ADVERSE EVENT REPORTING:
A sponsor must report severe Adverse Events to the Oregon Health Authority program staff the day they occur as outlined in OAR 333-010-0710. Adverse Event reports are prepared by project sponsor personnel with the intent that such reports will not contain information regarding the patient's identity. The information will be prepared as a brief anecdotal account to be submitted to the Oregon Health Authority.

"Adverse event" means harm caused by dental treatment, regardless of whether it is associated with error or considered preventable as defined under 333-010-0710.

Adverse Events may be categorized by severity in relation to patient harm as shown in Figure 1. Adverse Events or Suspected Adverse Events that classified as severe temporary or permanent harm (E2 or higher) must be reported to OHA the day they occur or are found to have occurred. Other Adverse Events or Suspected Adverse Events must be reported in a timely fashion.

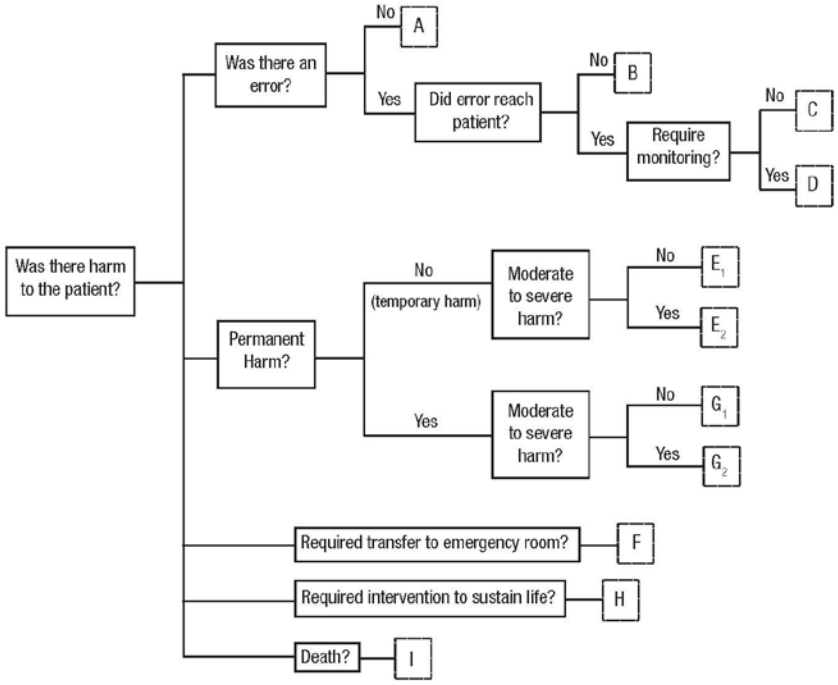
OHA staff will then work with project staff to determine if the incident is an Adverse Event and to finalize Adverse Event severity and category classifications based upon submitted narratives and patient chart documents.

INSTRUCTIONS:
1. Contact Program Staff via telephone (971-673-1563) or email on the date of the incident.
2. Complete Adverse Event Reporting Form and Submit the Completed Form via secured email to sarah.e.kowalski@state.or.us. Additional attachments must be in PDF format.
3. If the incident is determined by OHA to be an Adverse Event, a sponsor must perform and later submit a Root Cause Analysis of the incident.

Dental Pilot Project:	
Reporting Date:	
Date of Incident:	
Address of Incident:	
Incident Description: Please be as specific as possible	
Procedure Name(s) and CDT Code(s) performed on patient:	

AE Severity	Review Dental Adverse Severity Tree and choose the most appropriate category.	

Figure 1. Dental Adverse Event Severity Categories



Category	Description of Dental Adverse Event Severity Categories using the Dental AE severity tree
A	No errors
B	Error with no impact on patient
C	Error with minimal/mild impact to patient; does not require monitoring
D	Error with moderate to severe impact to patient; requires monitoring
E_1	Temporary (reversible or transient) minimal/mild harm to the patient
E_2	Temporary (reversible or transient) moderate to severe harm to the patient
F	Harm to the patient that required transfer to emergency room and/or prolonged hospitalization
G_1	Permanent minimal/mild patient harm
G_2	Permanent moderate to severe patient harm
H	Intervention required to sustain life
I	Patient death

Adapted from: Kalenderian E, Obadan-Udoh E, Maramaldi P, et al. Classifying Adverse Events in the Dental Office [published online ahead of print, 2017 Jun 30]. J Patient Saf. 2017;10.1097/PTS.0000000000000407. doi:10.1097/PTS.0000000000000407

Contact Name:	
Email:	

Project Manager Signature/Date

Examples of Adverse Events may include but are not limited to:

Example:	Possible Severity Category*:
Administration of medication, anesthetic, chemical that is in a dosage that results in a reaction	E1, E2
Allergic reactions to dental materials	E2, F
Anesthetizing the wrong site (only if harm occurs)	E1, E2
Aspiration/Ingestion of Foreign Body	E2
Bleeding that is uncontrolled or prolonged and requires intervention	E1, E2
Damage to tooth or bone	G1, G2
Death due to overdose of anesthesia	I
Foreign Body Response: object retained at site of treatment—file separation, overhang	E2
Infections that escalate after treatment or arise post-operatively	E1, E2
Infections with fluctuant swelling requiring I & D	E2
Laceration of lip/tongue/cheek during dental procedure	E1, E2, G1, G2
Pain following extraction/RCT without proper pain management	E2
Painful dry socket	E1, E2
Paresthesia following a dental procedure	G2
Paresthesia that presents with numbness with or without pain: triggered by report of tingling, paresthesia, dysesthesia, numbness, palsy between 0-30 days after a treatment/procedure	G2
Perforation of tooth due to endodontic treatment	E2
Peri-implantitis	E2
RCT on wrong tooth	G1, G2
Sinus infections (resulting from perforations or communications with oral cavity)	E2
Space infections: submandibular	E2, F
Tissue necrosis due to bleaching or rubber dam clamp	G1, G2
Wrong procedure/patient	G2
Wrong tooth extraction	G2

**Examples and possible severity category assigned in the table do not necessarily contain all of the information. For example, an allergic reaction to dental materials may be a localized reaction that was managed in the dental office. It may also mean that the patient required transfer to a hospital as the reaction was systemic and required management in a hospital. Chart notes provide more information to the scenario and are used to determine the severity category.*

The following are not considered Adverse Events:

- Causes or precursors to AEs (Underlying conditions)
- Errors
- Near Misses
- Poor/unacceptable quality of Care
- Natural course of disease