

**DENTAL HYGIENE COMMITTEE OF CALIFORNIA  
DEPARTMENT OF CONSUMER AFFAIRS**

**INITIAL STATEMENT OF REASONS**

**Hearing Date:** August 21, 2013

**Subject Matter of Proposed Regulations:** Expanded Functions Course Approval

**(2) Section(s) Affected:** 1107, 1108

Specific Purpose of each adoption, amendment, or repeal:

The purpose of the proposed language is to provide specific criteria and standards for the Dental Hygiene Committee of California's (Committee) approval of required courses in extended functions for Registered Dental Hygienists (RDH), consisting of instruction in three duties: 1) administration of local anesthetic agents, 2) administration of nitrous oxide and oxygen used as an analgesic, and 3) periodontal soft tissue curettage. Although Section 1909 of the Business and Professions Code authorizes the Committee to approve these courses, currently there are no regulations that provide standards and criteria for approval. While all dental hygiene programs in California include instruction in these duties, programs outside California either may not contain this instruction, or may not have equivalent instructional requirements. Graduates of hygiene programs outside of California must complete these courses before licensure.

Only four of the approximately 30 currently approved dental hygiene programs in California offer the expanded duties course to individuals who are not hygiene students within their program, so any applicant for dental hygiene licensure in California must wait for availability of one of these few courses before becoming licensed as a California RDH. These regulations will allow the Committee to approve individual courses that meet the same criteria and standards as those given within all California dental hygiene programs.

New Section 1107 describes general requirements for all courses seeking approval. Section 1108 specifies the requirements that all courses must contain in order to obtain and maintain approval. These requirements establish the minimum standards for course approval to ensure consumer protection and safety for dental hygiene patients. The regulations also provide staff with specific criteria and forms that course applicants will use to apply for approval, a standard certification form that courses must complete and issue to each student who successfully completes the course, and a biennial report to the Committee of courses given.

**Section 1107:** This text informs individuals that these are the general requirements to achieve and maintain course approval for RDH expanded duties courses.

**Proposed Change:** This new text is added to clarify that this is the section of law that governs the approval of required courses in administration of local anesthesia and nitrous oxide, and periodontal soft tissue curettage, and that courses must continue to meet the requirements for approval at all times. Course directors and instructors must be informed of the requirements for course approval so that they can meet them and gain approval of their courses, and know that the course may not fall below the specified standards for continued approval. The Committee needs this mechanism to ensure that courses maintain the standards needed for approval.

**Problem:** There are currently no regulations that govern the approval of these courses. Course provider applicants do not know how to apply for approval. Staff can provide no clear and specific direction to course applicants as to how to obtain course approval. Course providers are not notified that courses must not only achieve, but maintain particular standards for continued approval..

**Anticipated Benefits:** Applicants would benefit from knowing that this section governs the approval of expanded duties courses and that courses must maintain the requirements for approval at all times. Staff would benefit by the ability to direct applicants to this section of law which governs course approval. Students would benefit by knowing that approved courses will consistently meet the specified requirements and provide the instruction necessary to successfully perform the three duties on patients. Consumers would benefit by having specific written guidelines for approval of these required courses so that all California licensees are adequately instructed in the safe performance of the duties.

**Section 1107(a):** This new text defines the parameters of course instruction by specifying the three expanded duties that may be performed by a California registered dental hygienist and identifying the areas of instruction required to gain approval.

**Problem:** There is no language that specifies that a course must offer instruction in all of the three duties to achieve approval. Courses have applied to offer instruction in one or two duties, not knowing that all three duties must be taught within the course in order for the course to be approved. Students may inadvertently take a course that teaches only one or two duties, so must take another course to fulfill the requirements for licensure.

**Anticipated Benefits:** This text would inform students, instructors, and course providers that all three duties must be contained within each course so that students know what to expect from the course and directors and course providers can meet the requirements in order to gain approval.

The section specifies that instruction in administration of local anesthetic agents is

limited to the oral cavity so that there is no confusion as to the location that local anesthetic may be administered. The text further specifies that students be taught both infiltration and conductive methods of administration of local anesthetic agents, as both of these methods are used in dental practice.

The text specifies that instruction given in the administration of nitrous oxide and oxygen is for the purposes of analgesia, and fail-safe type machines containing no other general anesthetic agents must be used so that students learn to safely administer nitrous oxide and oxygen to patients using appropriate equipment.

**Section 1107.2(b)**: This new language specifies and incorporates by reference the form to apply for approval of a course, that a fee must accompany the form and that an expanded duties course must be approved prior to operation. The text further states that subsequent to denial of approval of a course, the reasons for denial must be provided in writing within 90 days.

**Problem**: There is no standardized form for application for course approval. Courses submit materials that they think may be appropriate and wait to receive a response from the Committee. This language ensures that only courses that meet the standards in regulation are approved, and that students do not pay for and complete a course that is not approved.

**Anticipated Benefits**: This section would benefit applicants and staff by creating a standard mechanism for courses to apply for approval without having to guess at what the Committee needs for its review. Applicants and staff would benefit by course approvals based upon the requirements set out within the regulations and not perceived as subjective or arbitrary. Applicants would benefit by specific reasons for denial of course approval being provided in writing within 90 days, so that the director or instructor of the course may timely correct it to meet the deficiencies and gain approval. This is sufficient time for the Committee to complete a thorough review of the application and make a determination as to whether the course meets the regulatory standards or is deficient, and to give the course provider written direction as to what corrections must be made in order to achieve Committee approval.

The application form mirrors the requirements set forth in the proposed regulations. It requires the course provider's name and phone number, for identification purposes and so Committee staff may easily contact the applicant for information or clarification. The name and title of the course director is necessary as an additional contact in case the course provider is not available. The Committee asks the name of the affiliated dental or dental hygiene program to confirm that the course is affiliated with one of these programs. The mailing address of the course provider is necessary for mailing documents and the approval, once granted, and the address of the clinical facility is needed so that the Committee knows where the course will be held. Requirements for Course must be answered with "Yes" to be approved. These questions notify course providers of the requirements for courses and request documentation in the form of

curriculum and extramural site agreement, if applicable, so the Committee may determine that the course meets the standards for instruction and of the regulations. The form requires course provider applicants to submit faculty information and documentation of licensure, educational methodology, and calibration so the Committee may determine that faculty have been licensed for at least two years and have received instruction in educational methodology and been calibrated. These requirements ensure that instructional faculty have 1) recent and current experience and 2) sufficient experience and education to be able to instruct in the procedures and fairly grade the procedures according to current educational standards in dental hygiene.

The form requires the course to have a lecture classroom, patient clinic area, radiology area, and laboratory for students use, and to provide a site map containing these areas so the Committee may ensure that students have access to adequate physical facilities to receive instruction in administering local anesthesia, administering nitrous oxide-oxygen analgesia and soft tissue curettage. The form asks for a list of equipment used so that the Committee may determine whether a course provider has sufficient and appropriate equipment to instruct students in the duties. The form specifies that students must receive a copy of the bloodborne and infectious diseases exposure control plan, including the emergency needlestick information and also have access to the course's hazardous waste management plan for disposal of needles, cartridges, medical waste, storage of nitrous oxide and oxygen tanks and the course's clinic and radiation hazardous communication plan, so that students have the knowledge of lawful protocols in these areas that are necessary for employment in California's dental offices and clinics and provide safety for students, patients and other workers. Course providers must attach a copy of each document so the Committee may verify that the plans are current according to the requirements of the California Code of Regulations Title 16, Section 1005 relative to Minimum Standards for Infection Control.

The form requires a copy of the course's curriculum and schedule, and specifies that students must develop and demonstrate competence in each of the three duties through a specified number of course hours and experiences by didactic, laboratory and clinical instruction, so that students learn about the duties through texts, lecture or CD, followed by structured performance in a laboratory and then a clinical setting to ensure that students are qualified to perform each process safely before proceeding to the next instructional phase, thereby gaining the knowledge and skill set necessary to safely perform the procedure before being allowed to do so on California consumers.

The form allows, but does not require, course providers to grant continuing education credits for the course, and asks for the provider's continuing education provider number, if continuing education will be given, so the Committee may confirm that the provider is an approved continuing education provider.

The form requires course providers to keep copies of curriculum, sample test questions and lab and clinic rubrics, copies of faculty credentials and individual student records and evaluations so that students and the Committee may have access to this relevant

information for at least 5 years after the student has completed the course. The form requires that a course issue a certificate of completion to each student who successfully completes the course to assist Committee staff by standardizing the document for all students taking the course from any approved provider, which is incorporated by reference in Section 1108(j) of these regulations. Please see justification on pages 16-17.

The form requires course provider applicants to acknowledge that they have reviewed the statutory and regulatory sections relative to the course, and will abide by the requirements contained in Business & Professions Code §1909 and Title 16 of the California Code of Regulations §1005, §1107 and §1108. This ensures that providers know exactly which laws and regulations govern the continued approval of their course. The form requires the course director to sign and date the application under penalty of perjury, so the Committee is assured that the application contains true information, and provides a mechanism to withdraw approval from a course who does not maintain the standards of the law and regulations when providing the course to students.

**Section 1107(c):** This proposed new text allows the Committee to withdraw approval at any time that it determines that a course does not meet the requirements of the section or other requirements of law.

**Problem:** Applicants and approved course providers may not know that the Committee may take action against courses that no longer meet the requirements of the law.

**Anticipated Benefits:** This section would benefit students and consumers by informing applicants and course providers that students are protected from paying for and taking courses that fail to instruct them in the duties to minimum competence. Consumers would be protected from students who complete an “approved” course successfully but are not competent in the duties.

**Section 1107(d):** This proposed new text requires that courses be established at the postsecondary education level.

**Problem:** Course provider applicants may not know that the minimum educational standard for instruction in the three duties must be at the postsecondary level.

**Anticipated Benefits:** This section would benefit course provider applicants and students by informing them that instruction must be at the postsecondary level in order for the course to be approved. All dental hygiene educational requirements are set at the postsecondary level, therefore this is consistent with other educational standards for dental hygiene programs.

**Section 1107(e):** – This new text specifies that the Committee may review an approved course at any time.

Problem: Course providers may not know that their course is subject to review at any time by the Committee. This new text specifies clearly in the regulations governing course approval that the Committee may review the course at any time.

Anticipated Benefits: Course providers would be notified that courses may be reviewed by the Committee at any time. Students and consumers would be protected by the Committee's ability to review courses for continued compliance with regulatory standards.

**Section 1107(f):** This new text requires that each approved course submit a biennial report on a specified form, incorporated by reference. The form must contain the name, address, provider number, phone number, contact person, name and dates of course provided, and names and qualifications of instructors, in addition to any changes made to the course based on student evaluations. This information is needed so the Committee can identify and contact the provider if necessary, and notifies the Committee of any changes in the course or faculty, so that continued compliance with statute and regulation can be documented.

Problem: Once a course is approved, there is no further contact or information received from the provider unless there is a complaint regarding the course or the provider.

Anticipated Benefits: The Committee would receive information about the course at least biennially. The biennial report would provide a mechanism by which the Committee can gain information regarding how often the course is given, the number of continuing education units offered, the success rate of students and any changes made due to student evaluations. Biennial reporting frequency is often enough to capture essential information regarding the course, but not so often as to be burdensome on the provider. Other information would be necessary for staff to contact the course provider.

**Section 1108(a):** This new section specifies the requirements for administration of courses.,

**Proposed Change:**

This proposed change requires the Committee be informed within 10 days of any changes to course content, physical facilities or faculty. The text specifies that students shall be issued a certificate of completion upon successful completion of the course. This Section specifies that students must either possess a valid, active dental hygiene license or be a graduate of a dental hygiene program and current certification in Basic Life Support for health care providers in order to be eligible to take the course, so that students meet the educational qualifications for dental hygiene licensure before taking a course that involves clinical practice on Californians that might otherwise be given to unqualified individuals or to students who have insufficient education to successfully complete the course. This text tells the course director exactly when he or she must notify the Committee of changes that could impact the approval of the course and

course provider. Ten days is a reasonable amount of time for the provider to notify the Committee of such changes, while giving the Committee this information on a timely basis, so that students are not taking a course that fails to meet the requirements and therefore may not be able to safely perform the duties on patients, even though they have successfully completed a Committee-approved course.

Problem: The Committee needs to know immediately if the course content, physical facilities or faculty of an approved course changes, in case such change impacts the ability of the course to meet the regulatory and instructional requirements. Course provider applicants do not know that students must complete the minimum requirements for California dental hygiene licensure before taking a course that includes clinical practice on Californians. Not all course provider applicants issue course completion certificates, and those that do are not standardized.

Anticipated Benefits:

Course providers and applicants would benefit from having specific requirements in writing. The Committee would benefit through the requirement of notification within 10 days of changes in course content, faculty or physical facilities, which might impact the provider's ability to give a course which meets students' instructional needs. Students and course providers would benefit by knowing course admission requirements in advance and by the convenience of having a standard certificate of completion.

Section 1108(b): This new language specifies the qualifications that every faculty member instructing in an expanded duties course must possess in order for the course to meet and retain approval. Qualifications include a current, valid, and active California license issued by the Committee or the Dental Board of California for at least two years, and the stipulation that no instructor may teach a procedure that he or she is not legally allowed to perform, as this could result in harm to students taking the course and clinical patients used for the course. This section of text requires that all faculty members have education in educational methodology within the past two years and be calibrated to instructional standards. These qualifications are standard for faculty who instruct in all California dental hygiene programs and ensure that faculty have recent license experience and have up-to-date educational methodology instruction so that students are instructed by knowledgeable faculty with the ability to instruct and evaluate students' progress according to current educational practices.

Problem: Unlicensed individuals or licensees who possess a revoked, cancelled, or expired license could instruct the course. Licensees who are not legally allowed to perform a particular duty would be able to instruct in the duty, potentially causing harm to students and patients.

Anticipated Benefits: This provision would protect consumers by requiring that only licensees with expertise in current dental practice, and who are legally allowed to perform the procedure instruct students in performing these duties that may cause harm to patients if performed incorrectly. Students would benefit by having qualified

instructors who are instructionally calibrated to the same standards.

**Section 1108(c)**: This new text specifies the requirements for approval in the areas of facilities and equipment. The regulations state the requirements, and that each student must have the access needed to develop skills in the expanded duties. This section informs directors and instructors that seating and writing space, audio-visual equipment, and infection control materials specified in regulation must be provided for students so that students have an adequate environment in which to learn to perform the duties, and infection control materials for their own protection as well as to learn California's specific protocols regarding infection control as described in Section 1005 of the California Code of Regulations.

**Problem**: Students might not have access to all necessary facilities and equipment, and course providers would not know what equipment and facilities are necessary for approval without this regulation. Infection control protocols may not be followed, resulting in harm to Californians.

**Anticipated Benefits**: This text would benefit all parties, including staff, by specifying the requirements for course facilities and equipment that are needed to achieve and maintain approval. Students coming from other states need to have the necessary facilities and equipment to learn the expanded duties and must follow California's established infection control protocols so they can practice safely and according to the requirements of California law on California consumers.

**Section 1108(d)**: This new regulatory text specifies that course providers must document compliance with health and safety policies in accordance with local, state, and federal laws and regulations, and provide students with access to the course's hazardous waste management plan for disposal of needles, cartridges, medical waste, and storage of oxygen and nitrous oxide tanks. This text informs course providers that documentation is required by local, state and federal entities regarding these activities. The text specifies that students have access to the course's clinic and radiation hazardous communication plan, and receive a copy of the course's bloodborne and infectious diseases exposure control plan, including emergency needlestick information, so that students know what to do in case of such emergencies.

**Problem**: There is currently nothing in regulation that requires that students have access to or be provided with this information. Students must have access to this important information to protect consumers from infection and exposure to hazards inherent to the provision of local anesthesia and nitrous oxide/oxygen.

**Anticipated Benefits**: Students coming from other states need to learn California health and safety policies and requirements for infection control and hazardous waste. Safety and infection control requirements are at least as important with students in an educational setting as with patients in an office setting. Also, these students will be coming from other states, and will not be aware of standard infection control procedures

and hazardous waste protocols used in California. This section would ensure that all parties are aware of the protocols and requirements for compliance with California's infection control and hazardous waste management standards for consumer protection and safety in the dental office.

**Section 1108(e)**: This new text specifies the clinical education requirements for courses, including provisions for direct supervision of clinical training.

**Problem**: Currently there are no specific requirements as to where clinical instruction can take place, nor that duties which require supervision when performed by licensees must have the same supervision during instruction. Course provider applicants, students and Committee staff need to know what constitutes clinical education for a course in administration of local anesthesia, administration of nitrous oxide and oxygen, and periodontal soft tissue curettage, so that course provider applicants may know how to gain approval, students are assured adequate clinical facilities and supervision, and staff is able to easily communicate the instructional requirements for clinical facilities and supervision to course provider applicants.

**Anticipated Benefits**: Course provider applicants, students and staff need clearly specified requirements for clinical education so there is no question as to where clinical instruction may take place, and the supervision levels required during instruction. Instruction needs to take place at a dental or dental hygiene school or at an approved extramural facility because these facilities have the classroom, laboratory and clinic areas, equipment, and supplies to instruct students in the administration of local anesthesia, administration of nitrous oxide-oxygen analgesia, and soft tissue curettage. Otherwise, students may be taught in a small dental office that does not have sufficient space for students to learn, or in a hotel, hall or other facility that does not provide an adequate laboratory or clinical environment in which to learn to successfully perform the three duties.

**Section 1108(f)**: This new language specifies the requirements for records to be kept by course providers for five years, including: course curricula containing a syllabus; copies of written examinations, lab and clinic rubrics, and competency evaluations; copies of faculty credentials, licenses, and certifications, including educational methodology within the last two years; individual student records, including those necessary to establish satisfactory course completion; and student course evaluations and summaries. This information needs to be retained for students who may lose their certificate or apply to another state that requires documentation of the course before issuing a permit to perform the duty or duties. The course provider may be asked for this information in the instance of a complaint or complaints to the Committee about the course provider, and therefore needs to investigate the course's content.

**Problem**: There are no written requirements for records that course providers are expected to keep, nor a timeframe for records to be kept. The Committee is not able to review or audit course providers, or to investigate any complaint regarding a provider's

course. Students do not know which records will be kept, or for what period of time.

Anticipated benefits: This text would benefit course providers and students by clearly listing the records that course providers are expected to keep and specifying a five-year period that the records must be kept. Five years is a reasonable time without being burdensome to expect course records to be kept for students who need to document exactly what instruction was received and for the Committee to review in the case of a complaint against the course provider. The Committee would be able to review and audit course providers, and students would know that the records establishing their satisfactory completion of the course will be retained for at least 5 years.

**Section 1108(g):** This new language specifies the requirements for curriculum and learning resources for courses, and the necessity for each one, as follows:

Section 1108(g)(1): This subsection requires that course curriculum be flexible, so that it may be adjusted for advances in the three expanded duties.

Problem: Course content and curriculum need to be adjusted periodically to accommodate new technologies and the results of research in the administration of local anesthesia, administration of nitrous oxide and oxygen and periodontal soft tissue curettage. Courses must contain instruction in methods and equipment used in current dental practice.

Anticipated benefits: Students and consumers would benefit by experiencing the most current and widely used techniques in current dental practice. Course providers would benefit from the ability to update courses as necessary to adapt to advances.

Section 1108(g)(2): This subsection requires that course curriculum provides students with a basic understanding of the three expanded duties, and the ability to perform each procedure competently.

Problem: There is currently no requirement that a course must provide students with a basic understanding and the ability to perform the expanded duties.

Anticipated Benefits: This language would alert course providers and students that an approved expanded duties course must provide each student with a basic understanding of the three duties and sufficient opportunity to develop minimum competency in the duties. Consumers would be protected from students who may otherwise successfully complete an approved course without achieving a basic understanding of and the ability to perform the three duties.

Section 1108(g)(3): This subsection requires that in order to be approved, course curriculum must prepare students to assess, plan, implement and evaluate the three expanded duties procedures.

Problem: There are no existing requirements that a course curriculum must contain the elements to prepare students with the necessary skills to plan, implement and evaluate the expanded duties. Students need to be instructed in the process and protocols involved in performance of each of the three duties.

Anticipated Benefits: This would benefit and protect the public by ensuring that a student has achieved the necessary skills to assess, plan, implement and evaluate the administration of local anesthetic agents, nitrous oxide and oxygen analgesia and periodontal soft tissue curettage before performing these duties on California consumers. Staff and course providers would benefit by knowing these elements must be contained within the curriculum in order for the course to be approved.

Section 1108(g)(3): This subsection requires that in order to be approved, course curriculum must include a remediation policy and procedures. Remediation is the process by which a student can achieve a passing grade after receiving a fail grade.

Problem: Students need to be informed of the process for remediation if they fail to successfully complete the course. Course providers need to be aware that they must have a remediation policy and procedures in place in order to achieve approval.

Anticipated Benefits: This would benefit course providers and students by having the course's remediation policy and procedures clearly stated in the curriculum, so there is no doubt as to the process needed to remediate if the student is unsuccessful.

Section 1108(g)(4): This subsection lists the following items that must be included in the course's syllabus and requires that it be provided to students in order to be approved by the Committee. The necessity for each item follows:

Section 1108(g)(4)(A): This subsection specifies that the course provide students with a course syllabus that contains course learning outcomes, so that students know the expected outcome of the course. Students who understand the expected course learning outcomes are more likely to successfully complete the course.

Section 1108(g)(4)(B): This subsection specifies that the course provide students with a course syllabus that contains textbooks published within the previous five years, in order for students to be instructed according to the most up-to-date texts so they learn the procedures as utilized in current dental practice. Textbooks and learning materials are constantly revised, so five years is a reasonable timeframe to instruct students in current dental practices without being burdensome to the course provider to update textbooks on a more frequent basis.

Section 1108(g)(4)(C): This subsection specifies that the course provide students with a course syllabus that contains content objectives, so that students can clearly see the areas of instruction that they will experience within the course and how they will result in the ability to perform the duties. Written content objectives inform students of exactly

what is needed and will be taught so they may successfully complete the course.

Section 1108(g)(4)(D): This subsection specifies that the course provide students with a course syllabus that contains grading criteria which includes competency evaluations and lab and clinic rubrics to include problem solving and critical thinking skills that reflect course learning outcomes. This ensures that students have complete information as to the course expectations regarding successful performance and the skills needed so they may successfully complete the course with the ability to safely perform the duties on patients.

Section 1108(g)(4)(E): This subsection specifies that the course provide students with a course syllabus that contains a remediation policy and procedures, so that students know the policy and process involved if they fail to successfully complete the course. Students might otherwise believe that they can repeat the course indefinitely at no cost until they achieve competency in all three duties.

Problem: Students do not know what to expect from the course, may be given out-of-date textbooks and think they are guaranteed to successfully complete the course without this language.

Anticipated Benefits: This would benefit course providers, students and Committee staff by clearly stating that students be provided with a syllabus that contains these elements that clarify what students may expect from the course so that students may successfully complete the course and perform the duties safely on patients.

Section 1108(h): This subsection lists the areas (beginning with Section 1108(h)(1) below) of general curriculum content instruction that must be included in the course in order to be approved by the Committee, and must include didactic, laboratory, preclinical and clinical instruction. Each of these types of instruction is necessary for the student to gain the knowledge, then practice on laboratory equipment, and on other students and volunteer patients to reach the level of expertise required to physically perform the duties to clinical standards on dental patients. The necessity for each item follows:

Section 1108(h)(1): This subsection requires that courses instruct in indications and contraindications for each of the three expanded duties so that students learn protocols for administering local anesthesia, nitrous oxide-oxygen analgesia and periodontal soft tissue curettage on obese, elderly, physically compromised, developmentally compromised and pediatric patients. Each type of patient presents challenges that must be taken into account and monitored by the dental hygienist and courses need to instruct students in the appropriate actions for patients' safety.

Section 1108(h)(2): This subsection requires that courses instruct in head and neck anatomy because airway management during the performance of these duties is extremely important to ensure patients' safety, particularly in children.

Section 1108(h)(3): This subsection requires that courses instruct in physical and psychological evaluation procedures since patients may be using drugs or substances that can interfere with procedures, and may have physical or mental issues that can complicate the administration of anesthesia or analgesia or lead to excessive blood loss during the curettage procedure. Students need specific instruction in evaluating patients' physical and psychological condition prior to the performance of the duties so that patients' safety is not compromised by the procedure.

Section 1108(h)(4): This subsection requires that courses review body systems as they relate to the course topics. Students need to review the circulatory system and the respiratory system as they relate to the three duties so they know signs and symptoms that may be of concern during these procedures for patients' safety.

Section 1108(h)(5): This subsection requires that courses instruct in the theory and psychological aspects of pain and anxiety control as these subjects directly affect the outcome of administration of anesthesia and analgesia. Students must be instructed in the latest methods for pain and anxiety control so they may safely and effectively provide pain and anxiety relief to patients.

Section 1108(h)(6): This subsection requires that courses instruct in the selection of pain control modalities since there is a serious concern regarding overdosing and students must be knowledgeable of the latest advances in pain control.

Section 1108(h)(7): This subsection requires that courses instruct in pharmacological considerations such as the action of anesthetics and vasoconstrictors, reversal and nitrous oxide-oxygen analgesia agents. In the case of an emergency during the performance of one of the three duties, the dental hygienist must know the reversal action that may be ordered by the supervising dentist and be ready to take the action without undue delay. In the event of an emergency the supervising dentist does not have time to instruct the licensee in the actions necessary, which should have been taught in the required course so that the licensee knows the appropriate choice of actions and be ready to take the action immediately upon word from the dentist.

Section 1108(h)(8): This subsection requires that courses instruct in recovery from and post-procedure evaluation of the three duties, since the dental hygienist may be the primary person in the operatory while the dental patient is recovering before being checked by the dentist in preparation to being dismissed. The student needs to learn what to look for in a normal recovery and when to call for the dentist or other assistance if the recovery is not proceeding normally.

Section 1108(h)(9): This subsection requires that courses instruct in complications and management of emergencies for each of the three duties. Students need to be knowledgeable regarding possible complications and the appropriate action to take in each potential emergency situation so they are prepared to anticipate complications

and emergencies and take appropriate action in each instance for patient protection.

Section 1108(h)(10): This subsection requires that courses instruct in armamentarium (complete equipment) required and current technology available for each of the three expanded duties. Students need to be knowledgeable about the equipment needed and the methods to complete each of the procedures successfully on patients. Many times the dental hygienist will set up the operatory prior to performance of these procedures, so students must have the knowledge to both prepare for and administer the expanded duties.

Section 1108(h)(11): This subsection requires that courses instruct in the techniques for administration of maxillary and mandibular local infiltrations, field blocks and nerve blocks, nitrous oxide-oxygen analgesia and periodontal soft tissue curettage. Students must be knowledgeable regarding techniques for administration of anesthesia, analgesia and curettage to safely perform these duties on patients.

Section 1108(h)(12): This subsection requires that courses instruct in proper infection control techniques according to existing dental regulations that specify minimum standards for infection control in California. These courses will be taken by students coming to California from other states, so it is imperative that they learn the minimum standards for infection control as practiced in all California dental offices.

Section 1108(h)(13): This subsection requires that courses instruct in patient documentation, including computation of maximum recommended dosages for local anesthetics and total lung capacity for nitrous oxide-oxygen analgesia. Students need to be knowledgeable in these areas, so that patients do not receive excessive dosages of local anesthesia or nitrous oxide-oxygen analgesia that may place them at risk.

Section 1108(h)(14): This subsection requires that courses instruct in medical and legal considerations including patient consent, standard of care and patient privacy so that students learn the standards for documentation and care, and do not inadvertently violate patients privacy.

Section 1108(h)(15): This subsection requires that courses instruct in the student course evaluation mechanism. All courses are required to obtain student evaluations and students must receive this instruction so they may properly evaluate the course.

Problem: General curriculum content is not listed or specified, leading to confusion on the part of course provider applicants, students and Committee staff as to the elements required to gain Committee approval. These elements are consistent with those contained in all California dental hygiene educational programs.

Anticipated Benefits: Course provider applicants, students and Committee staff would benefit by having clearly specified general curriculum requirements so that all parties know what the course curriculum must contain to achieve and maintain approval.

Consumers would benefit by a curriculum that contains all necessary elements to instruct students in the safe administration of the three duties.

Section 1108(i): This subsection lists specific curriculum content areas that a course must contain in order to achieve and maintain Committee approval.

Problem: There are no specifics regarding the curriculum content that a course must provide in order to gain and maintain Committee approval.

Anticipated Benefits: Course provider applicants, students and Committee staff would benefit by having specific curriculum content areas written into regulation, so that all parties know the content and hours that a course must contain in order to be approved.

Section 1108(i)(1): This new language requires courses to include at least 30 hours of instruction in the administration of local anesthetic agents, including at least 15 hours of didactic, laboratory and/or preclinical instruction, and at least 15 hours of clinical instruction that includes at least 3 clinical experiences per injection on 3 different patients, only 1 of which may be on a student. The text further specifies each of the techniques required, and that one of the clinical experiences will be used as a clinical competency and must be achieved at a minimum of 75%. This is equivalent to the requirements contained in California dental hygiene education programs.

Problem: There is no regulation that specifies the hours, number or types of injections that instruction in the administration of local anesthetic agents must contain in order to achieve Committee approval. There are no standards for clinical competency outside of a complete dental hygiene education program.

Anticipated Benefits: Course provider applicants would benefit through clearly specified requirements for course approval of instruction in the administration of local anesthetic agents. Students would benefit from having clearly stated hourly and competency requirements for successful completion. Staff would benefit by having clear written course requirements that can be communicated to applicants. This informs course providers and students that the course must include these elements, and ensures that students have adequate instruction and clinical practice to competency that prevents patient harm by the improper performance of local anesthesia injections.

Section 1108(i)(2): This new text requires courses to include at least 8 hours of instruction in administration of nitrous oxide-oxygen analgesia, including at least 4 hours of didactic, laboratory and/or preclinical instruction and at least 4 hours of clinical instruction that includes at least 3 clinical experiences on 3 different patients, only 1 of which may be on a student. The text further specifies that one of the clinical experiences will be used as a clinical competency to be achieved at a minimum of 75%. These requirements are equivalent to those contained within a complete California dental hygiene educational program.

Problem: There is no regulation that specifies the hours or number of experiences that instruction in the administration of nitrous oxide-oxygen analgesia must contain in order to achieve Committee approval. There are no standards for clinical competency.

Anticipated Benefits: Course provider applicants would benefit through clearly specified requirements for course approval of instruction in the administration of nitrous oxide-oxygen analgesia. Students would benefit from having clearly stated hourly and competency requirements for successful completion. Staff would benefit by having clear written course requirements that can be communicated to applicants. This would inform course providers and students that the course must include these elements, and ensure that students have adequate instruction and clinical experience to achieve competency that prevents patient harm by the improper administration of nitrous oxide-oxygen analgesia.

Section 1108(i)(3): This new text requires courses include at least 6 hours of instruction in periodontal soft tissue curettage, including at least 3 hours of didactic, laboratory and/or preclinical instruction and at least 3 hours of clinical instruction that includes at least 3 clinical experiences on 3 different patients which may include soft tissue laser, only 1 of which may be on a student. The text further specifies that 1 of the clinical experiences will be used as a clinical competency to be achieved at a minimum of 75%. These requirements are equal to those contained within a complete California dental hygiene educational program.

Problem: There is no regulation that specifies the hours of instruction or number of experiences that instruction in periodontal soft tissue curettage must contain in order to achieve Committee approval. There are no standards for clinical competency outside of a complete dental hygiene educational program.

Anticipated Benefits: Course provider applicants would benefit through clearly specified requirements for course approval of instruction in periodontal soft tissue curettage. Students would benefit from having clearly stated hourly and competency requirements for successful completion. Staff would benefit by having clear written course requirements that can be communicated to applicants. This would inform course providers and students that the course must include these elements, and ensure that students have adequate instruction and clinical experience to achieve competency that prevents patient harm by the improper performance of periodontal soft tissue curettage.

Section 1108(j): This subsection specifies that a course provider must issue a standardized certificate of completion form upon the student's achievement of clinical competency of the 3 procedures, and incorporates the form by reference. The form contains the student's name and last five digits of his or her social security number for identification purposes to confirm that the student is the California registered dental hygiene license applicant who successfully completed the course. The form requires the student's address, email address and phone numbers for contact purposes. The form requires the course provider's name, address, dates of course, phone number,

and email so the Committee may verify when the California registered dental hygiene license applicant (student) completed an approved course, and may contact the course provider for information or clarification. The form requires the printed name and signature of the course instructor or director certifying under penalty of perjury that the student (license applicant) listed successfully completed the required coursework and demonstrated clinical competency in the administration of local anesthesia, administration of nitrous oxide-oxygen analgesia, and soft tissue curettage, along with the seal or stamp of the course provider or institution as a mechanism to ensure that only students who successfully complete the instruction and demonstrate clinical competence may be licensed as California registered dental hygienists who may safely perform these duties on patients.

Problem: There is no requirement that a course issue each student who successfully completes the course a certificate of completion, and no standards for issuance.

Anticipated Benefits: Students would be assured that they will receive a standard document upon successful completion of the course that is easily recognizable by all parties. Course providers would benefit by the ability to use a form that will be accepted by the Committee without the need to create or design a certificate which may not contain complete and necessary information. Staff would benefit by receiving clear and consistent documentation from all out-of-state graduates regarding their completion of these mandatory requirements for California dental hygiene licensure.

#### Factual Basis/Rationale

The Committee is the regulatory entity responsible for the licensing and regulation of the dental hygiene profession in California. Business and Professions Code Section 1905(a)(1) gives the Committee the authority to evaluate all dental hygiene educational programs that apply for approval, and grant or deny approval of those applications in accordance with regulations adopted by the Committee. These regulations provide needed clarity as to the requirements for educational courses in administration of local anesthetic agents, administration of nitrous oxide-oxygen analgesia and soft tissue curettage that are required for California dental hygiene licensure and contained in all California dental hygiene educational programs, but are not necessarily included in out-of-state dental hygiene educational programs, and a mechanism by which these educational courses may apply to the Committee for approval. Business and Professions Code Section 1905(a)(3) requires the Committee to review and evaluate all registered hygienist applications for licensure to ascertain whether the applicant meets the appropriate licensing requirements specified by statute and regulations. These regulations will specify the required instruction in administration of local anesthetic agents, administration of nitrous oxide-oxygen analgesia and soft tissue curettage that all applicants for licensure must successfully complete in order to gain California licensure.

Business and Professions Code Section 1917(f) requires that before an applicant is granted a license as a registered dental hygienist in California, he or she must

satisfactorily complete Committee-approved instruction in administration of local anesthetic agents, administration of nitrous oxide-oxygen analgesia and soft tissue curettage. Applicants who have graduated from approved California dental hygiene programs have received this instruction. Out-of-state applicants may not have done so, requiring them to complete this instruction before a California registered dental hygienist license can be issued.

Business and Professions Code Sections 1905(a)(9) and 1906(a) authorize the Committee to adopt, amend and revoke rules and regulations to implement the requirements of Article 9. Section 1944(a)(11) relative to fees specifies the maximum allowable fee for review of courses required for licensure that are not accredited by a Committee-approved agency, the Council for Private Postsecondary and Vocational Education, or the Chancellor's Office of the California Community Colleges as \$300. At its December 2012 meeting the Committee resolved that the fee for approval of a provider of courses in administration of local anesthesia, administration of nitrous oxide-oxygen analgesia, and soft tissue curettage is \$300, the application fee specified on the application form incorporated by reference within these regulations.

These regulations provide criteria and a simpler mechanism for approval of courses that are required for graduates of out-of-state dental hygiene programs in order to achieve California licensure. By clearly specifying requirements for course approval, course provider applicants may use these regulations to ensure that their courses meet the necessary requirements for approval by the Committee. The Committee has placed standards in these regulations that would ensure that consumers are protected through instructional requirements for out-of-state graduates that are the same as those currently contained within California based dental hygiene educational programs.

#### Underlying Data

1. Minutes of December 3-4, 2012 Dental Hygiene Committee of California Meeting
2. Minutes of May 3, 2013 Dental Hygiene Committee of California Meeting

#### Business Impact

This regulation will not have a significant adverse economic impact on businesses. This regulation will impact course provider applicants who wish to provide courses in the expanded duties and applicants who graduated from out-of-state dental hygiene programs applying for California dental hygiene licensure. Of the approximately 700 licenses issued annually by the Committee, nearly 600 are issued to California graduates. The remaining 100 have graduated from other states and must successfully complete instruction in the expanded duties before becoming licensed.

It is unknown how many businesses will apply to be course providers for the expanded duties, due to the laboratory and clinical facilities and equipment needed to instruct and perform the duties. Existing course providers charge each student taking the course

approximately \$4,500. If each provider instructs thirty (30) students annually, the provider would take in \$135,000 per year. This regulation would require that course providers operating such businesses pay a \$300 one-time application fee to be approved to provide the courses, and provide specified facilities, equipment and faculty to instruct in the procedures. Existing course providers currently incur the costs of administering the course as operating expenses. The one-time application fee is less than 1% of the fee charged to one student taking the course from an existing provider.

### Economic Impact Assessment

This regulatory proposal will have the following effects:

- It would not create or eliminate jobs within the State of California because this proposed regulation only affects the few businesses that would provide expanded duties courses to approximately 100 out-of-state dental hygiene program graduates annually. At this time, providers of these courses are considered for approval on a case-by-case basis.
- It would create new businesses by clarifying the process by which course providers may apply and be approved to give an expanded duties course to non-California dental hygiene program graduates, making it easier for businesses to apply to become course providers. It would not eliminate existing businesses within the State of California because the proposal specifies requirements for a course of instruction that the provider met or exceeded to become approved.
- It would not affect the expansion of businesses currently doing business within the State of California because existing course providers are not prohibited from expanding their businesses to serve more out-of-state dental hygiene graduates, and these regulations do not place any restrictions on expansion of business.
- This regulatory proposal would benefit the health and welfare of California residents who will continue to be protected from individuals who have not learned or demonstrated the ability to safely perform soft tissue curettage, local anesthesia and nitrous oxide-oxygen analgesia on patients.
- This regulatory proposal would benefit California consumers by allowing more out-of-state dental hygiene graduates to become licensed in California, or become licensed sooner, due to increased availability of the required course.
- This regulatory proposal would enhance worker safety in places where dental hygiene is performed by ensuring that all California licensed dental hygienists are knowledgeable in the expanded duties so they do not endanger other workers.

- This regulatory proposal would benefit the state's environment because it requires that out-of-state graduates be instructed in California's standards for safe storage of oxygen and nitrous oxide tanks, hazardous waste management, infection control, and disposal of needles, cartridges and medical waste before performing duties involving the use of such equipment and materials.

### Specific Technologies or Equipment

This regulation would not mandate the use of specific technologies or equipment.

### Consideration of Alternatives

No reasonable alternative to the regulatory proposal would be either more effective in carrying out the purpose for which the action is proposed or would be as effective or less burdensome to affected private persons and equally effective in achieving the purposes of the regulation in a manner that ensures full compliance with the law being implemented or made specific.

Set forth below are the alternatives which were considered and the reasons each alternative was rejected:

Alternative No. 1: Do not pursue regulations. This is not reasonable because many comments have been received by the Committee from out-of-state graduates as well as existing providers that regulations are necessary to clarify requirements for these courses. These regulations would make it easier for course providers to apply for and be approved to give the required course, and thereby make the course more available to out-of-state graduates who cannot be issued a California registered dental hygiene license until they have successfully completed the required coursework.