

State of California
DENTAL HYGIENE COMMITTEE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

ADDENDUM TO INITIAL STATEMENT OF REASONS

**Registered Dental Hygiene (RDH) Educational Program Requirements
(Feasibility Study)**

Hearing Date: September 10, 2014

Sections Affected: Proposed adoption of new sections 1104, 1104.1, and 1104.2, title 16, California Code of Regulations (CCR)

UPDATED INTRODUCTION

The Introduction is updated as follows:

On September 8, 2015, the Office of Administrative Law (OAL) issued a Decision of Disapproval of Regulatory Action (Disapproval Decision) for the Dental Hygiene Committee of California's (Committee) proposed adoption of new sections 1104, 1104.1, and 1104.2, title 16, CCR, for the following reasons:

1. Failure to comply with the clarity standard of Government Code section 11349.1;
2. Failure to comply with the necessity standard of Government Code section 11349.1;
3. Failure to follow required Administrative Procedure Act (APA) procedures; and
4. Miscellaneous issues with the rulemaking record.

At its December 5, 2015 teleconference meeting, the Committee voted to adopt modifications to the proposed regulations (Cal. Code Regs., tit. 16, §§ 1104, 1104.1, and 1104.2) and the proposed document incorporated by reference in section 1104.1, "Instructions for Institutions Seeking Approval of a New RDH Education Program," (EDP-I-01 Rev 12/15) "Instructions," in order to be in compliance with APA procedures, provide additional clarification and make the changes as noted by the Disapproval Decision.

In order to address OAL's clarity concerns, provide adequate necessity for each provision of the proposed regulation, satisfy requirements and standards established by the APA, and to clean up other miscellaneous issues as identified in the Disapproval Decision for OAL Matter Number 2015-0722-03S, the Committee released the Second Notice of Public Availability of Modified Text, Proposed Second 15-day Modified Text, Proposed Second 15-Day Modifications to the Incorporated Feasibility Study Instructions Form (EDP-I-01 Rev 12/15), and added the following additional documents to the record:

1. This Addendum to the Initial Statement of Reasons (Addendum);
2. The Commission on Dental Accreditation of the American Dental Association "Accreditation Standards for Dental Hygiene Education Programs" (As Last Revised: February 6, 2015); and
3. The Commission on Dental Accreditation of the American Dental Association Self-Study Guide for the Evaluation of a Dental Hygiene Education Program (As Last Revised: January 1, 2016.)

The above documents are available for public inspection and/or comment at the location mentioned below and/or on the Committee's website at www.dhcc.ca.gov under QUICK HITS on the left hand side of the homepage. This notice and the above listed documents were mailed to all interested parties and individuals as required pursuant to section 44, title 1, California Code of Regulations. No comments were received during the original 45-day public comment period or first 15-day comment period.

UPDATED SPECIFIC PURPOSE OF EACH ADOPTION OR AMENDMENT

The Committee's proposed changes are updated as follows:

EDP-I-01 Rev 12/15 – “Instructions for Institutions Seeking Approval of a New Educational Program for Registered Dental Hygienists” (Instructions): One-Year Period to Complete the Process

Proposed Amendments to the “Instructions”: The Second 15-Day Proposed Modifications to the incorporated the proposed incorporated document “Instructions for Institutions Seeking Approval of a New RDH Educational Program,” (EDP-I-01 Rev 12/15), specifically Page 2 of 7, illustrates how the one-year period is calculated and identifies the criteria for determining an extension.

Purpose: The proposed amendments are necessary to clear up ambiguity, identify the criteria for the one-year extension, and to ensure compliance with the APA clarity standard.

Rationale: OAL identified the proposed incorporated document “Instructions for Institutions Seeking Approval of a New RDH Educational Program,” (EDP-I-01 Rev 12/15) in the proposed regulation (Cal. Code Regs., tit. 16, § 1104.1), as having two possible interpretations for the calculation of the one year period to complete the new educational program for Registered Dental Hygienists. Furthermore, OAL stated the regulation must list the criteria for determining whether a one-year extension will be granted.

The “Instructions” and the Proposed Regulation Text Regarding Accreditation

The Committee approved proposed modifications to clarify and provide consistency between the proposed regulation text, the “Instructions” and the ISR regarding the accreditation requirements. To clear up the OAL concern regarding ambiguity regarding whether accreditation by an accrediting body beside CODA is permitted, the clarification of adding “or an equivalent accrediting body, as determined by the Committee” after each provision that requires the minimum standards set by CODA. The Committee also clarified that if another accrediting body has not been established then the standards set by CODA shall be used.

Proposed Amendments to the incorporated “Instructions”: The Second 15-Day Proposed Modifications to the incorporated the proposed incorporated document “Instructions for Institutions Seeking Approval of a New RDH Educational Program,” (EDP-I-01 Rev 12/15), specifically:

1. Page 6 of 7, Step 5 – DHCC Action on the Feasibility Study, added “or an equivalent accrediting body, as determined by the Committee”
2. Page 7 of 7, Step 6 – Self-Study Report and Site Visit, added “or an equivalent accrediting body, as determined by the Committee”

Proposed Amendments to the Regulation Text: The Second 15-Day Proposed Modified Text, specifically:

1. Subsections 1104(b), 1104(b)(1), 1104(b)(2), 1104(b)(3), 1104(b)(4), 1104(c), added “or an equivalent accrediting body, as determined by the Committee”

Purpose: The above described amendments are necessary to provide clarity and consistency between the authorizing statute, regulation text, the “Instructions”, and the Initial Statement of Reasons and further clarify the accreditation requirements for new RDH educational programs by adding “, or an equivalent accrediting body, as determined by the Committee” at the end of each accreditation provision. This shows that there can be other accrediting standards. However the amendment also adds, “In the event that an equivalent body has not been established by the Committee, the standards shall be set by CODA”. This clarifies that when another accrediting standard has not been determined by the Committee, the minimum standards set by the Commission on Dental Accreditation of the American Dental Association or “CODA” apply. The above described amendments will further prevent ambiguity regarding whether accreditation by an accrediting body beside CODA is permitted.

Rationale: OAL indicated that there is a lack of clarity regarding whether the new RDH educational programs must obtain CODA accreditation, or whether accreditation by an equivalent accrediting body is sufficient. The Initial Statement of Reasons (ISR) did not describe accreditation by an equivalent accrediting body as an option and gives the impression that CODA accreditation is the only option. Furthermore, there is internal inconsistency between the regulation text, the incorporated proposed “Instructions” and the ISR that leads to ambiguity regarding whether accreditation by an accrediting body beside CODA is permitted. The proposed amendments prevent the impression that CODA accreditation is the only option.

Proposed Incorporated “Instructions” – EDP-I-01 Rev 12/15 [Step 6]: On-Site Review Criteria

Proposed Amendment: The CODA Self-Study Guide for the Evaluation of a Dental Hygiene Education Program (As Last Revised: January 1, 2016) is added to the proposed incorporated “Instructions” as a document incorporated by reference and specifies on-site review criteria the DHCC will use to evaluate the clinical sites.

Purpose: The proposed amendment is necessary to identify the criteria that will be used to evaluate the clinical sites during an on-site visit to those affected by the regulation. The proposed amendments will further provide the clinical sites with information on how to prepare for an evaluation.

Rationale: According to OAL, the initial proposed text did not state the criteria the Committee staff will use to evaluate the selected clinical sites during the on-site visit. The proposed text is amended by adding the document incorporated by reference the Self-Study Guide for the Evaluation of a Dental Hygiene Education Program (Last modified: August 15, 2015) into the “Instructions” and identifies the criteria used for the on-site reviews to meet the clarity standard of the APA.

Business and Professions Code section 1944(a)(1) – Conflict

The Disapproval Decision stated that under the proposed regulations, if an applicant's feasibility study is not approved, the Committee gets to keep the \$2,100 fee even though the committee never began the curriculum review or conducted the site visit. This possible scenario appears to be in direct conflict with BP Code Section 1944(a)(10) which states the fee is required only for curriculum review and site evaluation.

The Committee respectfully responds that pursuant to the recent statutory change (SB 800) as of October 1, 2015 adds "feasibility study" to Section 1944(a)(9) chaptered October 1, 2015.

Section 1104.1(a)(2): Citation to Section 1941(a)(2)

Proposed Amendment: The proposed amendment specifies the correct referenced statute.

Purpose: The proposed amendments are necessary to clarify the reference citation.

Rationale: OAL indicated the initial proposed text did not clearly identify the citation. There is a Business and Professions Code reference to section 1941 and a reference to California Code of Regulations section 1941, which are both related to this proposed regulatory action. The correct citation is specified to meet the clarity standard of the APA.

Proposed Incorporated "Instructions" – EDP-I-01 Rev 12/15 : Restatement of Business and Professions Code, section 1941

Proposed Amendment: The proposed amendments correctly restate the referenced statute.

Purpose: The proposed amendments are necessary to provide clarity and consistency of Business and Professions Code, section 1941.

Rationale: OAL indicated the initial proposed text did not accurately restate Business and Professions Code, section 1941. The correct statutory language is accurately restated to meet the clarity and consistency standards of the APA.

Proposed Incorporated "Instructions" – EDP-I-01 Rev 12/15: Miscellaneous Grammatical and Punctuation Issues

- Page 4, Section 4) e. Projected clinic revenue, I. Capital Expenditures, B. Equipment (for example):, 2. Radiography (unit) – Deleted comma and add underlined parenthesis.
- Page 6, Step 4, third sentence – Corrected grammatical error, removed "on the" added "to" underlined.

The Fee Amount

OAL stated that the Committee must include in the Initial Statement of Reasons a statement explaining why the Committee chose the highest possible fee amount authorized by Business and Professions Code (BPC) section 1944 (a)(10), and include supporting documentation. Following are statements of the specific purpose of the fee and its necessity, and the purpose and necessity of the fee amount of \$2,100.00:

As per Business and Professions Code (BPC) section 1944(a)(10), the \$2,100.00 Fee for each curriculum review and site evaluation for educational programs for dental hygienists who are not accredited by a committee-approved agency shall not exceed two thousand one hundred dollars (\$2,100).

While this fee to review the application for new Registered Dental Hygiene Educational Programs and associated Feasibility Study may seem high, the actual cost to perform a complete review of the application, feasibility study and associated expenses can be far above the \$2,100 maximum fee. The cost to review the application and study documents and facilities for a new dental hygiene programs includes:

- Staff cost for the initial review of the application and feasibility study to determine if further review is necessary;
- Subject Matter Expert (SME) cost for a further, in-depth expert review of the application and feasibility study. This could be a high number of hours depending upon the extent of the review at a \$100/hour rate;
- Staff and SME(s) travel costs including airfare, transportation, accommodations, meals, parking, and incidentals to perform site visits at the proposed dental hygiene educational site. This could occur one time or multiple times depending if the educational site and program applicant provide what is required to start a new dental hygiene educational program;
- DHCC member cost to review and possibly approve or deny the application and feasibility study at DHCC meetings; and
- Postage and/or package mail or courier services to send hardcopy documents or letters to program applicant.

Non-Refundable Fee

As detailed in Section 2.1, the review of the application, feasibility study, and proposed dental hygiene educational program site are very involved and expensive in consuming time and resources. Once the review process begins, the DHCC arranges for an SME's review to determine whether the content of the application and feasibility study convey the necessary answers to justify the startup of a new dental hygiene educational program. If the application and study are extensive, the SME may take over 21 hours to review the materials, which would use the entire \$2,100 application fee that was paid by the applicant for the review. This does not include any additional cost for site visit(s) and other associated costs. This is why the DHCC deemed this fee as non-refundable because when the review is completed, the DHCC usually subsidizes the cost of the program application review.

New Fee Required for Re-Submission

As detailed in Section 2.1 and 2.2, the review of the application, feasibility study, and proposed dental hygiene educational program site are very involved and expensive in consuming time and resources. If an applicant is rejected on the first attempt to apply for a new dental hygiene program, the full review of the resubmitted application, feasibility study, and site visit would commence and cost just as much as the initial application review because the fee does not provide adequate resources to cover the cost of a full review including SME and site visit costs as detailed above.

Incorporation by Reference

The Commission on Dental Accreditation's (CODA's) *Self-Study Guide for the Evaluation of a Dental Hygiene Education Program (As Last Revised: January 1, 2016)*, *Accreditation Standards for Dental Hygiene Education Programs (As Last Revised: January 1, 2016)*, and the *Instructions for Institutions Seeking Approval of a New RDH Educational Program, (EDP-I-01 Rev 12/15)*, were incorporated by reference as it would be cumbersome, expensive and impractical to publish the required documents in the CCR. Furthermore, the Instruction Form (EDP-I-01 Rev 12/15) is available on the DHCC website at www.dhcc.ca.gov, on the left hand side of the home page under QUICK HITS. The *Self-Study Guide for the Evaluation of a Dental Hygiene Education Program (As Last Revised: January 1, 2016)*, and *Accreditation Standards for Dental Hygiene Education Programs (As Last Revised: January 1, 2016)*, are available on CODA's website at http://www.ada.org/~media/CODA/Files/dh_ssg.ashx

Miscellaneous

In addition to the concerns above, OAL identified the following additional miscellaneous issues for correction. Therefore, the DHCC made the following additional corrections available for comment during the second 15-day notice period:

APA - Reference Standard

- 1. Proposed section 1104 – Reference citation**
Removed Business and Professions Code section 125.9 as a source of reference for title 16, section 1104, CCR.
- 2. Proposed Incorporated “Instructions” – EDP-I-01 Rev 12/15**
Added Business and Professions Code section 1944(a)(10) as a source of reference.
- 3. Proposed section 1104.1 and the Proposed Incorporated “Instructions” – EDP-I-01 Rev 12/15 – Incorporation by Reference**
The title of the proposed “Instructions” incorporated in section 1104.1 of the proposed regulation text and on the incorporated “Instructions” document was updated to accurately reflect the correct title and latest version of 12/2015, as the incorporated document was last approved for modifications by the Committee in December of 2015.

Non-Substantive Changes

Furthermore, the DHCC made additional non-substantive changes throughout the proposed regulatory text and in the incorporated “Instructions”. These changes do not materially alter any requirement, right, responsibility, condition, prescription or other regulatory element of the proposed regulatory provisions. The changes were identified in the second 15-day notice of modified text and second 15-day modifications to the “Instructions” such as revising structure, syntax, cross-references, grammar, and or punctuation.