DENTAL HYGIENE BOARD

FINAL STATEMENT OF REASONS

Subject Matter of Proposed Regulations: Approval of Curriculum Requirements for Radiographic Decision-Making and Interim Therapeutic Restoration Courses for the Registered Dental Hygienist, Registered Dental Hygienist in Alternative Practice (RDHAP), and Registered Dental Hygienist in Extended Functions (RDHEF) (collectively, RDHs)

Section(s) Affected: Section 1109 of Title 16 of the California Code of Regulations (CCR)

Updated Information

The Informative Digest and Initial Statement of Reasons are included in the rulemaking file and incorporated as though set forth herein.

Board staff noticed the proposed rulemaking on July 31, 2020, with a 45-day comment period ending on September 14, 2020. Staff received a comment on September 9, 2020.

The Board reviewed the comment at its November 21, 2020, meeting. The Board approved the responses to the comment, and advanced the proposed rulemaking.

The Board approved modified text at its November 21, 2020, meeting. The Board provided 15 days' notice of the modified text on December 1, 2020, which concluded on December 16, 2020. The Board did not receive any comments regarding the modified text.

The first modified text included the following amendments:

A. Subdivision (d)(2)(A)(ii) to provide:

(ii) Possess current certification in Basic Life Support (BLS) and Cardiopulmonary Resuscitation (CPR) from the American Heart Association (AHA) or the American Red Cross (ARC), or a provider approved by the American Dental Association's Continuing Education Recognition Program (CERP) or the Academy of General Dentistry's Program Approval for Continuing Education (PACE).

B. Subdivision (d)(2)(B)(ii) to provide:

(ii) Possess current certification in Basic Life Support (BLS) and Cardiopulmonary Resuscitation (CPR) from the American Heart Association

(AHA) or the American Red Cross (ARC), or a provider approved by the American Dental Association's Continuing Education Recognition Program (CERP) or the Academy of General Dentistry's Program Approval for Continuing Education (PACE).

C. Subdivision (d)(3)(B) to provide:

(B) Possess current certification in Basic Life Support (BLS) and Cardiopulmonary Resuscitation (CPR) from the American Heart Association (AHA) or American Red Cross (ARC), or a provider approved by the American Dental Association's Continuing Education Recognition Program (CERP) or the Academy of General Dentistry's Program Approval for Continuing Education (PACE);

As a condition of license renewal, current regulations require that licensees complete a mandatory course in Basic Life Support (BLS) that shall be met by completion of either (1) an American Heart Association (AHA) or American Red Cross (ARC) course in Basic Life Support (BLS), or (2) a BLS course taught by a provider approved by the American Dental Association's Continuing Education Recognition Program (CERP) or the Academy of General Dentistry's Program Approval for Continuing Education (PACE) (section 1016(b)(1)(C) of Title 16 of the California Code of Regulations).
The initial noticed language inadvertently excluded the allowance of course to be taken with a BLS provider approved by CERP or PACE. Therefore, the Board determined that the omission of allowing CERP or PACE-approved BLS courses would be contrary to current regulations and amended the language to include CERP or PACE-approved BLS courses as acceptable.

On July 7, 2021, the Office of Administrative Law (OAL) recommended amendments to improve clarity. The Board approved the second modified text and associated forms at its July 17, 2021 meeting. The Board provided 15 days' notice of the second modified text and forms on July 29, 2021, which concluded on August 13, 2021. The Board did not receive any comments regarding the modified text and associated forms.

The second modified text included the following amendments:

A. Insertion in subdivision (b)(1)(A) of "07/21" and deletion of "01/19" and associated edits to form "DHBC RDM-01 (New 07/21)."

OAL recommended amendments to form "DHBC RDM-01 (New 07/21)." These amendments included:

1. Insertion in question 4 of "/ITR".

OAL recommended insertion of "/ITR" to "RDM" for consistency, as faculty are required possess current licensure in both RDM and ITR placement pursuant to section

1109(d)(3)(c).

2. Insertion in question 4 of “completion letter (if training completed prior to September 1, 2021) or certificate pursuant to 16 CCR section 1109(f)” and deletion of “proof of.”

OAL recommended deletion of “proof of” as it was vague. Therefore, the Board inserted “completion letter (if training completed prior to September 1, 2021)” to clarify acceptable proof of training. Prior to this rulemaking, students were educated in RDM and ITR duties provided by the Health Workforce Pilot Project (HWPP) No. 172 through the Office of Statewide Health Planning and Development and were issued a “completion letter.”

Additionally, the Board inserts “or certificate pursuant to 16 CCR section 1109(f)” as acceptable proof of training in RDM and ITR if training is completed after September 1, 2021 (after approval of this proposed regulatory proposal).

3. Amendment of revision date of “DHBC RDM-01 (New 01/19)” to “DHBC RDM-01 (New 07/21).”

The Board approved edits to form “DHBC RDM-01 (New 01/19)” (the original noticed version), which necessitated the amendment to “DHBC RDM-01 (New 07/21)” in the text.

B. Insertion in subdivision (b)(1)(D) of “07/21” and deletion of “01/19” and associated edits to form “DHBC RDM-01 (New 07/21)”.

OAL recommended amendments to form “DHBC RDM-01 (New 07/21). The Board incorporates the rationale set forth in A. above.

C. Insertion in subdivision (b)(2)(A) of “07/21” and deletion of “01/19” and associated edits to form “DHBC ITR-03 (New 07/21).”

OAL recommended amendments to form “DHBC ITR-03 (New 07/21).” These amendments included:

1. Insertion in question 4 of “RDM/.”

OAL recommended insertion of “RDM/” to “ITR” for consistency, as faculty are required possess current licensure in both RDM and ITR placement pursuant to subdivision (d)(3)(c).

2. Insertion of “completion letter (if training completed prior to September 1, 2021) or certificate pursuant to 16 CCR section 1109(f)” and deletion of “proof of.”

OAL recommended amendments to form “DHBC ITR-03 (New 07/21)” as incorporated in response A2. above.

3. Amendment of revision date of “DHBC ITR-03 (New 01/19)” to “DHBC ITR-03 (New 07/21)”

The Board approved edits to form “DHBC ITR-03 (New 01/19)” (the original noticed version), which necessitated the amendment to “DHBC ITR-03 (New 07/21)” in the text.

D. Insertion in subdivision (b)(2)(D) of “07/21” and deletion of “01/19” and associated edits to form “DHBC ITR-03 (New 07/21).”

OAL recommended amendments to form “DHBC ITR-03 (New 07/21),” The Board incorporates the rationale set forth in C. above.

E. Insertion in subdivision (c)(1)(A) of “07/21” and deletion of “01/19” and associated edits to form “DHBC RDM-01 (New 07/21).”

OAL recommended amendments to form “DHBC RDM-02 (New 07/21).” These amendments included:

1. Insertion in question 4 of “/ITR”.

OAL recommended amendments to form “DHBC RDM-02 (New 07/21).” The Board incorporates the rationale set forth in A. above.

2. Insertion of “completion letter (if training completed prior to September 1, 2021) or certificate pursuant to 16 CCR section 1109(f)” and deletion of “proof of”.

OAL recommended amendments to form “DHBC RDM-02 (New 07/21).” The Board incorporates the rationale set forth in A. above.

3. Amendment of revision date of the form from “DHBC RDM-02 (New 01/19)” to “DHBC RDM-02 (New 07/21).”

The Board approved edits to form “DHBC RDM-02 (New 01/19)” (the original noticed version), which necessitated the amendment to “DHBC RDM-02 (New 07/21)” in the text.

F. Insertion in subdivision (c)(2)(A) of “07/21” and deletion of “01/19”.

OAL recommended amendments to form “DHBC ITR-04 (New 07/21).” These amendments included:

1. Insertion in question 4 of “completion letter (if training completed prior to September 1, 2021) or certificate pursuant to 16 CCR section 1109(f)” and deletion of “proof of”.

OAL recommended amendments to form “DHBC ITR-04 (New 07/21).” The Board incorporates the rationale set forth in A. above.

2. Amendment of revision date of the form from “DHBC ITR-04 (New 01/19)” to “DHBC ITR-04 (New 07/21).”

The Board approved edits to form “DHBC ITR-04 (New 01/19)” (the original noticed version), which necessitated the amendment to “DHBC ITR-04 (New 07/21)” in the text.

G. Insertion in subdivision (d)(3)(D) of “as provided in 16 CCR section 1105.1(c)(2)”.

OAL recommended insertion of “as provided in 16 CCR section 1105.1(c)(2)” after “Be calibrated in instruction and grading of RDM and ITR” for clarity. Faculty are required to be calibrated prior to teaching pursuant to section 1105.1(c)(2) in the “educational program's curriculum, policies and procedures, strategies for teaching, and student supervision and evaluation.”

H. Insertion in subdivision (d)(6)(A)(ii)(a) of “Guidelines on the Selection of Patients for Dental Radiographic Examinations” and deletion of “Dental Radiographic Examinations: Recommendations for Patient Selection and Limiting Radiation”.

OAL recommended the deletion of “Dental Radiographic Examinations: Recommendations for Patient Selection and Limiting Radiation” as this document was inserted in error and not referenced within HWPP No. 172 as required pursuant to BPC section 1910.5. The Board amended subdivision (d)(6)(A)(ii)(a) to state the correct reference as found in HWPP No. 172 (“The American Dental Association's Guidelines on the Selection of Patients for Dental Radiographic Examinations”).

I. Deletion in subdivision (d)(6)(D) of “, laboratory, and clinical”.

OAL recommended the deletion of “, laboratory, and clinical” from subdivision (d)(6)(D). Laboratory and clinical instruction were not included with “didactic instruction” in HWPP No. 172 as required pursuant to BPC section 1910.5(c), and is therefore removed.

J. Insertion in subdivision (d)(6)(D)(iii) of “which” and deletion of “; Criteria”.

“Criteria” was duplicative and erroneously inserted. The Board inserted “Which” to form a grammatically correct sentence.

K. Insertion in subdivision (d)(6)(E) of “Laboratory instruction in ITR placement shall

include placement of adhesive protective restorations where students and participants demonstrate competency in this technique on typodont teeth."

OAL recommended the insertion of (d)(6)(E) to mirror the text of HWPP No. 172 as required by BPC section 1910.5.

L. Insertion in subdivision (d)(6)(F) of "Clinical instruction in ITR shall include experiences where students and participants demonstrate placement of ITRs under direct supervision of faculty."

OAL recommended the insertion of (d)(6)(F) to mirror the text of HWPP No. 172 as required by BPC section 1910.5.

M. Renumbering of subdivision "(d)(6)(E)" to subdivision (d)(6)(G)", renumbering of subdivision "(d)(6)(F)" to subdivision (d)(6)(H)", renumbering of subdivision "(d)(6)(G)" to subdivision (d)(6)(I)", renumbering of subdivision "(d)(6)(H)" to subdivision (d)(6)(J)", and renumbering of subdivision "(d)(6)(I)" to subdivision (d)(6)(K)".

Based on amendments to the text, the Board re-numbered sections (d)(3)(E) through (d)(3)(I) to (d)(3)(G) through (d)(3)(K) in subdivision (d)(6).

Rationale for subdivisions (d)(6)(A)(iii) and (d)(6)(B) through (E)

The Board inadvertently omitted explanations of rationale for these subdivisions, and provides them below:

N. Subdivision (d)(6)(A)(iii): "The guidelines developed by Pacific Center for Special Care at the University of the Pacific Arthur A. Dugoni School of Dentistry (Pacific) for use in training for Health Workforce Pilot Project (HWPP) #172 including:"

BPS section 1910.5 requires the Board to adopt regulations "using the competency-based training protocols established by the Health Workforce Pilot Project (HWPP) No. 172 through the Office of Statewide Health Planning and Development." (Bus. & Prof. Code, subd. (c).) Subdivision (d)(6)(A)(iii) of the proposal incorporates the guidelines set forth HWPP No. 172 to provide context for the guidelines set forth in the subdivision.

O. Subdivision (d)(6)(A)(iii)(a): "Instruction on specific decision-making guidelines that incorporate information about the patient's health, radiographic history, time span since previous radiographs were taken, and availability of previous radiographs."

Subdivision (d)(6)(A)(iii)(a) of the proposal incorporates reference guidelines for radiographic history found within HWPP No. 172. This subdivision incorporates the recommendation at page 2 of HWPP No. 172 under "Content of Training" listed as

number 2. Judicious use of radiographs is necessary to ensure continued health of the patient. For example, Patient X (a cancer patient undergoing radiation therapy) presents to a clinician's office for a routine exam. Patient X has no dental complaints and presents with a full set of radiographs taken six months ago. The clinician would then determine Patient X has no current need for further radiographs at this visit. However, if Patient X presented with pain and presents with an abscess (an infection caused by a dying tooth) between two teeth, the clinician may decide to take one radiograph (limiting excess radiation to the patient) of the area to determine which tooth is infected. The radiograph would be necessary to allow for proper treatment of Patient X. Therefore, due to more judicious use of x-rays, the reduction in patient exposure to radiation will increase the health and safety of the public.

P. Subdivision (d)(6)(A)(iii)(b): "Instruction pertaining to the general condition of the mouth including extent of dental restorations present, visible signs of abnormalities, including broken teeth, dark stain within the tooth, and visible holes in teeth."

Subdivision (d)(6)(A)(iii)(b) of the proposal incorporates reference guidelines for RDM found in HWPP No. 172. This subdivision incorporates the recommendation at page 2 of HWPP No. 172 under "Content of Training" listed as number 2. Judicious use of radiographs is necessary to ensure continued health of the patient. For example, Patient Y presents to a clinician's office for a routine exam. Patient Y has no dental complaints and presents with a full set of radiographs taken six months ago. Additionally, Patient Y has little evidence of past decay (tooth infection which breaks down teeth) and teeth are relatively free of plaque (bacteria on teeth which causes decay). Therefore, the clinician would then determine Patient Y has no current need for further radiographs at this visit. However, if Patient Y presented with pain and presents with several broken teeth along with several abscesses, the clinician may decide to take a few radiographs (limiting excess radiation to the patient) of the areas to determine the extent of the infections. The radiographs would be necessary to allow for proper treatment of Patient Y.

Q. Subdivision (d)(6)(B): "RDM laboratory instruction shall include a review of clinical cases with instructor-led discussion about radiographic decision-making in clinical situations."

Subdivision (d)(6)(B) of the proposal incorporates reference guidelines for RDM found within HWPP No. 172. This subdivision incorporates the recommendation at page 2 of HWPP No. 172 under "Content of Training" listed as number 3. Laboratory instruction that reviews RDM clinical cases with an instructor provides real world knowledge experienced by the instructor in making decisions regarding taking radiographs utilizing X-rays. Decisions made in presented clinical cases may be applied to future experiences for radiographic decision-making by the student. The student will then have foundational knowledge to build upon to make future responsible decisions with which to treat patients safely and effectively.

R. Subdivision (d)(6)(C): “RDM simulated-clinical instruction shall include case-based examination with various clinical situations where trainees make decisions about which radiographs to expose and demonstrate competency to faculty based on these case studies.”

Subdivision (d)(6)(C) of the proposal incorporates reference guidelines for RDM found within HWPP No. 172. This subdivision incorporates the recommendation at page 2 of HWPP No. 172 under “Content of Training” listed as number 4. Subdivision (d)(6)(C), using case-based examinations with various clinical situations, will build upon requirements found in subdivision (d)(6)(B). These case-based examinations are used determine competency in RDM. Competency in RDM demonstrates knowledge to make future responsible decisions with which to treat patients safely and effectively when using x-rays. Additionally, requirements in proposed subdivision (d)(6)(C) are also mandated by 16 CCR section 1105.2(d), which provides the content of the curriculum shall include biomedical and dental sciences and dental hygiene sciences and practice. This content shall be of sufficient depth, scope, sequence of instruction, quality and emphasis to ensure achievement of the educational program's standard of competency.

S. Subdivision (d)(6)(D) “Didactic instruction in ITR placement shall include:”

Subdivision (d)(6)(D) of the proposal incorporates reference guidelines for ITR found within HWPP No. 172. This subdivision incorporates the recommendation at page 3 under “Content of Training” listed as number 1.

Subdivision (d)(6)(D)(i) requires didactic instruction in “Review of pulpal anatomy.” Subdivision (d)(6)(D)(i) of the proposal incorporates reference guidelines for ITR found in HWPP No. 172. This subdivision incorporates the recommendation at page 3 under “Content of Training” listed as number 1a. ITRs require removal of diseased tooth structure (enamel (outer surface of the tooth) and dentin (in between the enamel and pulp)). A clinician should be aware of the many shapes of the pulp (nerve and blood tissue to keep the tooth “alive”) which underlies tooth structure. Knowing pulpal anatomy will prevent accidental exposure of the pulp when removing diseased structure and prevent the clinician from “killing” the tooth and enhance patient safety.

Subdivision (d)(6)(D)(ii) requires didactic instruction in “Theory of adhesive restorative materials used in the placement of adhesive protective restorations including mechanisms of bonding to tooth structure, handling characteristics of the materials, preparation of the tooth prior to material placement, and placement techniques.” Subdivision (d)(6)(D)(ii) of the proposal incorporates reference guidelines for ITR found in HWPP No. 172. This subdivision incorporates the recommendation at page 3 under “Content of Training” listed as number 1b. Adhesive restorative materials are utilized on living tissues (teeth) and are very technique sensitive. For example, after a tooth is prepared for an ITR, the enamel is “etched” with 30-40% phosphoric acid which “dissolves” minerals in tissues to create a rough surface for the ITR to attach to. If

phosphoric acid is used incorrectly, it can severely burn the patient and kill other tissues it touches (gingiva (gums), tongue, etc.). Therefore, comprehensive instruction in theory of adhesive restorative materials is essential to maintain patient safety.

Subdivision (d)(6)(D)(iii) requires didactic instruction in "Criteria used in clinical dentistry pertaining to the use and placement of adhesive protective restorations which shall include, but not limited to:" Subdivision (d)(6)(D)(iii) of the proposal incorporates reference guidelines for ITR found with HWPP No. 172 in "Appendix B." This subdivision incorporates the recommendation at page 9 under "Criteria for ITR Placement."

Subdivision (d)(6)(D)(iii)(a) requires didactic instruction in "Patient factors." Subdivision (d)(6)(D)(iii)(a) of the proposal incorporates reference guidelines for ITR found in HWPP No. 172 in "Appendix B." This subdivision incorporates the recommendation at page 9 under "Criteria for ITR Placement" listed as number 1. Patient factors are taken into consideration as each patient is unique and presents different needs or health requirements.

Subdivision (d)(6)(D)(iii)(a)(1) requires patient factor criteria for ITR placement to be limited to Class III (ASA III) or less according to the American Society of Anesthesiologists (ASA) Physical Status Classification. Subdivision (d)(6)(D)(iii)(a)(1) of the proposal incorporates reference guidelines for ITR found in HWPP No. 172 in "Appendix B." This subdivision incorporates the recommendation at page 9 under "Criteria for ITR Placement" listed as number 1a. The ASA has been in existence since 1905 and created a physical status classification system in 1941 (last amended December 13, 2020) to provide clinicians a physiological status categorization system that assists to predict a patient's treatment risk. For example, an ASA III is a patient with a severe systemic disease that is not life-threatening (e.g., poorly controlled Diabetes Mellitus or Hypertension, Chronic Obstructive Pulmonary Disease, etc.).
Subdivision (d)(6)(D)(iii)(a)(2) requires patient factor criteria for ITR placement to include patients that are cooperative enough to have the interim restoration placed without the need for special protocols, including sedation or physical support.
Subdivision (d)(6)(D)(iii)(a)(2) of the proposal incorporates reference guidelines for ITR found in HWPP No. 172 in "Appendix B." This subdivision incorporates the recommendation at page 9 under "Criteria for ITR Placement" listed as number 1b. ITRs were developed to be an interim (long term temporary) procedure to allow for a more definitive treatment to be placed in the future. For example, a patient needs sedation for the ITR to be placed. Sedation is a serious procedure not to be used indiscriminately for temporary procedures. The better treatment for the patient at that point would be a permanent restoration.

Subdivision (d)(6)(D)(iii)(a)(3) requires patient factor criteria for ITR placement to include the patient, or responsible party, has provided consent for the ITR procedure.
Subdivision (d)(6)(D)(iii)(a)(3) of the proposal incorporates reference guidelines for ITR found in HWPP No. 172 in "Appendix B." This subdivision incorporates the

recommendation at page 9 under “Criteria for ITR Placement” listed as number 1c. To provide treatment to a patient without consent would be considered malpractice and subject to discipline.

Subdivision (d)(6)(D)(iii)(a)(4) requires patient factor criteria for ITR placement to include patient reports of the tooth being asymptomatic, or mild sensitivity which stops within a few seconds of the removal of the offending stimulus. Subdivision (d)(6)(D)(iii)(a)(4) of the proposal incorporates reference guidelines for ITR found in HWPP No. 172 in “Appendix B.” This subdivision incorporates the recommendation at page 9 under “Criteria for ITR Placement” listed as number 1d. This factor would indicate the tooth is still “alive” and ITR placement is appropriate to treat the tooth. If the tooth displayed severe sensitivity, the tooth would be “dying” or “dead”, and a different, permanent treatment would be necessary (root canal treatment or extraction of the tooth).

Subdivision (d)(6)(D)(iii)(b) requires didactic instruction in “Tooth Factors:”. Subdivision (d)(6)(D)(iii)(b) of the proposal incorporates reference guidelines for ITR found in HWPP No. 172 in “Appendix B.” This subdivision incorporates the recommendation at page 9 under “Criteria for ITR Placement” listed as number 2. Tooth factors are taken into consideration as each tooth is unique and presents different needs or treatments.

Subdivision (d)(6)(D)(iii)(b)(1) requires tooth factor criteria for ITR placement to include the lesion is accessible without the need for creating access using a dental handpiece. Subdivision (d)(6)(D)(iii)(b)(1) of the proposal incorporates reference guidelines for ITR found within HWPP No. 172 in “Appendix B.” This subdivision incorporates the recommendation at page 9 under “Criteria for ITR Placement” listed as number 2a. ITRs were developed to be an interim procedure for placement by dental auxiliaries (e.g., dental hygienist). Pursuant to BPC section 1908(b)(3), the practice of dental hygiene does not include surgery or cutting on hard and soft tissue. Therefore, a dental handpiece may not be used by a dental hygienist.

Subdivision (d)(6)(D)(iii)(b)(2) requires tooth factor criteria for ITR placement to include the margins of the lesion (diseased tissue) are accessible so that clean, non-involved margins can be obtained around the entire periphery of the lesion with the use of hand instrumentation. Subdivision (d)(6)(D)(iii)(b)(2) of the proposal incorporates reference guidelines for ITR found in HWPP No. 172 in “Appendix B.” This subdivision incorporates the recommendation at page 9 under “Criteria for ITR Placement” listed as number 2b. Additionally, as BPC section 1908(b)(3) does not allow surgery or cutting on hard and soft tissue, the lesion must be accessible using hand instrumentation only.

Subdivision (d)(6)(D)(iii)(b)(3) requires tooth factor criteria for ITR placement to include the depth of the lesion is more than two millimeters from the pulp on radiographic examination or is judged by the DDS or DMD to be a shallow lesion such that the treatment does not endanger the pulp or require the use of local anesthetic. Subdivision (d)(6)(D)(iii)(b)(3) of the proposal incorporates reference guidelines for ITR found within

HWPP No. 172 in “Appendix B.” This subdivision incorporates the recommendation at page 9 under “Criteria for ITR Placement” listed as number 2c. A shallow lesion not requiring the use of anesthesia is appropriate for ITR treatment as the diseased tissue may be easily removed and an ITR placed. If a lesion is closer than two millimeters to the pulp radiographically, the lesion may already have breached the pulp and ITR placement would be contraindicated. Once the lesion has reached the pulp, the tooth may be “dying” or “dead”, and a different, permanent treatment would be necessary (root canal treatment or extraction of the tooth).

Subdivision (d)(6)(D)(iii)(b)(4) requires tooth factor criteria for ITR placement to include the tooth is restorable and does not have other significant pathology. Subdivision (d)(6)(D)(iii)(b)(4) of the proposal incorporates reference guidelines for ITR found in HWPP No. 172 in “Appendix B.” This subdivision incorporates the recommendation at page 9 under “Criteria for ITR Placement” listed as number 2d. If a tooth is non-restorable (completely broken where an ITR would not adhere to the tooth that is left) or has other significant pathology (pulp is dead and needs root canal therapy), then a different, permanent treatment would be necessary (root canal treatment or extraction of the tooth).

Subdivision (d)(6)(D)(iv) requires didactic instruction to include theory of protocols to deal with adverse outcomes used in the placement of adhesive protective restorations including mechanisms of bonding to tooth structure, handling characteristics of the materials, preparation of the tooth prior to material placement, and placement techniques. Subdivision (d)(6)(D)(iv) of the proposal incorporates reference guidelines for ITR found in HWPP No. 172 in “Appendix B.” This subdivision incorporates the recommendation at page 10 under “Protocols for Adverse Outcomes After Placement of an ITR.” Adverse outcomes are a risk to any dental treatment as each tooth and patient are different. Requiring protocols to be in place to remedy adverse outcomes will increase a clinician’s knowledge and provide appropriate care options to increase patient safety. For example, a portion of the ITR breaks off after placement. The clinician would examine the restoration and depending on the break, would have the knowledge to identify the cause (adhesive liner did not adhere, or not enough of the tooth to hold it in). The clinician would then replace the ITR or, if too large of a break, send the patient to the dentist for more definitive treatment. Therefore, education in adverse outcome protocols is necessary for the health and safety of the patient.

Subdivision (d)(6)(D)(v) requires didactic instruction to include criteria for evaluating successful completion of adhesive protective restorations including, but not limited to, restorative material not in hyper occlusion, no marginal voids, and minimal excess material. Subdivision (d)(6)(D)(v) of the proposal incorporates reference guidelines for ITR found in HWPP No. 172 in “Appendix B.” This subdivision incorporates the recommendation at page 9 under “Criteria for Completion of an ITR.” Teeth are very exact in size (down to millimeters). Any slight deviation from the norm due to excess material may cause discomfort to the patient. For example, an ITR is placed in a patient’s tooth. During occlusion (biting down) there was one millimeter of excess

material on the occlusal surface (top biting surface of the tooth). If not removed, the patient could experience pain, break the tooth or ITR, or even damage the nerve due to excessive occlusal (biting) forces. Education in successful ITR completion is therefore necessary for the health and safety of the patient.

Subdivision (d)(6)(D)(vi) requires didactic instruction to include protocols for adverse outcomes after ITR placement including, but not limited to; exposed pulp, tooth fracture, gingival tissue injury, high occlusion, open margins, tooth sensitivity, rough surface, complications, or unsuccessful completion of adhesive protective restorations including situations requiring immediate referral to a dentist. Subdivision (d)(6)(D)(iv) of the proposal incorporates reference guidelines for ITR found in HWPP No. 172 in "Appendix B." This subdivision incorporates the recommendation at page 10 under "Protocols for Adverse Outcomes After Placement of an ITR." Adverse outcomes are a risk to any dental treatment as each tooth and patient are different. Requiring protocols to be in place to remedy adverse outcomes will increase a clinician's knowledge and provide appropriate care options to increase patient safety. For example, during ITR placement, there is exposure of the pulp. The clinician would examine the tooth and depending on the exposure, would have the knowledge to identify further patient needs.

If a small exposure, the clinician would place a glass ionomer cement (contains a chemical to stimulates healing) over the area and place the ITR. If there is too large of an exposure, the clinician would place a sterile cotton pellet over the exposure, place a glass ionomer cement over the area, place the ITR temporarily and send the patient to the dentist for more definitive treatment to take place within a few days. Therefore, education in adverse outcome protocols is necessary for the health and safety of the patient.

Subdivision (d)(6)(D)(vii) requires didactic instruction to include protocols for follow-up of adhesive protective restorations, including, but not limited to, at least two (2) follow-up examinations of the ITR within a twelve (12) month period. Subdivision (d)(6)(D)(iv) of the proposal incorporates reference guidelines for ITR found in HWPP No. 172 in "Appendix B." This subdivision incorporates the recommendation at page 10 under "Protocols for Follow-Up for an ITR". HWPP No. 172 "Appendix B: Guidelines for Placement of Interim Therapeutic Restorations" provides general guidance as to criteria for placement, completion, follow-up, and adverse outcomes ITRs. Appendix B states that these guidelines are designed to provide general guidance, not precise instructions that are applicable in all circumstances. This approach recognizes that providers delivering care will need to adapt to local circumstances and develop customized procedures for performance and follow-up for this duty." The regulation requires at least two follow-up examinations of the ITR within a twelve-month period was necessary as it is very difficult to gain compliance for the patients in need of ITRs. The ITR patient is usually from an "in need" population and would not normally receive care had it not been for an ITR provider. Therefore, follow-up protocols are necessary for the health and safety of the patient.

Local Mandate

A mandate is not imposed on local agencies or school districts.

Summary of Comments Received During the 45-Day Comment Period

On September 9, 2020, the Dental Hygiene Board of California (Board) received a letter from Ralph M. Shenefelt, Senior Vice President of the Health and Safety Institute (Comments) on the Board's proposed amendments to 16 CCR section 1109. Below is the Board's response to the comment made therein.

Comment A-1

Comment Summary:

This comment requests the Board add "Health and Safety Institute" to the list of approved providers of Cardiopulmonary Resuscitation (CPR) in proposed Title 16, section 1109, subdivisions (d)(2)(A)(ii), (d)(2)(B)(ii) and (d)(3)(B).

Response:

The Board accepts this comment.

Business and Professions Code (BPC) section 1936.1(b) requires as a condition of renewal that licensees shall complete a portion of the required continuing education hours in specific areas adopted in regulation by the Board. Additionally, BPC section 1936.1(c) states: "The providers of courses referred to in this section shall be approved by the dental hygiene board. Providers approved by the dental board shall be deemed approved by the dental hygiene board."

Title 16, California Code of Regulations (CCR), section 1016(b)(1)(C), promulgated by the Dental Board, states:

The mandatory requirement for certification in Basic Life Support shall be met by completion of either:

(i) An American Heart Association (AHA) or American Red Cross (ARC) course in Basic Life Support (BLS) or,

(ii) A BLS course taught by a provider approved by the American Dental Association's Continuing Education Recognition Program (CERP) or the Academy of General Dentistry's Program Approval for Continuing Education (PACE).

Accordingly, the Board amended section 1109 as follows:

A. Subdivision (d)(2)(A)(ii) to provide:

(ii) Possess current certification in Basic Life Support (BLS) and Cardiopulmonary Resuscitation (CPR) from the American Heart Association (AHA) or the American Red Cross (ARC), or a provider approved by the American Dental Association's Continuing Education Recognition Program (CERP) or the Academy of General Dentistry's Program Approval for Continuing Education (PACE).

B. Subdivision (d)(2)(B)(ii) to provide:

(ii) Possess current certification in Basic Life Support (BLS) and Cardiopulmonary Resuscitation (CPR) from the American Heart Association (AHA) or the American Red Cross (ARC), or a provider approved by the American Dental Association's Continuing Education Recognition Program (CERP) or the Academy of General Dentistry's Program Approval for Continuing Education (PACE).

C. Subdivision (d)(3)(B) to provide:

(B) Possess current certification in Basic Life Support (BLS) and Cardiopulmonary Resuscitation (CPR) from the American Heart Association (AHA) or American Red Cross (ARC), or a provider approved by the American Dental Association's Continuing Education Recognition Program (CERP) or the Academy of General Dentistry's Program Approval for Continuing Education (PACE);

Incorporation by Reference

Forms DHBC RDM-01 (01/19), DHBC RDM-02 (01/19), DHBC ITR-03 (01/19), and DHBC ITR-04 (01/19).

The Board incorporates these documents by reference because it would be impractical and cumbersome to publish application forms for Radiographic Decision-Making (RDM) and Interim Therapeutic Restoration (ITR) Courses in the California Code of Regulations (CCR). The application forms were created to assist the course providers in applying for approval of courses in RDM and ITR, ensuring that pertinent information is collected from course providers in a consistent manner to enable fair and efficient processing of the request by the Board. If the application forms were incorporated into the CCR, it would increase the size of Division 3 and may cause confusion to the user. The application forms will be available to the public at the Board's office in hardcopy form and will be posted on the Board's website in electronic form.

Fiscal Impact

An Associate Governmental Program Analyst will need approximately three hours to complete workload related to approving an institution at a cost of $103 per hour, which results in total costs of $306 per institution.

The Board anticipates 27 RDH and 23 Continuing Education institutions will initially apply for approval, which will result in one-time costs of approximately $15,300.

To the extent an RDH or Continuing Education institution is approved by the Board and modifies its curriculum and needs to be re-approved by the Board or a new institution applies for approval in the future, the Board will incur costs of $306 per institution.

Consideration of Alternatives

No reasonable alternative which was considered or that has otherwise been identified and brought to the attention of the Board, including those raised in the public comments, would be more effective in carrying out the purpose for which the regulation was proposed or would be as effective and less burdensome to affected private persons than the adopted regulations or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.