 (Q2 2018)	8/1/2018
7/1/2018 – 9/30/2018 (Q3 2018)	11/1/2018
10/1/2018 – 12/31/2018 (Q4 2018)	2/1/2019
1/1/2019 – 3/31/2019 (Q1 2019)	5/1/2019
4/1/2019 – 6/30/2019 (Q2 2019)	8/1/2019
7/1/2019 – 9/30/2019 (Q3 2019)	11/1/2019
10/1/2019 – 12/31/2019 (Q4 2019)	2/1/2020

Attach in Excel Format.
Submit a copy of the **Data**.
Attachment: Label DATA.

5. Training/Didactic.

Provide a summary and description of all activities included in this phase. Provide a description of the trainee's progress in achieving their stated objectives as indicated in the approved Dental Pilot Project Application and approved Evaluation & Monitoring Plan.

Submit a copy of the Training/Didactic.
Attachment: Label Attachment, EU.

6. Employment/Utilization.

Provide a summary and description of all activities included in this phase. Provide a description of the trainee's progress in achieving their stated objectives as indicated in the approved Dental Pilot Project Application and approved Evaluation & Monitoring Plan.

Submit a copy of the Employment/Utilization.
Attachment: Label Attachment, EU.

7. Patient Safety. Trainee Competency.

Provide a description of methods utilized to assess trainee competency and monitor for patient safety in the employment/utilization phase. A summary of de-identified trainee monitoring records should be included to ascertain patient safety and trainee competence.

Submit a copy of the Patient Safety. Trainee Competency.
Attachment: Label Attachment, PSTC.

8. Complaints.

Provide a copy and description of any complaints reported or received on behalf of patients treated by the trainee during the current quarterly reporting period.
Attach in PDF Format.

Submit a copy of the **Complaints.**
Attachment: Label Attachment, CP.

9. Adverse Events.

Provide a **detailed** description of identified adverse outcomes or patient safety concerns by concept, including that information which has already been reported to the Oregon Health

Authority. Examples may include, **but are not limited to,** the following:

- Injury to a patient as the result of medical/dental intervention
- Unintentional harm to a patient
- Unanticipated patient response to medical/dental intervention
- Hospitalization of a patient following medical/dental intervention
- Death of a patient
- Poor decision-making
- Poor communications
- Inadequate resources
- Insufficient staffing
- Insufficient training
- Poor documentation
- Lack of safeguards and check points
- Failure to follow rules/protocols
- Technical mistakes
- Inability to cope with the complexities or demands of protocols

Provide a copy and description of each adverse event reported during the current reporting period to the Oregon Health Authority.
Attach in PDF Format.

Submit a copy of the **Adverse Events.**
Attachment: Label Attachment, AE.

10. External Evaluation.

Provide a description of the external evaluator's processes during the current reporting period. Examples include the number of abstraction records reviewed by the external dentist, the data generated by the evaluation, the number of interviews conducted, etc.
Attach in PDF Format.

Submit a copy of the **External Evaluation.**
Attachment: Label Attachment, EE.

11. Financial Status Update

Provide a copy and description of any changes in financial status including receiving new grants or other changes in funding sources.

Submit a copy of the **Financial Status.**
Attachment: Label Attachment, FS.

12. **Miscellaneous**.

Any additional documents that pertain to the project but do not fall into one of the other categories must be added to the Quarterly Progress Report. Examples of items which should be included are:

- Copies of Educational Material and/or Manuals provided to Trainees.
- Programmatic Updates to the Educational Institution accreditation, i.e. progress towards applying for CODA accreditation.
- Description of professional development activities for trainees, staff and/or associated dentists.
- Changes in clinical staff, administrative staff, project managers.
- Changes in approved project sites including both clinical sites and mobile sites.

- Copies of requests for project modifications as submitted to the Oregon Health Authority.

Submit a copy of the **Miscellaneous.**
Attachment: Label Attachment, MS.

Submission.

Follow submission instructions as outline on page 3 of this document.

Secretary of State

STATEMENT OF NEED AND FISCAL IMPACT

A Notice of Proposed Rulemaking Hearing or a Notice of Proposed Rulemaking accompanies this form.

Oregon Health Authority, Public Health Division | 333

Agency and Division | Administrative Rules Chapter Number

Dental Pilot Projects

Rule Caption

In the Matter of: Adopting Oregon Administrative Rules in chapter 333, division 10 in order provide administrative oversight of Dental Pilot Projects.

Statutory Authority: Oregon Laws 2011, chapter 716

Other Authority:

Stats. Implemented: Oregon Laws 2011, chapter 716

Need for the Rule(s):

The Oregon Health Authority (OHA), Public Health Division, Oral Health Program is proposing to permanently amend administrative rules in chapter 333, division 10 to provide administrative oversight of Dental Pilot Projects as defined in SB 738 (2011 OL Ch. 716), which passed during the 2011 Legislative Session.

The amended rules provide clarification around the administrative guidance to the required content of Dental Pilot Project applications, amend the process for review and approval by the Authority, require project sponsors to conduct background checks on trainees, amend the minimum standards that approved projects are required to meet, clarify quarterly monitoring reports that are required by the Authority, amend informed consent requirements, outline a process for corrective action in the event that the project fails to meet the administrative rules and clarify the steps to terminate or conclude a Dental Pilot Project.

Clarification of the rules was needed due to the following: There was not a defined process in the event of non-compliance with the administrative rules as they currently stand. The amended rules were necessary to allow applicants to the program to receive provisional approval prior to spending significant resources on a full scale evaluation and monitoring plan. The current administrative rules did not require projects to conduct background checks. Project sponsors requested clarification on the informed consent requirements that were required by the Authority. There was not a defined process for suspension and termination of existing projects in the event of non-compliance with the administrative rules.

Due to complexity of the proposed changes in the administrative rules and the reorganization of the rules for the Dental Pilot Project program, OHA is proposing to repeal the current version of the administrative rules and replace them with the proposed text.

Proposed changes to sections of 333-010-XXXX “Purpose”:
Language is being added to clarify purpose of the Dental Pilot Project Program, clarify who the rules apply to and outline timeline for implementation of existing dental pilot projects.

Proposed changes to sections of 333-010-XXXX “Definitions”:
Language is being added to specify and define terminology used throughout the administrative rules.

Proposed changes to sections of 333-010-XXXX “Application Procedure”:

Language is being added to clarify components required in an application to the program.

Proposed changes to sections of 333-010-XXXX "Application Review Process":
Language is being added to clarify the review process conducted by the OHA.

Proposed changes to sections of 333-010-XXXX "Project Application Provisional Approval or Denial":
Language is being proposed to incorporate a new process for approval of dental pilot project applications. The proposed language will delineate the process and timelines under a provisional approval and extend the public comment period timeline.

Proposed changes to sections of 333-010-XXXX "Provisional Approval; Final Approval":
Language is being proposed to clarify project sponsor requirements once provisional approval is obtained from OHA.

Proposed changes to sections of 333-010-XXXX "minimum Standards":
Language is being proposed that incorporates additional minimum standard requirements for patient safety, requires project participants to not engage in unprofessional conduct as defined in ORS 676.150, ensure patient records are kept in accordance with standards listed, clarify process for reporting emergency incidents to OHA, clarify quarterly reporting requirements to OHA, require projects to develop standing operating procedures and require projects to operate only at approved pilot sites.

Proposed changes to sections of 333-010-XXXX "Informed Consent":
Language is being proposed to clarify process required by project sponsors around obtaining informed consent for treatment and treatment by the trainee as part of an approved dental pilot project.

Proposed changes to sections of 333-010-XXXX "Evaluation and Monitoring by Sponsor":
Language is being proposed to describe requirements of project sponsors in their evaluation of the approved dental pilot project.

Proposed changes to sections of 333-010-XXXX "Authority Responsibilities":
Language is being proposed to outline a process for corrective action in the event OHA conducts a site visit and finds the project is in non-compliance.

Proposed changes to sections of 333-010-XXXX "Project Modifications":
Language is being proposed to clarify what constitutes a minor modification, what is allowed under project modifications and what will require a new application.

Proposed changes to sections of 333-010-XXXX "Discontinuation or Completion of Project":
Language is being proposed to clarify expectations and requirements at the conclusion of the pilot project by the project sponsor.

Proposed changes to sections of 333-010-XXXX "Suspension or Termination of Project":
Language is being proposed to clarify the process that may occur in the event a project is suspended or terminated by OHA.

Documents Relied Upon, and where they are available:

- SB 738 (Oregon Laws 2011, chapter 716): https://olis.leg.state.or.us/liz/2011R1/Downloads/MeasureDocument/SB738/Enrolled
- SB 606 (Oregon Laws 2015, chapter 716): https://olis.leg.state.or.us/liz/2015R1/Downloads/MeasureDocument/SB606/Enrolled

- Barclay's California Code of Regulations Title 22, Division 7, Chapter 6 – Health Workforce Pilot Project Program. https://www.oshpd.ca.gov/HWDD/HWPP.html
- Oregon Administrative Rules, 333-010-0400 through 333-010-0470, Oregon Health Authority, Public Health Division, Chapter 333, Division 10, Health Promotion and Chronic Disease Prevention

Fiscal and Economic Impact:

There is no direct fiscal or economic impact from the proposed rule amendments to the Oregon Health Authority or public.

Approved dental pilot projects and previously approved pilot projects will be required to comply with the revised administrative rules by June 1, 2019. Costs may be incurred by already operating pilot projects to hire a project dental director if the project does not currently employ or contract with an individual to satisfy the new rule. Additional costs may also be incurred to develop written standing operating procedure documents.

Statement of Cost of Compliance:

1. Impact on state agencies, units of local government and the public (ORS 183.335(2)(b)(E)):

There is no cost of compliance impact to state agencies, units of local government or the public as a result of the proposed rule amendments.

2. Cost of compliance effect on small business (ORS 183.336):

a. Estimate the number of small businesses and types of business and industries with small businesses subject to the rule:

A small number of small businesses may be subject to the proposed rule amendments. Current dental pilot projects are operated by larger organizations such as educational institutions, dental care organizations, tribal organizations and federally qualified health centers. Private practice dentists that operate within a dental pilot project may be considered a small business. We cannot estimate exactly how many there are, but any entity operating in an approved dental pilot project would need to comply with the proposed rule amendments.

b. Projected reporting, recordkeeping and other administrative activities required for compliance, including costs of professional services:

Small businesses may be impacted if they operate within a dental pilot project. However, there is no requirement that small businesses must operate within a pilot project. The proposed amended rules define and clarify reporting, recordkeeping and administrative activities that pilot projects must complete to continue operating an approved dental pilot project. Costs may be incurred for staff time needed to comply with requirements such as having written standing operating procedures and submitting quarterly reports to the Oregon Health Authority.

c. Equipment, supplies, labor and increased administration required for compliance:

Small businesses may be impacted if they operate within a dental pilot project. However, there is no requirement that small businesses must operate within a pilot project. Labor and equipment costs may be incurred to comply with reporting, recordkeeping and administrative activities. For example, staff time may be needed to modify an electronic health record system to gather specific data points for a quarterly report submission.

How were small businesses involved in the development of this rule?

Small businesses were not involved in the development of the rules because no small business representatives applied to participate on the Rules Advisory Committee (RAC). An invitation to apply for the RAC was sent to over 100 individuals, an announcement was made by the Oregon Healthy Authority listserv and GovDelivery subscription channels.

Administrative Rule Advisory Committee consulted?:

Yes, a Rules Advisory Committee (RAC) was established. The committee included twelve representatives from various organizations that would be impacted, including Advantage Dental, Oregon Board of Dentistry, Capitol Dental, Willamette Dental Care, Northwest Portland Area Indian Health Board, Native American Rehabilitation Association, AllCare CCO, Oregon Health & Science University Dental School, Oregon Dental Association and Pacific Source CCO.

If not, why?:

Brittany Hall , Administrative Rules Coordinator

Signature | Printed name | Date