

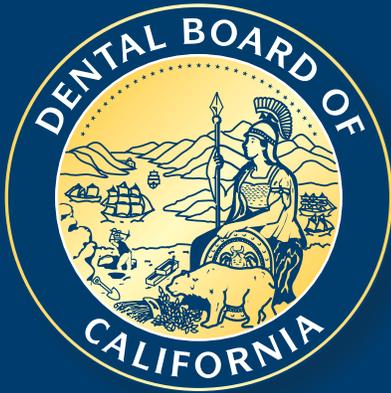


**DENTAL BOARD OF CALIFORNIA  
BACKGROUND INFORMATION  
AND OVERVIEW OF THE CURRENT  
REGULATORY PROGRAM**

Submitted to the Legislature December 1, 2018

**VOLUME 3**





## **ATTACHMENT C**

# **DENTAL BOARD OF CALIFORNIA MAJOR STUDIES (CF., SECTION 1, QUESTION 4)**

- d. Report on the Portfolio Examination as Provided by Business and Professions Code Section 1632.6
- e. Dental Board of California Pediatric Anesthesia Study, December 2016
- f. Report on the Elective Facial Cosmetic Surgery Permit Program as Provided by Business and Professions Code Section 1638.1, January 1, 2017
- g. Dental Board of California Review of the Registered Dental Assistant Practical Examination, April 2017
- h. Dental Board of California Review of the Registered Dental Assistant in Extended Functions Clinical and Practical Examinations, January 2018



**DENTAL BOARD OF CALIFORNIA**

**REPORT ON THE PORTFOLIO EXAMINATION AS  
PROVIDED BY  
BUSINESS AND PROFESSIONS CODE SECTION 1632.6**

**December 1, 2016**

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## **Introduction**

Pursuant to Business and Professions Code Section 1632.6, the Dental Board of California (Board) is required to review the Portfolio Examination to ensure compliance with the requirements of Business and Professions Code Section 139 and to certify that the Portfolio Examination meets those requirements. If the Board determines that the Portfolio Examination fails to meet those requirements, the Portfolio Examination will cease to be implemented and it will no longer be an option for applicants. The Board's review and certification or determination is required to be completed and submitted to the Legislature and the Department of Consumer Affairs by December 1, 2016.

Business and Professions Code Section 139 establishes the requirements for the Department of Consumer Affairs to develop a policy regarding examination development and validation, and occupational analysis. Additionally, Section 139 requires that every regulatory board and bureau within the Department of Consumer Affairs submit to the Director on or before December 1<sup>st</sup> annually, its method for ensuring that every licensing examination administered by or pursuant to the contract with the board is subject to periodic evaluation. The evaluation is required to include a description of the occupational analysis serving as the basis for the examination, sufficient item analysis data to permit a psychometric evaluation of the items, an assessment of the appropriateness of prerequisites for admittance to the examination, and an estimate of the costs and personnel required to perform these functions. The evaluation may be conducted by the Board, program, or bureau, the Department of Consumer Affairs' Office of Professional Examination Services, or pursuant to a contract with a qualified private testing firm. A board, program, or bureau that provides for the development or administration of a licensing examination pursuant to contract with a public or private entity may rely on an occupational analysis or item analysis conducted by that entity.

The Board is submitting this report on the Portfolio Examination pursuant to Business and Professions Code (Code) Section 1632.6 (Assembly Bill 1524, Chapter 446, Statutes of 2010). The statute requires a report to be submitted by December 1, 2016.

## **Examination Validation & Development**

In 2008, the Board began considering alternative pathways for initial licensure for dentists and contracted with Comira, a psychometric consulting company, to explore the feasibility of those pathways. The Board had concerns about existing clinical examinations, especially in terms of validity of the content tested and the reliability of judgments made on examinee performance. Comira identified four alternatives to initial licensure based on interviews, observations, and documentation; those alternatives were: (1) Curriculum Integrated Format (CIF), (2) Objective Standardized Clinical Examination (OSCE), (3) traditional portfolio, and (4) a hybrid portfolio examination. The hybrid portfolio examination was an alternative based upon the synthesis of the traditional portfolio and test cases (or competency cases) used in the dental schools for competency evaluations.

Comira studied the feasibility of these alternative pathways in consultation with the Board-approved pre-doctoral dental schools located in California. In February 2009,

Comira prepared a report for the Board entitled *Alternative Pathways for Initial Licensure for General Dentists, Final Report, February 9, 2009* which provided findings and evidence to support the feasibility of an additional examination for the Board to add as a pathway to initial licensure. The report supported the conclusion that the hybrid portfolio examination model satisfied the criteria identified by the Board and the psychometric consultants. Minimum competence could be built into standardized rating scales and extensive calibration and re-calibration of the examiners would address psychometric issues such as reliability and validity. Psychometric issues of validity and reliability could be addressed through careful specification of standards, criteria and scoring guides, and thorough calibration and training of designated examiners. The Board would be responsible for final approval of portfolio information, conducting site visits, and performing periodic audits of detailed portfolio documentation.

Comira concluded that the most noticeable strength of the Board-approved pre-doctoral dental schools located in California was the thoroughness of their clinical training and the commitment of their faculty to the students. The faculty understood the distinction between their role as a mentor and as an examiner in that there was no intervention during any competency examination unless the patient was in danger of being harmed. All of the dental school's programs had extensive training to calibrate their examiners, including detailed PowerPoint presentations, trial grading sessions, and training and mentorship of new examiners with experienced examiners. There were rating systems in place at each of the schools which evaluated the same competencies; however, the rating systems for key competencies would require standardization across schools in order to interpret the scores derived from the competency examinations on a common metric. Calibration to these rating systems would need to be implemented as well. The involvement of independent parties to make decisions about minimum competence could ensure fairness of ratings if faculty from other departments within the school and/or faculty from other schools are used in the rating process.

Comira also noted that there are important advantages of using actual patients of record within the dental schools instead of simulated (manikin) patients. First, procedures are performed as part of treatment thereby eliminating circumstances fostering commercial procurement of patients, particularly the cost of such patients. Second, the safety and protection of patients is ensured because procedures are performed in the course of treatment. Third, candidates would be treated similarly at all of the dental schools in a manner that allows communication of examination logistics and results.

Subsequently, Comira prepared an additional report for the Board entitled *Portfolio Examination to Qualify for California Dental Licensure, December 1, 2009* which defined the competencies to be tested in the portfolio examination and provided background research for the examination's implementation process. Comira had conducted focus groups of key faculty from the Board-approved pre-doctoral dental schools located in California to identify the competencies to be assessed in a systematic way beginning with an outline of major competency domains and ending with a detailed account of major and specific competencies organized in outline fashion. All participants provided input in a systematic, iterative fashion, until consensus was achieved. The competencies

identified from this report served as the framework for the evaluation system, training and calibration procedures for examiners, and audit procedures for evaluating the efficacy of the final process.

Using the findings of these two reports, the Board sponsored legislation, Assembly Bill 1524, during the 2009-2010 Legislative Session. Assembly Bill 1524 was authored by Assembly Member Mary Hayashi and eliminated the clinical and written examination administered by the Board and replaced it with a portfolio examination of an applicant's competence to enter the practice of dentistry, to be conducted while the applicant is enrolled in a Board-approved dental school located in California. The bill required the portfolio examination to utilize uniform standards of clinical experiences and competencies as approved by the Board. The bill provided that at the end of that dental school program, the passage of a final assessment of the applicant's portfolio was required, subject to certification by his or her dean and payment of a \$350 application fee. The bill specified that the portfolio examination could not be conducted until the Board adopted regulations to implement the portfolio examination. The bill required the Board to oversee the portfolio examination and final assessment process, and required the Board to biennially review each dental school with regard to the standardization of the portfolio examination. The bill also set forth specified examination standards, including direction for the Board to consult with the Board-approved dental schools located in California to approve portfolio examination competencies and the minimum number of clinical experiences necessary for the successful completion of the portfolio examination. The bill specified that the Board would require and verify successful completion of competency examinations that were performed on a patient of record of the dental school, including, but not limited to, the following: (1) comprehensive oral diagnosis and treatment planning, (2) periodontics, (3) direct restorations, (4) indirect restorations, (5) removable prosthodontics, and (6) endodontics. On September 29, 2010, Governor Arnold Schwarzenegger signed Assembly Bill 1524 (Chapter 446, Statutes of 2010), enacting the portfolio examination pathway to dentistry licensure in California.

Once the Board received its statutory authority to implement the portfolio examination via Assembly Bill 1524, the Board once again contracted with the same psychometric consultants, who moved from Comira to PSI Services LLC, to work with the Board-approved dental schools located in California to develop the final framework and write the report entitled *Development and Validation of a Portfolio Examination for Initial Dental Licensure, May 1, 2013* for the Board to utilize in the development of proposed regulations to implement the portfolio examination. The Board-approved dental schools located in California include: (1) Loma Linda University, (2) University of California, Los Angeles, (3) University of California, San Francisco, (4) University of the Pacific, (5) University of Southern California, and (6) Western University of Health Sciences. Using the information contained in the report, proposed regulatory language was developed and the Board voted to initiate the rulemaking process on August 26, 2013.

## Implementation

At its August 2013 meeting, the Dental Board of California (Board) approved proposed regulatory language relative to the Portfolio Examination Requirements and directed staff to initiate the rulemaking. Board staff filed the initial rulemaking documents with the Office of Administrative Law (OAL) on Tuesday, October 29th and the proposal was published in the California Regulatory Notice Register on Friday, November 8, 2013. The 45-day public comment period began on Friday, November 8, 2013 and ended on Monday, December 23, 2013. The Board held a regulatory hearing in Sacramento on Monday, January 6, 2014.

The Board received notification that the regulatory package was signed by the Secretary of State on November 5, 2014 and became effective immediately.

The Board-approved dental schools located in California were notified in December 2014 that they could begin the implementation of the Portfolio pathway to licensure and the calibration of the examiners at their schools. The schools received a reference binder that included a copy of the applicable legislation, the Candidate and Examiner Handbooks, the regulatory requirements, and all applicable forms. The schools also received a compact disc that included everything that was in the reference binder as well as the Board-approved calibration courses.

In June 2015 the Board received its first applications from candidates that had completed the requirements to obtain their license through the Board's Portfolio Examination pathway.

Table 1 illustrates the number of applications submitted to the Board in 2015 and 2016. It also indicates how many were received from each of the participating schools.

In 2015, seven (7) applicants applied for a license through the portfolio pathway. One (1) application was received from the University of California, San Francisco. Six (6) applications were received from the University of the Pacific.

In 2016, thirty (35) applicants applied for a license through the portfolio pathway. One (1) application was received from the University of California, Los Angeles. Twelve (12) applications were received from the University of California, San Francisco. Nineteen (19) applications were received from the University of the Pacific. Three (3) applications were received from the University of Southern California.

**Table 1: Persons applying for a license through the Portfolio pathway**

| <b>Application Status</b>               | <b>2015</b> | <b>2016</b> |
|---|-------------|-------------|
| <b>Total Applications Received</b>      | <b>7</b>    | <b>35</b>   |
| Loma Linda University                   | 0           | 0           |
| University of California, Los Angeles   | 0           | 1           |
| University of California, San Francisco | 1           | 12          |

|                                       |   |    |
|---------------------------------------|---|----|
| University of the Pacific             | 6 | 19 |
| University of Southern California     | 0 | 3  |
| Western University of Health Sciences | 0 | 0  |

Table 2 illustrates the number of licenses issued by the Board during 2015 and 2016 to the applicants that applied through the Board’s Portfolio Examination pathway.

In 2015, seven (7) licenses were issued to applicants applying through the Board’s Portfolio Examination pathway to licensure. One (1) license was issued to a graduate of the University of California, San Francisco. Six (6) licenses were issued to graduates of the University of the Pacific.

Currently in 2016, Thirty-four (34) licenses were issued to applicants applying through the Board’s Portfolio Examination pathway to licensure. One (1) license was issued to a graduate of the University of California, Los Angeles. Twelve (12) licenses were issued to graduates of the University of California, San Francisco. Eighteen (18) licenses were issued to graduates of the University of the Pacific. Three (3) licenses were issued to graduates of the University of Southern California.

**Table 2: Licenses Issued by the Board to persons that applied through the Portfolio pathway**

|   | 2015     | 2016      |
|---|----------|-----------|
| <b>Total Number of Licenses Issued</b>  | <b>7</b> | <b>34</b> |
| Loma Linda University                   | 0        | 0         |
| University of California, Los Angeles   | 0        | 1         |
| University of California, San Francisco | 1        | 12        |
| University of the Pacific               | 6        | 18        |
| University of Southern California       | 0        | 3         |
| Western University of Health Sciences   | 0        | 0         |

**Materials Relied Upon (Attachments)**

1. “Alternative Pathways for Initial Licensure for General Dentists, Final Report”, Prepared by Comira, February 9, 2009
2. “Portfolio Examination to Qualify for California Dental Licensure”, Prepared by Comira, December 1, 2009
3. Assembly Bill 1524 (Chapter 446, Statutes of 2010)
4. “Development and Validation of a Portfolio Examination for Initial Dental Licensure”, Prepared by PSI Services LLC, May 10, 2013
5. California Code of Regulations, Title 16, Sections 1028 through 1036.01

## **Findings**

The Board's Portfolio Examination is in compliance with Business and Professions Code Section 139 in that the current examination requirements are based on the report entitled "Development and Validation of a Portfolio Examination for Initial Dental Licensure, May 10, 2013", prepared by PSI Services LLC, a psychometric contractor hired by the Board to conduct the analysis and evaluation. This report included the basis for the Portfolio Examination, item analysis to permit a psychometric evaluation of the items, and an assessment of the appropriateness of the prerequisites for admittance to the examination. The Board implemented these requirements provided in the report via regulations. The regulations prescribe the following requirements for the Board's Portfolio Examination:

- Portfolio Examination eligibility requirements;
- Requirements for the demonstration of clinical experience;
- Requirements for clinical experiences and competency examinations for Oral Diagnosis and Treatment Planning;
- Requirements for clinical experiences and competency examinations for Direct Restorations;
- Requirements for clinical experiences and competency examinations for Indirect Restorations;
- Requirements for clinical experiences and competency examinations for Removable Prosthodontics;
- Requirements for clinical experiences and competency examinations for Endodontics;
- Requirements for clinical experiences and competency examinations for Periodontics;
- Qualification requirements for Portfolio Examination competency examiners;
- Training requirements for Portfolio Examination competency examiners;
- General procedures and policies for the Portfolio Examination;
- Portfolio competency examination grading requirements; and,
- Remedial education requirements for Portfolio competency examinations.

## **Certification/Evaluation**

The Board certifies that its Portfolio Examination pathway to dental licensure is in compliance with Business and Professions Code Section 139 and recommends the continuance of the pathway as a viable option for candidates seeking dental licensure in the State of California. Additionally, the Board will continue an ongoing evaluation of the Portfolio Examination by performing examination audits and maintaining current and relevant examiner calibration.

**Dental Board of California**

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December 30, 2016

The Honorable Jerry Hill, Chair  
Senate Committee on Business, Professions & Economic Development  
State Capitol – Room 2053  
Sacramento, CA 95814

RE: Pediatric Anesthesia Report

Dear Senator Hill:

The enclosed document was prepared in response to your February 8, 2016 letter requesting the Dental Board of California (Board) to conduct research of California's present laws, regulations and policies related to pediatric dental anesthesia in order to determine whether or not they are sufficient to guard against unnecessary use of general anesthesia in the treatment of pediatric patients, and whether these laws assure patient safety. This report also is being submitted to the California State Legislature in accordance with the reporting requirements of Assembly Bill 2235.

California dental sedation and anesthesia laws are similar to laws in other states, and differ primarily in the area of personnel requirements. Approximately half of other states specify the number of staff who must be present, in addition to the dentist, when general anesthesia or moderate sedation is administered. No state requires the presence of an individual dedicated to both the monitoring and administration of general anesthesia or moderate sedation.

California policies, laws and regulations are generally consistent with professional dental association guidelines with the exception of a recommendation in the American Academy of Pediatrics-American Academy of Pediatric Dentistry Guidelines for a person dedicated to the monitoring and administration of deep sedation and general anesthesia.

While the Board concluded that California's present laws, regulations and policies are sufficient to provide protection of pediatric patients during dental sedation, it recommends the following enhancements to current statute and regulations to provide an even greater level of public protection:

1. The board should continue to research the collection of high quality pediatric dental sedation and anesthesia related data to inform decision making.
2. The definitions of general anesthesia, conscious sedation, pediatric and adult oral sedation should be updated.
3. Proposed changes to the sedation and anesthesia permit system:
  - a. Pediatric Minimal Sedation Permit for patients under age thirteen (13). (This permit would replace the existing Oral Conscious Sedation for Minors permit)
    - i. Education: To be eligible for this permit, the dentist must complete 24 hours of instruction in pediatric sedation plus one clinical case; this training must include airway management and patient rescue from moderate sedation.
    - ii. Administration is limited to a single dose of a single sedative drug via the oral route, plus nitrous oxide and oxygen that is unlikely to produce a state of unintended moderate sedation.
    - iii. A minimum of one staff member, in addition to the dentist, trained in the monitoring and resuscitation of pediatric patients must be present.
  - b. Pediatric Moderate Sedation permit for patients under age 13. (This permit could either be a new pediatric permit or an endorsement on an existing moderate (conscious) sedation permit.)
    - i. Education: To be eligible for this permit, the dentist must have completed a Commission on Dental Accreditation (CODA) accredited residency in pediatric dentistry, or equivalent training in pediatric moderate sedation, as determined by the board. The applicant must provide proof of completion of a sufficient number of cases to establish competency, both at time of initial application and at renewal.
    - ii. Administration of the drugs utilized is unlikely to produce an unintended state of deep sedation
    - iii. Personnel: The dentist and at least one member of the support staff must be trained in pediatric advanced life support and airway management, equivalent to the AAP-AAPD Guidelines or as determined by the board. For children under age 7, two support staff, in addition to the dentist, must be present, and one staff member shall serve as a dedicated patient monitor.
  - c. Pediatric general anesthesia permit for children under age 13. (This permit could either be a new pediatric permit or an endorsement on an existing general anesthesia permit.)

- i. Education: the dentist must have completed a CODA accredited or equivalent residency training program that provides competency in the administration of deep sedation/general anesthesia for children under age 13. For patients under age 7 the applicant must provide proof of completion of a sufficient number of cases to establish competency, both at time of initial application and at renewal.
- ii. Personnel: Personnel: For patients ages 7-13, the dentist and at least two support staff must be present. The dentist and at least one staff member must be trained in Pediatric Advanced Life Support and Airway Management, equivalent to the AAP-AAPD Guidelines or as determined by the board. One staff member, trained in patient monitoring, shall be dedicated to that task.

For children under seven, there shall be at least 3 people present during the procedure. One person shall be the practicing dentist. One person shall be a general anesthesia permit holder, who shall be solely dedicated to administering anesthesia, monitoring the patient, and managing the airway through recovery. One person shall be an anesthesia support staff, dedicated to the anesthesia process, and shall be trained in Pediatric Advanced Life Support and Airway Management, equivalent to the AAP-AAPD Guidelines or as determined by the Board.

- iii. When a dedicated anesthesia provider is utilized, in addition to the dentist, both the dentist and at least one staff member must be trained in pediatric advanced life support and airway management, equivalent to the AAP-AAPD Guidelines or as determined by the board.
4. Requirements for records and equipment should be updated and include the use of capnography for moderate sedation.
  5. The Dental Board should be provided with additional authority to strengthen the onsite inspection and evaluation program.

Few topics generate more controversy than the use of anesthesia, especially for children; and the challenge of reaching a consensus among interested parties on this issue is difficult. Although patient safety is always the foremost concern, the effects of regulatory change on healthcare can be fraught with unintended consequences. Any proposal should, therefore, strike a balance between established practice and evidence based changes that provide greater patient safety.

The Board recognizes that the manpower and economic considerations for pediatric dental sedation are beyond the scope of the present report. These considerations will be critical to the successful implementation of any changes to dental sedation laws. The

Board therefore recommends that there be an analysis of the effects of any proposed new legislation or regulation on access to care for pediatric dental patients prior to the implementation of any changes. Factors such as whether the costs of sedation and anesthesia are reasonable depends on how cost effectiveness is defined and calculated, and on the perspective taken. For example, clinicians often view cost implications differently than would payers or society at large. There needs to be consideration of the resource constraints of the healthcare system (for example, Denti-Cal versus private insurance). Feasibility issues must be considered, including the time, skills, staff, and equipment necessary for the provider to carry out the recommendations, and the ability of patients and systems of care to implement them.

If you have any questions, please contact the Board's Executive Officer, Karen Fischer. She can be reached at (916) 263-2188 or by email at [Karen.Fischer@dca.ca.gov](mailto:Karen.Fischer@dca.ca.gov).

Sincerely,



Steven G. Morrow, DDS, MS  
President

cc: Assembly Member Rudy Salas Jr, Chair – Assembly Business & Professions  
Committee  
Assembly Member Tony Thurmond  
Dental Board Members

Enclosure

# PEDIATRIC ANESTHESIA STUDY

DECEMBER 2016



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# PEDIATRIC ANESTHESIA STUDY

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## Dental Board Pediatric Anesthesia Study

### **EXECUTIVE SUMMARY**

This document is prepared in response to Senator Jerry Hill's February 8, 2016, letter requesting a subcommittee investigation of California's present laws, regulations and policies related to pediatric dental anesthesia, whether or not they are sufficient to guard against unnecessary use of general anesthesia in the treatment of pediatric patients, and whether these laws assure patient safety.

California dental sedation and anesthesia laws are similar to laws in other states, and differ primarily in the area of personnel requirements. Approximately half of other states specify the number of staff who must be present, in addition to the dentist, when general anesthesia or moderate sedation is administered. No state requires the presence of an individual dedicated to both the monitoring and administration of general anesthesia or moderate sedation.

California policies, laws and regulations are generally consistent with professional dental association guidelines with the exception of a recommendation in the American Academy of Pediatrics-American Academy of Pediatric Dentistry Guidelines for a person dedicated to the monitoring and administration of deep sedation and general anesthesia.

A review of the relevant medical and dental literature revealed that, although serious adverse events related to dental sedation and anesthesia are rare, there are few if any high quality studies of pediatric dental sedation. Available data do not reveal an association between adverse outcomes and the type of provider or practice model.

The Dental Board's (Board) enforcement staff prepared data from mandatory reports of death/hospitalization (BPC 1680z) for patients under age 21 received between January 1, 2010 and December 31, 2015. The data for this six-year period revealed that death or serious injury associated with sedation and anesthesia for dental treatment are extremely rare, including only two patients who died in association with oral sedation, and one patient who died in association with a general anesthetic administered in a dental office. The Board estimates that approximately 133,000 patients under age 21 receive sedation or general anesthesia each year in conjunction with dental treatment.

The Board recommends updating terminology, staffing requirements, educational requirements, and monitoring standards in an effort to improve the safety of pediatric dental anesthesia and sedation.

The Board recognizes that the manpower and economic considerations for pediatric dental sedation are beyond the scope of the present report. These considerations will be critical to the successful implementation of any changes to dental sedation laws. The Board therefore recommends that there be an analysis of the effects of any proposed new legislation or regulation on access to care for pediatric dental patients prior to the implementation of any changes.

# **Dental Board of California Pediatric Sedation Study**

## **INTRODUCTION**

In February 2016, Senator Jerry Hill, Chair of the Senate Committee on Business, Professions, and Economic Development, was made aware of a tragedy in which an otherwise healthy child died after receiving general anesthesia at a dentist's office. He notified the Dental Board of California (Board) of his concern about the rise in the use of anesthesia for young patients and asked the Board to investigate whether California's present laws, regulations, and policies are sufficient to protect the public. In doing the research, Senator Hill asked the Board to review all incident reports collected by the Board related to pediatric anesthesia in California for the past five years.

The Board President appointed a two-person subcommittee to work with staff to research this issue; the study was expanded to include review of incident reports related to all levels of pediatric sedation including conscious sedation, oral conscious sedation, and general anesthesia as well as administration of local anesthetic in California for the past six years (2010-2015).

This report reflects three parts of the study: (1) the present laws, regulations, and policies in California and a comparison of these laws, regulations and policies to those of other states and dental associations, (2) review of relevant dental and medical literature, and (3) review of all incident reports in California for patients < 21 years of age.

## **BACKGROUND**

### **History of Anesthesia and the Scope of Practice of Dentistry**

Although both dentists and physicians contributed to early developments in the field of anesthesiology, each profession evolved differently. Advances in medical anesthesiology evolved slowly until 1923 when a few physicians had the novel idea of creating a separate department of anesthesia in medical schools. This advance allowed all teaching, training, and research endeavors to be organized and supervised by one department head. This marked the beginning of medical anesthesiology as a scientific discipline.

The practice of anesthesiology in dentistry took a different path, with dentists practicing various forms of anesthesia as a technique taught by practitioners to one another. This approach did not initially provide an environment for formal research. Anesthesia techniques developed specifically for dentistry became more widely accepted by the profession in the middle of the 20th century. Drs. Morgan Allison, Adrian Hubbell, Leonard Monheim and others first utilized

new techniques and new anesthetics that became available at the time. Other dentists developed what was then a new technique, termed “conscious sedation” which utilized sub-anesthetic doses of general anesthetic drugs along with local anesthesia. These new anesthesia concepts and ideas led to the establishment of the American Dental Society of Anesthesiology (ADSA) in 1953. Among the chief goals of these pioneer dentists was to provide education in advanced pain and anxiety control for all dentists.

Case law has clarified the place of anesthesia within the scope of dental practice. The courts that have reviewed anesthesia scope of practice cases have consistently viewed anesthesiology as being within the scope of practice of dentistry as well as other health care disciplines. However, the courts have ruled that individual providers are limited to their scope of practice as defined by state law. Anesthesia should therefore be administered according to the statutes and regulations that each state uses to govern an individual’s core license to practice.<sup>1</sup>

### **History and Function of the Dental Board of California**

The California Legislature created the Dental Board of California (Board) in 1885 to regulate the practice of dentistry. Today, the Board regulates approximately 86,000 licensed dental healthcare professionals in California, including approximately 40,000 dentists, 44,000 registered dental assistants (RDAs) and 1,500 registered dental assistants in extended functions (RDAEFs). In addition, the Board is responsible for setting the duties and functions of approximately 50,000 unlicensed dental assistants. The Board's last sunset review was in 2015.

The practice of dentistry is defined in Business and Professions Code Section 1625 as:

*“The diagnosis or treatment, by surgery or other method, of diseases and lesions and the correction of malpositions of the human teeth, alveolar process, gums, jaws, or associated structures; and such diagnosis or treatment may include all necessary related procedures as well as the use of drugs, anesthetic agents, and physical evaluation.”*

The Board meets at least four times throughout the year to address work completed by the various committees, and, as noticed on the agenda, may meet in closed session as authorized by Government Code Section 11126 et. seq.

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<sup>1</sup> Boynes, S.G., *A Guide to Dental Anesthesiology Rules and Regulations*, 5<sup>th</sup> ed., Chicago, No-No Orchard Publishing, 2013. P33.

[http://www.mediafire.com/download/b0p8rhh9imk4939/Fifth Edition Dental Anesthesiology Guide to the Rules and Regulations.pdf](http://www.mediafire.com/download/b0p8rhh9imk4939/Fifth_Edition_Dental_Anesthesiology_Guide_to_the_Rules_and_Regulations.pdf)

The mission of the Board is defined in Business and Professions Code Section 1601.2, which states:

*“Protection of the public shall be the highest priority for the Dental Board of California in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.”*

To meet its obligations, the Board implements regulatory programs and performs a variety of functions. These programs and activities include setting licensure requirements for dentists and dental assistants, including examination requirements, and issuing and renewing licenses, including a variety of permits and certifications. The Board also has its own enforcement division, with sworn and non-sworn staff, which is tasked with investigating both criminal and administrative violations of the Dental Practice Act (Act) and other laws. As part of the disciplinary function of the Board, it also monitors dentists and RDAs who may be on probation, and manages a Diversion Program for licensees whose practice may be impaired due to abuse of dangerous drugs or alcohol.

### **Board Membership and Committees**

The Board is composed of 15 members: eight practicing dentists, one registered dental hygienist (RDH), one RDA, and five public members, which account for one-third of the membership. The Governor appoints the dentists, the RDH, the RDA, and three public members. The Speaker of the Assembly and the Senate Rules Committee each appoint one public member. Of the eight practicing dentists, one must be a member of the faculty of any California dental school, and one is required to be a dentist practicing in a nonprofit community clinic. Members of the Board are appointed for a term of four years, and each member may serve no more than two full terms.

### **Purpose of State Laws**

State laws and regulations are general rules governing people's rights or conduct. Laws and regulations do not contain recommendations, model procedures, lists of resources, or information about practice or procedures, otherwise known as guidance documents.

Laws are developed following a legislative plan that includes an analysis of the existing law, an analysis of the necessity of legislation, a statement that no other regulatory choice would be effective; analysis of potential danger areas (constitutional, legal, practical); and an analysis of the practical implications of the legislative proposal. Regulations are developed to implement, interpret, and make specific the law. Statutes and regulations are, of necessity, concise and in the case of dental laws, establish the minimum standards for the safe practice of dentistry.

Laws and regulations are usually applied literally and can limit the ability of the licensee to exercise discretion.

### **Dental Board Enforcement Unit**

The Board utilizes its disciplinary process to enforce the Dental Practice Act. The Board has broad authority over its licensees and may issue administrative citations, impose fines, and reprimand, revoke, suspend, or place conditions upon a dental license. All complaints against a licensee are reviewed and if there is sufficient evidence of professional misconduct an accusation is filed.

Accusations may be based on specific acts or omissions of those duties described in the Practice Act, or as established by expert testimony of gross negligence or incompetence sufficient to require discipline. This provision makes it unnecessary to state every conceivable practice standard, as to do so would clearly be impractical.

### **DEFINITIONS USED IN DENTAL SEDATION AND ANESTHESIA**

The American Society of Anesthesiology developed new definitions of levels of sedation in 1999. These definitions were subsequently adopted by most other organizations involved in the provision of sedation and anesthesia care. The Dental Board first suggested adoption of these definitions into its laws in 2005 and again in 2010.

Appendix 2 Table 1 includes a side-by-side comparison of California's current definitions of oral conscious sedation, parenteral conscious sedation, and general anesthesia with contemporary definitions.

- **analgesia** – the diminution or elimination of pain.
- **anxiolysis** – the diminution or elimination of anxiety.
- **conscious sedation** – a minimally depressed level of consciousness that retains the patient's ability to independently and continuously maintain an airway and respond appropriately to physical stimulation or verbal command and that is produced by a pharmacological or non-pharmacological method or a combination thereof.
- **deep sedation** – a drug-induced depression of consciousness during which patients cannot be easily aroused, but respond purposefully after repeated verbal or painful stimulation. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. A state of deep sedation may be accompanied by partial or complete loss of protective airway reflexes. Patients may readily pass from a state of deep sedation to the state of general anesthesia.

- **enteral** – any technique of administration in which the agent is absorbed through the gastrointestinal (GI) tract or oral mucosa.
- **general anesthesia** – a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilation is often impaired. Patients often require assistance in maintaining a patent airway, and positive-pressure ventilation may be required. Cardiovascular function may be impaired.
- **incremental dosing** – administration of multiple doses of a drug until a desired effect is reached, but not to exceed the maximum recommended dose (MRD).
- **inhalation** – a technique of administration in which a gaseous or volatile agent is introduced into the lungs and whose primary effect is due to absorption through the gas/blood interface.
- **local anesthesia** – the elimination of sensation, especially pain, in one part of the body by the topical application or regional injection of a drug.
- **maximum recommended dose (MRD)** – maximum FDA-recommended dose of a drug, as printed in FDA-approved labeling for unmonitored home use.
- **minimal sedation** – a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, breathing and cardiovascular functions are unaffected. In accord with this particular definition, the drug(s) and/or techniques used should carry a margin of safety wide enough never to render unintended loss of consciousness. Further, patients whose only response is reflex withdrawal from repeated painful stimuli would not be considered to be in a state of minimal sedation.
- **moderate sedation** – a drug-induced depression of consciousness during which patients respond purposefully to verbal commands or after light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.
- **parenteral** – a technique of administration in which the drug bypasses the gastrointestinal tract.
- **recovery** – the ability to regain full health, or a return to baseline status.
- **supplemental dosing** – during minimal sedation, supplemental dosing is a single additional dose of the initial dose of the initial drug that may be necessary for prolonged procedures.
- **titration** – the administration of small incremental doses of a drug until a desired clinical effect is observed.

- **transdermal** – a technique of administration in which the drug is administered by patch or iontophoresis through skin.
- **transmucosal** – a technique of administration in which the drug is administered across mucosa such as intranasal, sublingual, or rectal.

## **DENTAL BOARD GENERAL ANESTHESIA, CONSCIOUS SEDATION AND ORAL CONSCIOUS SEDATION PERMIT PROGRAMS**

### **Legislative History**

The California Dental Practice Act regulates the use of sedation and general anesthesia by California dentists. These laws and regulations may be accessed through the Dental Board of California's website. There is an annual publication of the California Dental Practice Act that is available from the legal and professional document publisher Lexis Nexis.

The Board has long sought to improve the safety of sedation and anesthesia in California, working with the California Dental Association to co-sponsor Senate Bill 386 (Keene, 1979), the first legislation to regulate the use of general anesthesia by dentists in California. This bill included a requirement for mandatory office inspections that were based on a voluntary program originally developed by Southern California oral surgeons. Conscious sedation laws, AB 1276 (Tucker, 1986) also sponsored by the Board and CDA, followed as did Assembly Bill 2006 (Keeley, 1998) and AB 1386 (Laird, 2005), the most recent update of sedation laws. These laws were sponsored as proactive measures to improve patient safety. An exception was AB 564 (Keene, 2001), a bill that established reporting requirements for patient deaths, that was introduced at the request of a mother whose son suffered brain damage after he was given chloral hydrate, an oral sedative, by his dentist.

In 2002, the Board called for a review of anesthesia laws and patient outcomes to see if any improvements could be made to the existing regulatory program. To accomplish this goal the Board appointed the Blue Ribbon Panel on Anesthesia (Panel), an ad hoc committee composed of general dentists and dental specialists who were recognized experts in the field. The Panel reviewed laws in other states, dental association guidelines, death statistics provided by the Board, and closed claims from an insurance carrier, as well as current laws.

The Panel's recommendations were approved by the Board and ultimately enacted through statute and regulation beginning in 2006.<sup>2</sup> There is no record of any significant opposition to the recommended changes which included the addition of an adult oral conscious sedation permit, new requirements for pre-anesthetic physical evaluation of patients, and improvements

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<sup>2</sup> Dental Board of California: Recommendations of the Blue Ribbon Panel, November 7, 2003.

to the office inspection program. The Panel did not recommend that a specific number of personnel be present, nor was there any recommendation for staff training other than basic CPR. There was no recommendation for pre-operative dietary instructions due to controversy about appropriate requirements. At the time, the Board was aware of the need to update anesthesia terminology to achieve consistency with new definitions adopted by the American Dental Association, but chose to defer this until a later date, and recommended that these changes be made during sunset review.

In 2010, the Board president appointed a subcommittee to study the definitions to make recommendations for their adoption and to review the relevant statutes and regulation for currency. The 2010 subcommittee recommended that the anesthesia and sedation laws be reviewed and updated every five years and suggested strategies for accomplishing this task. Once statutes were amended, other changes could be implemented by regulation. A series of informal stakeholder meetings followed and the subcommittee submitted a legislative proposal to the Board in November 2013. This item was noticed for discussion and possible action at the November 22, 2013 meeting. The California Society of Pediatric Dentists stated support but provided no specific comments. The proposal was identified as a future Board priority.

## **PART 1: THE PRESENT LAWS, REGULATIONS, AND POLICIES IN CALIFORNIA; AND A COMPARISON OF THESE LAWS, REGULATIONS AND POLICIES TO THOSE OF OTHER STATES AND DENTAL ASSOCIATIONS**

### **CURRENT CALIFORNIA SEDATION AND ANESTHESIA LAWS**

A summary of California's current dental sedation and anesthesia laws is provided in the attached Appendix 2, Tables 2-8. California Business and Professions Code (BPC) Sections 1646 and 1647 describe educational qualifications and other requirements necessary for a dentist to become eligible for a permit to administer general anesthesia or sedation. These laws include a requirement for general anesthesia and conscious sedation permit holders to undergo an office inspection every 5-6 years; completion of continuing education every 2 years; a list of violations that are considered unprofessional conduct; and requirements for a physician and surgeon to obtain a permit to administer general anesthesia in a dental office. BPC Sections 1680 and 1682 describe acts that constitute unprofessional conduct specifically related to sedation and anesthesia.

BPC Section 1647 addresses conscious sedation and includes the statement that "the drugs and techniques used shall have a margin of safety wide enough to render unintended loss of consciousness unlikely." This broad approach to limiting the use of potent sedatives recognizes that almost any drug or combination of drugs, when used in sufficient quantity, can produce

loss of consciousness, particularly in the very young, very old, and medically compromised patients.

The duties of dental assistants are described in BPC Section 1750, and includes patient monitoring and other sedation related duties they may perform. California Code of Regulations (CCR) Section 1070 specifies the educational course and program approval process for dental assistants, including the Dental Sedation Assistant.

CCR Sections 1043 and 1044 provide requirements for supervision of sedated patients, definitions of levels of sedation, and additional details of permit requirements. CCR Section 1043 provides the details of the office inspection program, including composition of the inspection team, office facility requirements, equipment requirements, including patient monitors, preoperative evaluation, records, emergency drugs, conduct of the evaluation including a demonstration of general anesthesia and performance of the 13 simulated emergencies, and administrative procedures for the office evaluation process. The Board presently issues the following permits:

1. Pediatric oral conscious sedation
2. Adult oral conscious sedation
3. Parenteral conscious sedation
4. General anesthesia
5. Physician anesthesiologist dental anesthesia

## **DENTAL SEDATION AND ANESTHESIA LAWS IN OTHER STATES**

Compilations of dental sedation and anesthesia laws for all 50 states are available from the American Dental Association,<sup>3</sup> <sup>4</sup> the American Dental Society of Anesthesia<sup>5</sup> and the American Association of Oral and Maxillofacial Surgeons.<sup>6</sup> These publications provide summaries of all laws and regulations relevant to general anesthesia and deep sedation as well as moderate and

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<sup>3</sup>American Dental Association, "Statutory Requirements for General Anesthesia and Deep Sedation Permits," 2009. [http://www.ada.org/en/~media/ADA/Advocacy/Files/anesthesia\\_general\\_permit](http://www.ada.org/en/~media/ADA/Advocacy/Files/anesthesia_general_permit)

<sup>4</sup> American Dental Association, "Statutory Requirements for General Anesthesia and Deep Sedation Permits," 2009. [http://www.ada.org/en/~media/ADA/Advocacy/Files/anesthesia\\_sedation\\_permit](http://www.ada.org/en/~media/ADA/Advocacy/Files/anesthesia_sedation_permit)

<sup>5</sup>Boynes, S.G., *A Guide to Dental Anesthesiology Rules and Regulations*, 5<sup>th</sup> ed., Chicago, No-No Orchard Publishing, 2013. [http://www.mediafire.com/download/b0p8rhh9imk4939/Fifth\\_Edition\\_Dental\\_Anesthesiology\\_Guide\\_to\\_the\\_Rules\\_and\\_Regulations.pdf](http://www.mediafire.com/download/b0p8rhh9imk4939/Fifth_Edition_Dental_Anesthesiology_Guide_to_the_Rules_and_Regulations.pdf)

<sup>6</sup> American Association of Oral and Maxillofacial Surgeons, *State Requirements for General Anesthesia Delivery – Summary*, Rosemont, IL, updated 4/19/2016.

minimal sedation in all 50 states. The Board obtained additional information related to minimal and moderate enteral sedation laws from the Dental Organization for Conscious Sedation (DOCS Education).<sup>7</sup> The Canadian provinces have adopted the American model for dental sedation and anesthesia and utilize a similar regulatory framework. The subcommittee did not review provincial laws for this report.

Laws in California and most other states reference guidelines published by the American Dental Association<sup>8 9</sup> and the educational standards of the Commission on Dental Accreditation of the American Dental Association,<sup>10</sup> and frequently incorporate some but not all of the recommendations included in these guidance documents.

## **COMPARISON OF CALIFORNIA LAWS WITH LAWS IN OTHER STATES**

### **Methods**

The subcommittee summarized information from compilations of state laws for this report. Where information was incomplete or missing, the practice act for that state was downloaded from the state board website and reviewed for relevant sections. If necessary, the individual dental board was contacted to obtain additional information. For some states there were questions that required legal interpretation that could not be completely resolved. Texas, South Carolina, and Alaska have rulemaking in progress so their existing rules were reviewed.

Certain state laws and regulations were relatively uniform across all 50 states. Other state laws were less consistent.

The subcommittee made every effort to verify the accuracy of information presented, however due to the variability, complexity, and ever changing nature of state laws and regulations this report may include some inaccuracies. The Board welcomes the opportunity to provide additions or corrections to this information.

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<sup>7</sup> DOCS Education <http://www.sedationregulations.com/>

<sup>8</sup> American Dental Association. (2012). "Guidelines for the Use of Sedation and General Anesthesia by Dentists". In *Society* (Vol. 80, pp. 75–106). <http://doi.org/10.1112/S0024611500012132>  
[http://www.ada.org/en/~media/ADA/Advocacy/Files/anesthesia\\_use\\_guidelines](http://www.ada.org/en/~media/ADA/Advocacy/Files/anesthesia_use_guidelines)

<sup>9</sup> American Dental Association. (2012). "Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students". In ADA (Ed.), (pp. 1–18). Chicago. Retrieved from: [http://www.ada.org/en/~media/ADA/MemberCenter/Files/anxiety\\_guidelines](http://www.ada.org/en/~media/ADA/MemberCenter/Files/anxiety_guidelines)

<sup>10</sup> Commission on Dental Accreditation: (2012). "Accreditation Standards for Advanced Specialty Education Programs in Oral and Maxillofacial Surgery". Retrieved from <https://www.ada.org/~media/CODA/Files/oms.pdf?la=en>

## **AREAS OF COMPARISON**

### **Permitting of Practice Locations**

For the majority of states, including California, the permit to administer sedation or general anesthesia is assigned to the individual dentist and not to a facility. The California Dental Board maintains broad authority over its licensees and may conduct an inspection of any dental facility at its own discretion. Although the majority of states, including California, require a periodic facility inspection, only a single facility utilized by the permit holder is usually inspected. The permit holder is assigned the responsibility for assuring that all facilities where sedation is administered are appropriately equipped and staffed as required by law.

The Board identified nine (9) states that require permitting individual practice locations in addition to the dentist. This has the advantage of assuring that facilities are properly equipped, but requires a significantly greater number of inspections. In contrast, the Medical Board of California is responsible for the accreditation of all locations where sedation or anesthesia, other than local anesthesia, is administered. Accreditation is done by three different board-approved accrediting entities. Practitioners are approved to administer sedation or anesthesia by the individual facility instead of by the regulatory board. For a discussion of the regulatory structure of outpatient facilities in California see the 2015 report from Klutz Consulting.<sup>11</sup>

### **Education**

#### **Minimal Sedation/Anxiolysis**

Minimal sedation is defined as the administration of a dose of a drug to a patient that does not exceed the FDA recommended maximum dose for unmonitored home use. Minimal sedation is not defined in the California sedation laws and a permit to administer minimal sedation is not required. Training in minimal sedation, including the administration of a mixture of nitrous oxide and oxygen, either alone or in combination with minimal oral sedation, may be taught to the level of basic competency at the predoctoral (dental school) level. Nineteen (19) states require completion of a 16-hour course prior to issuing a minimal sedation permit.

#### **Moderate sedation**

Dental practice acts in most states specify that moderate sedation is regulated by route of administration. Sixteen states have recently adopted uniform educational standards for moderate sedation regardless of route of administration.

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<sup>11</sup> "Outpatient Surgery Services in California: Oversight, Transparency and Quality". B&R Klutz Consulting, 2015. <http://www.chcf.org/~media/MEDIA%20LIBRARY%20Files/PDF/PDF%20S/PDF%20Sacto07292015OutpatientSurgeryKlutz.pdf>; accessed 6/16/2016.

### **Oral (moderate) Conscious Sedation Certification for Adults/Minors**

To obtain a California permit for administration of Oral (moderate) Conscious Sedation Certification for Adults/Minors the applicant must have completed an approved post doctoral or residency training program that includes sedation training; or, a board approved course that includes 25 hours of instruction including a clinical component utilizing at least one age-appropriate patient; training for either adult patients or minor patients (13 or younger); training requirements reference the ADA and AAP-AAPD definitions of levels of sedation. ( See BPC 1647.12; CCR 1044-1044.5.)

### **Moderate Parenteral Sedation**

In California, to obtain a moderate IV conscious sedation permit, the applicant must complete at least 60 hours of instruction and 20 clinical cases of administration of parenteral (intravenous) conscious sedation for a variety of dental procedures. The course must comply with the requirements of the *Guidelines for Teaching the Comprehensive Control of Anxiety and Pain in Dentistry* of the American Dental Association as approved by the Board (see BPC 1647.3) The majority of states (37/50) require similar training, also to ADA standards; five states (5) require completion of fewer clinical cases or hours of instruction and four (4) states require more. All states accept proof of completion of a CODA accredited residency program that includes sedation training in lieu of course completion.

California, as well as other states, limit moderate sedation providers to utilizing drugs and techniques that have a margin of safety wide enough to render unintended loss of consciousness unlikely. A few states restrict moderate sedation permit holders from using potent anesthetics such as propofol, methohexital, and ketamine.

### **General Anesthesia**

Educational requirements for a general anesthesia permit issued by the Dental Board of California include either completion of one year of advanced training in anesthesiology and related academic subjects approved by the Board or equivalent experience as determined by the Board (BPC Section 1646). This requirement is further defined in regulation (CCR Section 1043.1) to include either a one-year residency in anesthesiology or completion of a Commission on Dental Accreditation (CODA)-approved graduate program in oral and maxillofacial surgery.<sup>12</sup> Although this requirement is generally consistent with the laws in the other 49 states there are some variations. For example, some states require completion of either a two-year residency in dental anesthesiology or a residency in oral and maxillofacial surgery. Other states require

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<sup>12</sup> Commission on Dental Accreditation: (2012). "Accreditation Standards for Advanced Specialty Education Programs in Oral and Maxillofacial Surgery". Retrieved from <https://www.ada.org/~media/CODA/Files/oms.pdf?la=en>

completion of at least three years of an oral and maxillofacial residency; others require board certification, but most states (33/50) require completion of an advanced residency education program accredited by the CODA that includes training to competency in general anesthesia. The subcommittee was unable to identify a state that restricts a general anesthesia permit holder from using any anesthetic agent, including inhalation agents such as Sevoflurane and the intravenous agent propofol.

## **ADVANCED EDUCATIONAL PROGRAMS THAT INCLUDE SEDATION TRAINING**

### **Commission on Dental Accreditation (CODA) Accreditation of Advanced Educational Programs**

CODA accreditation is a non-governmental, voluntary peer review process by which educational institutions or programs may be granted public recognition for compliance with accepted standards of quality and performance. Accreditation standards are developed in consultation with those affected who represent broad communities of interest. CODA was established in 1975 and is nationally recognized by the United States Department of Education (USDE) as the sole agency to accredit dental and dental-related education programs conducted at the post-secondary level. A comparison table of CODA accreditation standards for advanced residency programs that include training in sedation and general anesthesia is attached. See Appendix 1 “Educational programs that include training in moderate sedation, deep sedation, and general anesthesia”.

### **American Dental Association (ADA) Educational Guidelines**

The ADA “Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students” are educational guidelines published by the ADA for programs and courses that teach sedation techniques.<sup>13</sup> These guidelines have been revised periodically but have been relatively consistent for the past 16 years. The guidelines for teaching moderate sedation are summarized below. The guidelines do not address training in deep sedation and general anesthesia and defer to the CODA standards for advanced educational programs, stating that these are advanced specialty techniques. The ADA educational guidelines are summarized as follows:

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<sup>13</sup> American Dental Association. (2012). “Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students”. In ADA (Ed.), (pp. 1–18). Chicago.

### **Moderate Enteral Sedation**

- a minimum of 24 hours of instruction plus management of at least 10 adult case experiences (at least three live patients in groups no larger than five with remainder being on mannequins or by virtual reality).
- participants should be provided supervised opportunities for clinical experience to demonstrate competence in airway management to prevent office emergencies.
- clinical experience is provided in managing healthy adult patients.
- course is not designed for the management of children (age 12 and under).
- additional supervised clinical experience is necessary to prepare participants to manage medically compromised adults (ASA PS II-IV) and special needs patients.

### **Moderate Parenteral Sedation**

- a minimum of 60 hours of instruction plus management of at least 20 patients by the intravenous route per participant is required to achieve competency in moderate parenteral sedation.
- participants should be provided supervised opportunities for clinical experience to demonstrate competence in airway management for prevention of emergencies.
- typically clinical experience provided in managing healthy adult patients (not ASA PS II-IV).
- additional supervised clinical experience is necessary to prepare participants to manage children (age 12 and under) and medically compromised adults.

### **Continuing Education Requirements**

Forty-seven states, including California, require general anesthesia permit holders to maintain current certification in Advanced Cardiac Life Support (ACLS). The majority of states, other than California, also require moderate sedation permit holders to complete ACLS. Seventeen states require completion of a Pediatric Advanced Cardiac Life Support (PALS) course usually in practices where children are treated. California does not presently require completion of PALS training. Some professional association guidelines, including the AAP-AAPD Guidelines, recommend completion of PALS training.

Twenty nine states, including California, require completion of continuing education courses as a condition of renewal of a sedation or anesthesia permit. Most states require continuing education specifically related to sedation or anesthesia. California requires the completion of 25 hours of anesthesia-related continuing education every two years for a general anesthesia permit, the most of any state, and requires 12 hours per renewal for conscious sedation and seven hours for oral sedation. California's continuing education requirements, therefore, exceed those of most other states.

## **Preoperative Evaluation**

California law requires a preoperative evaluation for all patients undergoing sedation or anesthesia prior to each administration of sedation or anesthesia. This includes an adequate medical history and a focused physical evaluation recorded and updated as indicated. Records must include but are not limited to the recording of the age, sex, weight, physical status (American Society of Anesthesiologists Classification I-V), medication use, any known or suspected medically compromising conditions, rationale for sedation of the patient, and visual examination of the airway, and, for general anesthesia only, auscultation of the heart and lungs as medically required (CCR Section 1043.3). All other states reviewed have equivalent or lesser requirements.

## **Personnel**

California law requires patients undergoing sedation or anesthesia to be monitored on a one-on-one ratio until fully recovered. In contrast, 33 other states require that a prescribed number of staff members be present during administration of sedation or general anesthesia. The American Dental Association Guidelines and AAP-AAPD Guidelines recommend that a minimum of two persons, in addition to the dentist, are present whenever general anesthesia or deep sedation is administered; one person in addition to the dentist should be present for the administration of moderate or minimal sedation.

## **Staff Training and Qualifications**

Nearly all states (44/50) including California require dental assistants to maintain current certification in basic cardiac life support, and most require completion of a provider CPR course that includes use of the AED. Although dental assistants may assist with dental treatment, including sedation and anesthesia care under supervision, practice acts in most states prohibit the administration of anesthesia, other than local anesthesia, by dental assistants or dental hygienists.

Twenty-nine states require that an individual be designated to monitor patients undergoing sedation or anesthesia, to observe vital signs including pulse, blood pressure, oxygenation, ventilation and circulation. Fourteen states, including California, specify the duties and education for dental assistants participating in sedation and anesthesia care.

California law (BPC Section 1750) specifies that:

*“The supervising dentist shall be responsible for determining the competency of the dental assistant to perform basic supported dental procedures as defined, that include monitoring patient sedation, limited to reading and transmitting information from patient monitors, as specified, for the purpose of interpretation and evaluation by the supervising dentist, who shall be present at chairside during the procedure.”*

In addition, the supervising dentist is responsible for ensuring that assistants in his or her employ complete required courses, including California law, infection control, and an approved CPR course.

### **Specialty Training for Dental Assistants**

Since 1967, The California Association of Oral and Facial Surgeons has sponsored a training course for dental assistants. The course consists of 24 hours of didactic education, including 10 hours of lecture, completion of progress exams, and 14 hours of home study followed by completion of a written exam. Upon successful course completion, the assistant is provided with a certificate of completion. A similar course for assistants is offered by the AAOMS but includes a psychometrically validated exam given at secure testing centers.

Dental assistants may complete a Dental Sedation Assisting Course following one year of employment (BPC Sections 1750.4, 1750.5). This course must be approved by the Board and requires completion of 40 hours of didactic education, 28 hours of laboratory instruction and 20 supervised cases that involve sedation or general anesthesia. The assistant may apply to take a secure exam which may qualify them for licensure as a dental sedation assistant (CCR Section 1070.8). The course requires completion of a minimum of 110 hours of education, over four times that required by any other state.

Approved training for sedation assistants in five states consists of the satisfactory completion of courses offered by professional associations such as the AAOMS or the ADSA that require approximately 24 hours of education. We were unable to identify any state that requires the presence of a registered nurse or other medical professional during sedation or anesthesia for dental treatment. We were unable to identify any state that requires the presence of an individual dedicated to both the monitoring and administration of anesthesia or sedation who is not involved in the procedure.

### **Facilities**

State laws specify facility requirements such as a treatment room of adequate size to accommodate the patient and three individuals, adequate lighting, a power operated chair or table, suction, a supply of oxygen, and appropriate backup systems to allow completion of a procedure in the event of a power failure. These requirements are relatively uniform for all states the subcommittee reviewed.

### **Monitors and Ancillary Equipment**

State laws generally require the dentist to equip the treatment room with the appropriate patient monitors and to possess the ancillary equipment necessary to provide safe anesthesia and sedation. Required equipment varies depending on the level of sedation, with additional monitors such as the electrocardiogram (ECG), a defibrillator, and capnography usually

required for general anesthesia but not for moderate or minimal sedation. California's requirements are consistent with those of other states as well as with the recommendations included in professional association guidelines.

### **Records**

State laws specify the records that must be maintained for sedation and anesthesia, including a time dependent record of pulse, blood pressure, oxygen saturation, ECG where appropriate, the doses of medications administered and the time they are given, and any complications. Monitoring of exhaled carbon dioxide is an emerging trend, and this is now required in twenty states not only for deep sedation and general anesthesia but also for moderate sedation. In California monitoring of exhaled CO<sub>2</sub> is mandatory only for patients who require endotracheal intubation.

### **Informed Consent**

A written consent form must be completed and signed by the patient, parent, or legal guardian prior to the administration of anesthesia or sedation in California as well as other states.

### **Discharge**

State law requires an evaluation of the patient by a qualified person prior to discharge, and notation of their condition in the treatment record. California requires this evaluation notation as do most other states.

### **Drugs Necessary for the Treatment of Medical Emergencies**

State laws require the dentist to possess the drugs necessary for the treatment of medical emergencies and to have the knowledge and ability to use these drugs. The specific medications necessary for the management of sedation and anesthesia related emergencies are listed in the sedation laws of the majority of states, as well as in professional association guidelines. These include medications necessary for the treatment of allergic reactions, respiratory emergencies, cardiac conditions including cardiac arrest, diabetic conditions, high blood pressure, low blood pressure, and antidotes (reversal agents) for sedatives and narcotics. Medications for the treatment of malignant hyperthermia are required where appropriate. Additional medications are usually required when general anesthesia is administered as compared to moderate or minimal sedation. The medications required in California are consistent with those required in other states and recommended by professional association guidelines.

### **Office Inspections**

California, along with 37 other states, requires the state board to conduct an inspection of dental offices where moderate sedation and general anesthesia are given. Inspections are not usually required for offices where minimal sedation or nitrous oxide/oxygen alone are utilized.

Dentists with permits for minimal or moderate enteral sedation are required to certify that they possess the specified equipment and emergency drugs and are capable of managing emergencies.

Facilities such as ambulatory care centers and hospitals where dental treatment may occur are usually accredited and licensed by other state agencies or accrediting organizations.

Most states require an inspection of dental offices by the board of dentistry every five years. The inspection is either very similar to either the process utilized by the California Dental Board or the similar process described in the AAOMS Office Evaluation Manual. The office inspection requires two peer evaluators appointed by the Board to inspect the facility, equipment, and emergency drugs. The evaluators must observe at least one clinical case performed by the dentist and his or her staff appropriate for the type of permit they possess. The inspection requires the dentist and his or her team to physically demonstrate the performance of up to thirteen simulated emergencies. The simulated emergencies include airway obstruction, laryngospasm, bronchospasm, and respiratory depression, scenarios that are widely recognized as being among the most significant complications of sedation and anesthesia. In addition, the dentist and his or her team must demonstrate their skills in basic CPR and for general anesthesia permit holders advanced cardiac life support. This provides the evaluation team with an opportunity to assess the competency of sedation/anesthesia providers in their own facilities and with their own team members, including team dynamics, closed loop communication, and appropriate activation of emergency backup from first responders.

Inspections are usually graded on a pass/fail basis and the results are reported for a final determination by the board. A failing grade requires the inspection to be repeated and a second failure usually results in denial of the permit to administer sedation or general anesthesia.

### **Pediatric Sedation Requirements**

States have taken differing approaches to the regulation of pediatric sedation. Twenty-five states, including California, have included special requirements for young patients. California requirements apply to patients age 13 or under. An increasing number of states have adopted pediatric sedation educational requirements and permits over the past 10 years.

Nine states (California, Colorado, Florida, Georgia, Kentucky, Louisiana, Missouri, Mississippi, and North Carolina) require a permit for sedating pediatric patients. Sixteen states require specific training to administer moderate/conscious sedation to pediatric patients. Twenty-five states have specific requirements for pediatric sedation administered by the oral route.

A number of states define the pediatric patient as under the age of 12 consistent with ADA Guidelines; however other states use 13, 14, 16 and 18 years of age. Most states, including California, specify that the practitioner must have appropriately sized equipment for pediatric patients. In most states, Advanced Cardiac Life Support (ACLS) certification is deemed sufficient for treating pediatric patients; twenty states currently require Pediatric Advanced Life Support (PALS) certification. California does not presently require certification in PALS.

Although ten states have adopted the AAP-AAPD Guidelines, these apply to minimal and moderate sedation only. The subcommittee was unable to identify any state that requires an individual dedicated to monitoring and administration of deep sedation or general anesthesia for children or adults.

### **Utilization of Certified Registered Nurse Anesthetists (CRNAs) and Physician (MD) Anesthesiologists**

All states allow anesthesia to be provided in dental offices by CRNAs and physician anesthesiologists. For some states, it is difficult to determine the requirements for non-dentist anesthesia providers because they may be regulated by nursing and medical practice acts, not the dental practice act. The subcommittee felt that other professional practice acts were beyond the scope of this review.

Twenty-nine states, including California, require a dentist who orders the administration of sedation or anesthesia by a CRNA to possess either a moderate sedation or general anesthesia permit issued by the board that corresponds to the level of sedation administered. A number of states, including California, require a physician anesthesiologist to obtain a permit from the Dental Board if they administer sedation or anesthesia in a dental office.

### **SUMMARY OF COMPARISON OF CALIFORNIA LAWS AND REGULATIONS TO OTHER STATES**

**California's laws and regulations for dentists providing general anesthesia and moderate sedation are generally consistent with laws in other states in the following areas:**

- Education
- Pre-operative evaluation
- Facility
- Monitoring and Equipment
- Records
- Emergency Drugs
- Office inspection
- Pediatric and adult oral conscious sedation

**California's laws and regulations differ from those in other states in the following areas:**

- Personnel
- Pre-operative dietary instructions
- Pediatric moderate sedation (Pediatric Oral Conscious Sedation Permit)

## **DISCUSSION OF DIFFERENCES**

- **Personnel**

California does not require the presence of a specific number of staff for general anesthesia and moderate sedation. Thirty-three states specify that there be at least two persons present, in addition to the dentist, when general anesthesia is administered, and thirty one states specify that at least one person be present when moderate sedation is administered.

In addition, twenty-nine states require the presence of a designated anesthesia monitor. Fourteen states specify training requirements for the sedation monitor, usually completion of an educational program offered by a professional association such as the AAOMS or ADSA.

- **Pre-operative Dietary Instructions**

California does not presently require that instructions for pre-operative fasting be given. Approximately ten states require instructions based on the planned level of sedation similar to those described in the ADA Guidelines. The ADA Guidelines recommend that preoperative dietary restrictions be considered based on the sedative technique prescribed. Some states require instructions that are consistent with those for general anesthesia, usually according to the “2-4-6” rule, with no oral intake for 2 hours prior to sedation for liquids, 4 hours for breast milk, and 6 hours for solids.

- **Pediatric Sedation**

Although thirty-three states have requirements for dentists who administer pediatric sedation, these vary, ranging from completion of a PALS course to completion of an advanced residency education program in pediatric dentistry. Requirements usually include training in pediatric oral sedation similar to California. Ten states, including California, issue a permit to dentists who administer sedation to children under thirteen, most often for moderate parenteral sedation.

For a state-by-state comparison of pediatric sedation regulations see Appendix 2, Table 10.

## PROFESSIONAL DENTAL ASSOCIATION GUIDELINES, POSITION PAPERS, AND POLICY STATEMENTS

The dictionary definition of “guideline” is “general rule, principle, or piece of advice.” Guidelines come in the form of “Statements,” “Practice Advisories,” “Clinical Policies,” or “Recommendations.” These documents range from broad descriptions of appropriate monitoring and treatment to those offering specific guidelines on the use of particular drugs or techniques. The guidance documents reviewed by the subcommittee were developed by professional associations.

The subcommittee’s charge was to review state laws and association policies from the dental profession, not the medical profession. However, due to requests from stakeholders, the subcommittee addressed requests from all interested parties including the American Academy of Pediatrics and the California Society of Anesthesiologists.

Guidelines and position papers reviewed include:

- American Dental Association *“Guidelines for Use of Sedation and General Anesthesia By Dentists”*
- American Academy of Pediatrics-American Academy of Pediatric Dentistry *“Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures”*
- American Academy of Pediatrics *“Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures”*
- American Society of Anesthesiology – *“Standards for Basic Anesthetic Monitoring” Oct. 2015.*
- ASA *“Statement on the Anesthesia Care Team”*
- ASA *“Statement on Granting Privileges to Non-Anesthesiologist Physicians for Personally Administering or Supervising Deep Sedation”*
- American Dental Association *“Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students”*
- American Society of Anesthesiology: *“Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists”*
- American Society of Anesthesiology *“Advisory on Granting Privileges for Deep Sedation to Non-Anesthesiologists Sedation Providers”*

The Center for Medicare and Medicaid Services (CMS) includes dentists among practitioners who are authorized to administer anesthesia under the *Hospital Anesthesia Services Condition of Participation* (42 CFR 482.52(a)). CMS Conditions of Participation are federal regulations that

describe the health and safety requirements for hospitals and ambulatory surgery centers that participate in the Medicare and Medicaid programs.

The American Academy of Pediatrics submitted the “Guidelines for Monitoring and Management of Pediatric Patients Before, during and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016” for review. This document is fundamentally the same document adopted by the American Academy of Pediatric Dentistry and will therefore not be addressed separately. As previously noted, the California Society of Anesthesiologists submitted three documents for review.

Guidelines for general anesthesia and sedation utilized by dentists are published by the American Dental Association (ADA) as the “Guidelines for Use of Sedation and General Anesthesia By Dentists” and “Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students.” For children 12 years of age and under, the American Dental Association supports the use of the “American Academy of Pediatrics/American Academy of Pediatric Dentistry Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures” (AAP-AAPD Guidelines).<sup>14</sup> These guidelines are directed toward all dentists treating children and are not limited to members of specialty organizations or specific professional associations. Both the ADA and the AAP-AAPD Guidelines are currently undergoing revision.

Guidance documents are also published by dental specialty associations, including the American Association of Oral and Maxillofacial Surgeons and the American Society of Dentist Anesthesiologists, that are directed to their members.<sup>15 16</sup>

State dental associations, such as the California Dental Association, usually incorporate American Dental Association documents by reference into their own guidance documents and do not develop their own. However there are exceptions such as in Pennsylvania.

The methodologies used to develop guidelines vary from organization to organization. For example, the American Dental Association’s *Guidelines for the Use of Sedation and Anesthesia*

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<sup>14</sup> Coté, C. J., & Wilson, S. (2016). “Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016”. *Pediatrics*, 138(1), 1–87. <http://doi.org/10.1542/peds.2016-1212>

<sup>15</sup> AAOMS. (2012). *Parameters of Care: Clinical Practice Guidelines for Oral and Maxillofacial Surgery* (AAOMS ParCare 2012).

<sup>16</sup> American Society of Dentist Anesthesiologists. (2013). *American Society of Dentist Anesthesiologists Parameters of Care The Continuum of Sedation and Anesthesia*, 1–13.

*by Dentists and the American Academy of Pediatrics – American Association of Pediatric Dentists Guidelines* are based on a careful consideration of the available literature and expert opinion. The exact nature of how studies were weighted and how conclusions were drawn is not explicitly described.

### **Guideline Development Process**

There are many publications that describe the clinical guideline development process and full discussion of this topic is beyond the scope of this report. To summarize, the process begins by defining a clinical question. Related evidence is identified through a systematic review of the scientific literature. The quality of evidence is assessed and data are extracted and classified according to the strength of the evidence. When there is insufficient evidence, expert opinion is used as a basis for recommendations, however, opinion is usually given less weight than results of studies and opinion may be subject to bias. There is currently no optimal process for the assessment of opinion, and the process utilized should be as explicit as possible. In addition to scientific evidence and expert opinion, guidelines must take into account resource implications and the feasibility of interventions. Judgments about whether the costs of tests or treatment are reasonable may depend on the perspective taken, for example clinicians may view cost considerations differently than would payers or the public. Feasibility issues include time, skills, staff, and equipment necessary for the provider to carry out the recommendations, and the ability of the system of care to implement them.<sup>17</sup> None of the guidelines reviewed by the subcommittee addressed resource considerations or feasibility considerations.

### **American Dental Association Guidelines**

The ADA *Guidelines for the Use of Sedation and General Anesthesia by Dentists* and the *Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students* (Sedation and Anesthesia Guidelines) are policy of the ADA and receive final approval by the ADA House of Delegates.

According to the ADA Constitution and Bylaws, the Council on Dental Education and Licensure (CDEL) has subject matter authority for dental anesthesiology and sedation and recommends regular proposed revisions to the Board of Trustees and House of Delegates, with the House of Delegates as the final authority. CDEL's Anesthesiology Committee, comprised of seven sedation and anesthesiology experts and chaired by a CDEL member, develops recommendations for CDEL's consideration using available literature, policies and guidelines of other national health care organizations and expert opinion. All proposed revisions of the

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<sup>17</sup> Shekelle, P. G., Woolf, S. H., Eccles, M., & Grimshaw, J. (1999). Clinical guidelines: developing guidelines. *BMJ (Clinical Research Ed.)*, 318(7183), 593–596. <http://doi.org/10.1136/bmj.318.7183.593>

Sedation and Anesthesia Guidelines are circulated to anesthesiology communities of interest; comments are invited from any individual or organization.

### **American Academy of Pediatric Dentistry Guidelines**

The AAPD's guideline development process is outlined in an overview statement outlined in their reference manual posted on their website.<sup>18</sup> Guidelines are defined as:

*"Systematically developed recommendations designed to assist the practitioner, patient, and caregiver in making decisions relating to specific clinical situations. Guidelines are intended to be more flexible than standards. Guidelines should be followed in most cases, but they recognize that treatment can and should be tailored to fit individual needs, depending on the patient, practitioner, setting, and other factors. Deviations from guidelines could be fairly common and could be justified by differences in individual circumstances. Guidelines are designed to produce optimal outcomes, not minimal standards of practice."*

The AAPD Council on Clinical Affairs (CCA) is charged with the development of oral health policy guidelines. Oral health policies and clinical guidelines utilize two sources of evidence: the scientific literature and experts in the field. CCA, in collaboration with the Council on Scientific Affairs, performs a comprehensive literature review for each document. When scientific data do not appear conclusive, experts may be consulted. The CCA's recommendations are submitted to AAPD's Board of Trustees for review, with eventual approval at the AAPD's General Assembly.

In the case of the current American Academy of Pediatrics-American Academy of Pediatric Dentistry Guidelines for the Monitoring and Management of Pediatric Patients Before, during and After Sedation for Diagnostic and Therapeutic Purposes,<sup>19</sup> the guidelines are developed jointly by the both organizations. Physician anesthesiologists and other pediatric medical specialists are involved in the development of the document, as are AAPD specialists in dentist-administered anesthesia. Non-member dentists, representatives from outside organizations, and members of the public may attend AAPD reference committee hearings where a draft document is being considered before adoption and may ask to speak or provide testimony on any details of the proposed guideline.

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<sup>18</sup> American Academy of Pediatric Dentistry. (2011). Definitions and scope of pediatric dentistry. *Reference Manual*, 33(6), 2–349. Retrieved from [http://www.aapd.org/media/Policies\\_Guidelines/Intro1.pdf](http://www.aapd.org/media/Policies_Guidelines/Intro1.pdf).

<sup>19</sup> Coté, C. J., & Wilson, S. (2016). "Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016." *Pediatrics*, 138(1), 1–87. <http://doi.org/10.1542/peds.2016-1212>

The AAP-AAPD Guidelines were last submitted to the ADA House of Delegates for consideration in 2012. The ADA House of Delegates voted to support the AAP-AAPD Guidelines for the dental treatment of children under twelve. This approach to policy for the treatment of children has been utilized by the ADA for many years.

Guidelines of the American Society of Anesthesiologists (ASA) and American College of Emergency Physicians (ACEP) are founded on an evidence-based review of the sedation literature and the methodologies are quite explicit. Even in these cases, the lack of definitive or comparative data on outcomes of sedation necessitate that many of the guidelines are based on “consensus” rather than “evidence.”<sup>20</sup> The ASA represents approximately 35,000 practicing anesthesiologists in the United States. Anesthesiology is recognized as a leading specialty of medicine in the field of patient safety research, particularly as it relates to sedation and general anesthesia. Sedation guidance documents in all branches of the healing arts are heavily influenced by standards and guidelines established by ASA.

The ASA periodically publishes guidance documents on a wide variety of topics related to sedation and anesthesia. The ASA Committee on Standards and Practice Parameters, other ASA committees, and task forces periodically collect evidence to determine whether new or existing practice guidelines are needed. The Committee develops these documents, which are then approved by a vote of the ASA membership at the ASA House of Delegates annual meeting.

**ASA Standards, Guidelines, Statements and Practice Parameters**<sup>21</sup> provide guidance to improve decision-making and promote beneficial outcomes for the practice of anesthesiology. They are not intended as unique or exclusive indicators of appropriate care. The interpretation and application of Standards, Guidelines and Statements takes place within the context of local institutions, organizations and practice conditions. A departure from one or more recommendations may be appropriate if the facts and circumstances demonstrate that the rendered care met the physician's duty to the patient.

**Standards** provide rules or minimum requirements for clinical practice. They are regarded as generally accepted principles of patient management. Standards may be modified only under unusual circumstances, e.g., extreme emergencies or unavailability of equipment.

**Guidelines** are systematically developed recommendations that assist the practitioner and patient in making decisions about health care. These recommendations may be adopted, modified, or rejected according to clinical needs and constraints and are not intended to replace local institutional policies. In addition, practice guidelines are not intended as standards

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<sup>20</sup> Cravero, J.P: “Sedation Policies, Recommendations and Guidelines Across the Specialties and Continents”. In, K.P. Mason (ed.), *Pediatric Sedation Outside of the Operating Room: A Multispecialty International Collaboration*, 17.DOI 10.1007/978-1-4939-1390-9\_2, © Springer Science+Business Media New York 2015

<sup>21</sup> American Society of Anesthesiologists. Resources, Clinical information, <https://www.asahq.org/resources/clinical-information>, accessed 7/7/2016.

or absolute requirements, and their use cannot guarantee any specific outcome. Practice guidelines are subject to revision as warranted by the evolution of medical knowledge, technology, and practice. They provide basic recommendations that are supported by a synthesis and analysis of the current literature, expert opinion, open forum commentary, and clinical feasibility data.

**Statements** represent the opinions, beliefs, and best medical judgments of the House of Delegates. As such, they are not necessarily subjected to the same level of formal scientific review as ASA Standards or Guidelines. Each ASA member, institution or practice should decide individually whether to implement some, none, or all of the principles in ASA statements based on the sound medical judgment of anesthesiologists participating in that institution or practice.

**Practice parameters** provide guidance in the form of requirements, recommendations, or other information intended to improve decision-making and promote beneficial outcomes for the practice of anesthesiology. The use of practice parameters cannot guarantee any specific outcome. Practice parameters are subject to periodic revision as warranted by the evolution of medical knowledge, technology and practice. Variance from practice parameters may be acceptable, based upon the judgment of the responsible anesthesiologist.

**Practice advisories** are systematically developed reports that are intended to assist decision-making in areas of patient care. Advisories provide a synthesis and analysis of expert opinion, clinical feasibility data, open-forum commentary, and consensus surveys. Practice Advisories developed by the American Society of Anesthesiologists (ASA) are not intended as standards, guidelines, or absolute requirements, and their use cannot guarantee any specific outcome. They may be adopted, modified, or rejected according to clinical needs and constraints and are not intended to replace local institutional policies.

Practice Advisories are not supported by scientific literature to the same degree as standards or guidelines because of the lack of sufficient numbers of adequately controlled studies. Practice Advisories are subject to periodic update or revision as warranted by the evolution of medical knowledge, technology, and practice.

The subcommittee reviewed three documents submitted by the California Society of Anesthesiologists, including:

- *Statement on Granting Privileges to Non-Anesthesiologist Physicians for Personally Administering or Supervising Deep Sedation*
- *The ASA Statement on the Anesthesia Care Team*
- *ASA Standards for Basic Anesthesia Monitoring.*

The subcommittee reviewed the following definitions published by the ASA that apply to these statements.<sup>22</sup>

- 1.1 Anesthesia Professional: An anesthesiologist, anesthesiologist assistant (AA), or certified registered nurse anesthetist (CRNA).
- 1.2 Non-anesthesiologist Sedation Practitioner: A licensed physician (allopathic or osteopathic); or dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law; who has not completed postgraduate training in anesthesiology but is specifically trained to administer personally or to supervise the administration of deep sedation.
- 1.3 Unrestricted general anesthesia shall only be administered by anesthesia professionals within their scope of practice (anesthesiologists, certified registered nurse anesthetists and anesthesiologist assistants).

### **National Guidelines Clearinghouse**

The U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality, hosts the National Guidelines Clearinghouse. The Clearinghouse maintains a database of guidelines that must meet inclusion standards. Clinical practice guidelines must be submitted by a medical specialty association, relevant professional society, government, or healthcare organization and must be based on a systematic review of evidence that is intended to assist practitioners and patients with decisions for specific clinical circumstances.<sup>23</sup> None of the professional association guidance documents we reviewed are listed by the Clearinghouse. It is unclear whether or not they met inclusion criteria or were submitted for consideration by the Clearinghouse.

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<sup>22</sup> American Society of Anesthesiologists. (2010). "Advisory on granting privileges for deep sedation to non-anesthesiologist sedation practitioners". Retrieved from <http://www.asahq.org/~media/Sites/ASAHQ/Files/Public/Resources/standards-guidelines/advisory-on-granting-privileges-for-deep-sedation-to-non-anesthesiologist.pdf>

<sup>23</sup> Inclusion Criteria, National Guideline Clearinghouse, <https://www.guideline.gov/about/inclusion-criteria.aspx>

## **DISCUSSION OF DIFFERENCES AND SIMILARITIES BETWEEN CALIFORNIA LAWS AND THE ADA AND AAP-AAPD GUIDELINES**

A side-by-side comparison table of California's dental sedation laws, the American Dental Association Guidelines and the AAP-AAPD Guidelines is provided as Appendix 2. Although these guidelines are not recognized by all states they come close to establishing national parameters for sedation and anesthesia care for the dental profession. Other professional dental association guidelines include similar information that appears to be directed toward a specific association membership. The following guidance documents are provided for reference but are not included in the comparison tables.

1. American Association of Oral and Maxillofacial Surgeons, Parameters of Care, Clinical Guidelines
2. American Society of Dentist Anesthesiologists Parameters of Care

*Comparison tables to show differences and similarities between California laws and the ADA and AAP-AAPD Guidelines are organized by topic. Please see Appendix 2, Tables 1-9.*

### Area of comparison

- Definitions Table 1
- Education Table 2
- Pre-operative Evaluation Table 3
- Pre-operative Dietary Instructions Table 3
- Personnel Table 4
- Facility Table 5
- Monitoring and Equipment Table 6
- Records Table 7
- Emergency Drugs Table 8
- Office Inspection Table 9

## **SUMMARY OF DIFFERENCES AND SIMILARITIES BETWEEN CALIFORNIA LAWS AND THE ADA AND AAP-AAPD GUIDELINES**

Areas where California requirements are consistent with professional guidance documents include:

- Pre-operative evaluation
- Facility
- Monitoring and equipment
- Records
- Emergency drugs
- Office inspection

Areas where California requirements are different:

- Monitoring
- Personnel
- Education
- Pre-operative fasting

## **DISCUSSION OF AREAS WHERE CALIFORNIA REQUIREMENTS ARE DIFFERENT FROM PROFESSIONAL GUIDANCE DOCUMENTS**

### **Monitoring**

The ADA Guidelines are prescriptive and state which monitors should be used for each level of sedation. The ASA Standards for Basic Anesthetic Monitoring use a similar approach.<sup>24</sup>

The ADA guidelines specify that ECG monitoring should be considered during moderate sedation for patients with cardiovascular disease and that use of the ECG is required for patients receiving general anesthesia. They also state when an intravenous line must be established, and how ventilation and respiration are monitored.

In contrast, California law states the dentist must possess the necessary equipment, but leaves the use of the equipment to the discretion of the dentist. The use of a pulse oximeter is required for all levels of sedation. California law specifies the records that must be maintained and specifies the recording intervals for vital signs. It would be impossible for the dentist to maintain the required records without monitoring, therefore adding a specific monitoring requirement for vital signs and pulse oximetry might be considered redundant. Capnography is required for intubated general anesthesia only which is consistent with ADA guidelines. ASA monitoring standards indicate capnography is required for all patients undergoing sedation or anesthesia.

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<sup>24</sup> American Society of Anesthesiology. *Standards for Basic Anesthetic Monitoring*. Oct 2015.

The AAP-AAPD Guidelines follow a similar approach to that used by California and list the drugs and equipment that should be present and available and which records should be maintained, but does not state which monitors or techniques must be used. California law is consistent with AAP- AAPD Guidelines in this area.

The *ASA Statement on Granting Privileges to Non-Anesthesiologist Physicians for Personally Administering or Supervising Deep Sedation* includes the following language:

*“Nonanesthesiologist physicians may neither delegate nor supervise the administration or monitoring of deep sedation by individuals who are not themselves qualified and trained to administer deep sedation, and the recognition of and rescue from general anesthesia.”*

California law permits delegation of limited monitoring duties to dental assistants, but does not permit delegation of the administration of sedation or anesthesia other than nitrous oxide and oxygen. Trained and licensed assistants may assist with sedation or anesthesia as specified. ADA Guidelines and AAP-AAPD Guidelines also describe the role of personnel who may monitor moderate sedation as well as deep sedation/general anesthesia, although the qualifications of these personnel are not specifically addressed, but must be appropriately trained and qualified.

The *ASA Statement on the Anesthesia Care Team* indicates that although the Anesthesia Care Team may include non-physicians, the team should be directed by an anesthesiologist.

California law does not presently require the presence of an anesthesiologist in a dental office where anesthesia is given and authorizes dentists who hold a general anesthesia permit to administer deep sedation/general anesthesia. The AAP-AAPD Guidelines address the administration of deep sedation and general anesthesia in dental facilities such as dental offices through a description of the necessary skills and qualifications. For facilities that function under a department of anesthesiology the AAP-AAPD guidelines defer to the ASA policies implemented by the department.

The *ASA Standards for Basic Anesthesia Monitoring* describe which monitors should be used for the different levels of sedation and general anesthesia, and indicate that there should be continuous monitoring with an ECG, pulse oximeter, capnograph and blood pressure recorded every five minutes.

Current California law requires continuous pulse oximetry for all levels of sedation and anesthesia. Although an ECG must be available for dentists who administer general anesthesia, its use is not required. Vital signs must be recorded at five minute intervals. Dentists who administer moderate sedation are not required to possess or use an ECG or capnograph, and must record vital signs at regular intervals. The ADA Guidelines specify continuous ECG monitoring for patients receiving deep sedation or general anesthesia, but do not indicate

mandatory use of capnography except for intubated patients or those receiving volatile agents. The AAP-AAPD Guidelines indicate that monitors must be available.

### **Personnel**

California does not require that a specific number of staff be present for general anesthesia or moderate sedation. Both the ADA and AAP-AAPD Guidelines specify that there be two persons present in addition to the dentist for general anesthesia or deep sedation, and at least one other person for sedation. The AAP-AAPD Guidelines specify the presence of one person whose only responsibility is to constantly observe the patient's vital signs, airway patency, and adequacy of ventilation and to either administer drugs or direct their administration, for deep sedation/general anesthesia. California, like other states, does not have specific requirements for pediatric deep sedation or general anesthesia other than possession of a general anesthesia permit.

### **Education**

California's educational requirements for moderate sedation, adult and pediatric oral conscious sedation (OCS), conscious sedation, and general anesthesia permits are consistent with the ADA Guidelines but differ from the corresponding ADA educational guidelines in several areas. See Appendix 2, Table 2, for a side-by-side comparison.

- Adult oral conscious sedation permits - California law requires one patient experience. ADA Guidelines recommends three patient experiences.
- Pediatric sedation - In California there are specific training requirements for the Oral Conscious Sedation for Minors permit. The ADA Guidelines specify that additional experience should be required for sedating pediatric patients.
- California does not have age-specific requirements for sedation administered via parenteral routes or for pediatric deep sedation/general anesthesia. The ADA and AAP-AAPD also do not provide specific pediatric sedation training requirements and defer to CODA accreditation standards for advanced education.
- California law does not require completion of PALS for dentists who sedate pediatric patients. The value of the PALS course for sedation providers may be limited. A course dedicated to pediatric sedation that focuses on airway management, preferably with a patient simulator component, may be more appropriate.

### **Pre-operative Dietary Instructions**

- California does not specify that pre-operative dietary instructions be given. ADA Guidelines state that dietary precautions should be considered based on the sedative technique prescribed. The AAP-AAPD Guidelines include the following statement:

- *“the practitioner should evaluate preceding food and fluid intake, ...but because the absolute risk of aspiration during procedural sedation is not yet known, guidelines for fasting periods before elective sedation generally should follow those used for elective general anesthesia. For emergency procedures in children who have not fasted, the risks of sedation and the possibility of aspiration must be balanced against the benefits of performing the procedure promptly. Further research is needed to better elucidate the relationships between various fasting intervals and sedation complication.”*
- The 2016 draft ADA Guidelines incorporate the ASA Practice Guidelines on Preoperative Fasting by reference.<sup>25</sup>

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<sup>25</sup> American Society of Anesthesiologists Committee on standards and practice parameters. (2011). “Practice guidelines for preoperative fasting and the use of pharmacologic agents to reduce the risk of pulmonary aspiration: application to healthy patients undergoing elective procedures: an updated report by the American Society of Anesthesiologists Com.” *Anesthesiology*, 114(3), 495–511.  
<http://doi.org/10.1097/ALN.0b013e3181fcbfd9>

## **PART 2: LITERATURE REVIEW - SEDATION AND GENERAL ANESTHESIA FOR PEDIATRIC DENTAL PATIENTS**

The published literature on pediatric sedation and anesthesia is extensive and a comprehensive review is beyond the scope of this assignment. This section should be considered an overview, not an in-depth analysis of the available literature.

The subcommittee considered a number of approaches to a literature review, including an evidence based systematic review. The subcommittee found that recent systematic reviews of the pediatric sedation literature have been completed, although not in the United States.<sup>26</sup> Because there is insufficient evidence to support recommendations for some aspects of pediatric sedation, most guidance documents must also rely on a consensus of opinion. This reduces the strength of certain recommendations. Controversies nearly always involve differences of opinion that are unlikely to be resolved by additional systematic reviews.

### **Search Strategy**

The subcommittee conducted an electronic literature search of the Medline, Cochrane Library, and DOSS EBSCO databases. Search terms included safety, morbidity, mortality, complications, moderate sedation, deep sedation, general anesthesia and dental offices; Fields: all; Limits; within the last 10 years, humans, all children from birth through age 21, language: English; clinical trials and literature reviews.

The subcommittee selected articles judged to be relevant pediatric dental sedation safety within the United States healthcare system. Articles on local anesthesia, nitrous oxide, and minimal sedation were excluded. In an effort to reduce risk of bias references were requested from stakeholders and interested parties. Additional articles were obtained by reviewing references. Selected articles with abstracts were downloaded into a reference manager. Full text versions of the most relevant articles are provided as references for this report. **See Figure 1**

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<sup>26</sup> National Clinical Guideline Center. (2010). "Sedation in children and young people". National Institute for Clinical Excellence, Royal College of Surgeons, London.

**Figure 1 - Anesthesia outcomes – Literature Reviewed**

| INVESTIGATOR   | YEARS     | DATA TYPE  | ANESTHESIA RELATED MORTALITY         | ANESTHESIA SOLELY RESPONSIBLE    |
|----------------|-----------|--|--------------------------------------|----------------------------------|
| Eichorn et al  | 1976-1988 | 1,001,000 anesthetics in ASA I and II - reports to malpractice carrier   | 1:200,200                            | ---                              |
| Lagasse et al  | 1995-1999 | peer review reports<br>ASA I and II patients   | 1:126,711                            | 0                                |
| Li et al       | 1999-2005 | ICD codes, Center for Health Statistics, CDC   | 8.2/1,000,000<br>(95% CI 7.4-9.0)    | ---                              |
| Gonzales et al | 2001-2011 | systematic review of 20 trials<br>pediatric studies all ASA  | 0.41-13.4/10,000                     | ---                              |
| Schiff et al   | 1999-2010 | Core data set – national standardized tracking data base<br>1,374,678 anesthetics<br>ASA I and II elective cases<br>Secondary German hospitals | 26.2/1,000,000<br>(95% CI 19.4-34.6) | 7.3/1000,000<br>(95%CI 3.9-12.3) |

### Anesthesia Outcomes Research

Anesthesia outcomes research has undergone considerable evolution over time. Although randomized trials remain the gold standard for clinical evidence, results obtained from such efficacy trials often generalize poorly. Furthermore, conventional randomized trials are limited in that mortality and other serious complications are usually too rare to practically address. There is thus increasing interest in clinical effectiveness studies in which interventions are evaluated over an entire health care environment. Researchers from the Anesthesia Outcomes Consortium at the Cleveland Clinic are presently utilizing innovative randomized effectiveness studies in which decision support systems, combined with electronic anesthesia records are utilized.<sup>27</sup> Cravero and others have reported the development of an integrated outcome database for pediatric anesthesia which holds great promise for the future.<sup>28</sup>

### Pediatric Sedation Studies

Review articles identify very few high quality published reports and clinical trials related to pediatric sedation for dentistry.<sup>29 30</sup> This may be due to the practical difficulties of enrolling sufficient number of children into adequately controlled and blinded studies.

<sup>27</sup> Kurz A, Sessler D. outcomes research. HSR Proceedings in Intensive Care and Cardiovascular Anesthesia 2012; 4 (1): 5-9.

<sup>28</sup> Cravero JP, Sriswasdi P, Lekowski R, Carpino E, Blum R, Askins N, Zurakowski D, Sinnott S. "Creation of an integrated outcome database for pediatric anesthesia". *Paediatr Anaesth*. 2016 Apr;26(4):345-55. doi: 10.1111/pan.12857.

<sup>29</sup> Mittal, N., Goyal, A., Jain, K., & Gauba, K. (2015). "Pediatric Dental Sedation Research: Where Do We Stand Today?" *J Clin Pediatr Dent*, 39(3), 284–291. <http://doi.org/10.17796/1053-4628-39.3.284>

<sup>30</sup> Ashley, P. F., Williams, C. E., Moles, D. R., & Parry, J. (2015). "Sedation versus general anaesthesia for provision of dental treatment to patients younger than 18 years." *Cochrane Database Syst Rev*, 9, Cd006334. <http://doi.org/10.1002/14651858.CD006334.pub4>

Ashley et al have published one of the few systematic reviews of pediatric dental sedation, and stated that they found no randomized controlled trials that compared sedation to general anesthesia for pediatric dentistry.<sup>31</sup> Lourenco-Matharu et al, in their systematic review, were able to find weak evidence of the effectiveness of midazolam, but identified few if any high quality pediatric sedation studies.<sup>32</sup>

Lee<sup>33</sup> noted that the study of the safety of pediatric dental anesthesia has been limited. Although there are a number of reports of serious injury or death related to pediatric dental anesthesia, there is also a lack of systematic research in this area. Because significant anesthesia injury is a relatively rare occurrence, it is difficult to study prospectively or by retrospective medical record review, even when data is collected from multiple institutions.

### **Anesthesia Morbidity and Mortality Data**

Morbidity and mortality figures have been used to determine patient risk and, hence, have played a prominent role in establishing malpractice premiums and in efforts to legislate the practice of sedation and general anesthesia in dentistry.<sup>34</sup> Though it is important to know the frequency of these events, their incidence can be misleading, because the numbers do not describe the events. Questions concerning characteristics of the patients, the practitioners, drugs used, patient monitoring, and resuscitative efforts remain obscure. Thus, incidence figures cannot explain why morbidity and mortality occurs, nor how to prevent it. For example, do these events represent acute hypersensitivity reactions of healthy patients in the hands of practitioners performing proficiently or do they result from the negligent efforts of incompetent professionals? Answers to these questions are as important as incidence data for judging safety, assessing patient risk, and for determining the need and direction of future legislative efforts.

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<sup>31</sup> Ashley, P. F., Williams, C. E., Moles, D. R., & Parry, J. (2015). "Sedation versus general anaesthesia for provision of dental treatment to patients younger than 18 years." *Cochrane Database Syst Rev*, 9, Cd006334. <http://doi.org/10.1002/14651858.CD006334.pub4>

<sup>32</sup> Lourenco-Matharu, L., Ashley, P. F., Furness, S., Lourenco-Matharu, L., PF, A., & Furness, S. (2012). "Sedation of children undergoing dental treatment." *Cochrane Database of Systematic Reviews*, 3(3), N.PAG–N.PAG 1p. <http://doi.org/10.1002/14651858.CD003877.pub4>

<sup>33</sup> Lee, H. H., Milgrom, P., Starks, H., & Burke, W. (2013). "Trends in death associated with pediatric dental sedation and general anesthesia." *Paediatr Anaesth*, 23(8), 741–746. <http://doi.org/10.1111/pan.12210>

<sup>34</sup> Krippaehne, J. A., & Montgomery, M. T. (1992). "Morbidity and mortality from pharmacosedation and general anesthesia in the dental office." *Journal of Oral and Maxillofacial Surgery*. [http://doi.org/10.1016/0278-2391\(92\)90099-L](http://doi.org/10.1016/0278-2391(92)90099-L)

The subcommittee reviewed anesthesia morbidity and mortality studies of the general and pediatric populations because pediatric morbidity and mortality is thought to represent a subset of adult morbidity and mortality, although there are important differences. Li et al<sup>35</sup> provide recent estimates of anesthesia mortality risk based on studies conducted in Europe, Japan, and Australia. They hypothesize that the paucity of anesthesia mortality studies in the United States in recent years is compounded by several factors. First, improvement in anesthesia safety has made anesthesia-related deaths rare events' and studying rare events usually requires large sample sizes and considerable resources. Second, there is not an established national surveillance data system for monitoring anesthesia mortality. Lastly, clinical practice of anesthesia has expanded so much that it is extremely difficult to gather exposure data. It is estimated that most surgical anesthesia procedures are now performed in ambulatory care settings. The use of anesthesia for therapeutic and diagnostic purposes is also on the rise.

A systematic review of Brazilian and worldwide literature<sup>36</sup> provides a summary of the studies of mortality incidence of pediatric patients who underwent anesthesia in developed countries between 2001 and 2011. This review reports mortality as 0.41-13.4 per 10,000 hospital discharges. Major risk factors include age < 1 year old, ASA III or higher physical status, emergency surgery, general anesthesia and cardiac surgery. Although this report reviewed outcomes from all ASA levels the authors note although rare, anesthesia related mortality still occurs in ASA physical status I-II children.

The subcommittee searched for studies that reported outcomes for relatively healthy patients because dentists are more likely to provide office sedation and anesthesia to ASA I and II patients. A recent report by Schiff<sup>37</sup> provides anesthesia related mortality statistics from the first study to utilize a standardized national tracking data base that allows calculation of the total number of cases, a "denominator", that is not available from closed claims data. This study reports outcomes for 1,374,678 patients, including ASA I and II patients undergoing elective surgery in secondary hospitals, and indicates that risk of death or a serious complication from anesthesia is approximately 10 per million anesthetics.

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<sup>35</sup> Li G, Warner M, Lang BH, Huang L, Sun LS. [Epidemiology of anesthesia-related mortality in the United States, 1999-2005](#). *Anesthesiology*. 2009 Apr;110(4):759-65. PubMed PMID: 19322941; PubMed Central PMCID: PMC2697561.

<sup>36</sup> Gonzalez, L., Pignaton, W., Kusano, P., Modolo, N., Braz, J., & Braz, L. (2012). "Anesthesia-related mortality in pediatric patients: a systematic review." *Clinics*, 67(4), 381–387. [http://doi.org/10.6061/clinics/2012\(04\)12](http://doi.org/10.6061/clinics/2012(04)12).

<sup>37</sup> Schiff, J. H., Welker, A., Fohr, B., Henn-Beilharz, A., Bothner, U., Van Aken, H., ... Heinrichs, W. (2014). "Major incidents and complications in otherwise healthy patients undergoing elective procedures: Results based on 1.37 million anaesthetic procedures." *British Journal of Anaesthesia*, 113(1), 109–121. <http://doi.org/10.1093/bja/aeu094>

A 1989 Harvard study<sup>38</sup> reported ASA I-II anesthetic related deaths, following implementation of improved monitoring standards, to be 1:244,000, but due to study limitations the data was not statistically significant. Lagasse<sup>39</sup> includes a review of published research related to anesthesia mortality prior to 1999 and reports similar findings.

The authors of these studies caution the reader that there is no standardized definition of anesthesia related mortality, and that this determination often relies on subjective interpretation of various definitions. Differences in methodology make it difficult to compare mortality rates among different studies because the mortality rate may depend on the surgical population being studied.<sup>40</sup> Although these studies do not support a firm conclusion, they suggest that anesthesia related mortality for ASA I and II patients treated in inpatient facilities may be in the range of 1:250,000.

### **Office-Based Surgery and Anesthesia Outcomes**

The subcommittee searched for reports of anesthesia safety data from office based facilities because dental treatment is usually provided in the office setting. Shapiro<sup>41</sup> reports a lack of randomized controlled trials that have measured morbidity and mortality in office based surgery and office-based medical procedures. However, there are numerous retrospective studies that compare morbidity and mortality outcomes in office, hospital, and ASC settings. The author concludes that much of the available literature confirms that there is a low rate of complications during office-based procedures and that risk in office based surgery is similar to other ambulatory settings.

Results from outcome studies of office-based surgery usually include complications from surgical procedures, including cosmetic procedures such as liposuction and abdominoplasty with liposuction. These procedures are associated with death from pulmonary embolism and other complications not usually encountered with dental procedures. Data from the AAAASF quality assurance program included over a million outpatient procedures from 2001-2006 and reported a mortality rate of 0.002%.<sup>42</sup> Thirteen of 23 deaths were caused by pulmonary embolism. Studies of office based cosmetic procedures emphasize that there is inherent risk

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<sup>38</sup> Eichhorn JH. "Prevention of intraoperative anesthesia accidents and related severe injury through safety monitoring." *Anesthesiology*. 1989 Apr;70(4):572-7. PubMed PMID: 2929993.

<sup>39</sup> Lagasse, R. S. (2002). "Anesthesia safety: model or myth? A review of the published literature and analysis of current original data." *Anesthesiology*, 97(6), 1609–1617. <http://doi.org/10.1097/00000542-200212000-00038>

<sup>40</sup> Gonzalez, L., Pignaton, W., Kusano, P., Modolo, N., Braz, J., & Braz, L. (2012). "Anesthesia-related mortality in pediatric patients: a systematic review." *Clinics*, 67(4), 381–387. [http://doi.org/10.6061/clinics/2012\(04\)12](http://doi.org/10.6061/clinics/2012(04)12)

<sup>41</sup> Shapiro, F. E., Punwani, N., Rosenberg, N. M., Valedon, A., Twersky, R., & Urman, R. D. (2014). "Office-based anesthesia: Safety and outcomes." *Anesthesia and Analgesia*, 119(2), 276–285. <http://doi.org/10.1213/ANE.0000000000000313>

<sup>42</sup> Keyes GR, Singer R, Iverson RE, McGuire M, Yates J, Gold A, Reed L, Pollack H, Thompson D. "Mortality in outpatient surgery." *Plast Reconstr Surg* 2008; 122:245–50

related to certain office based cosmetic procedures that should not be generalized to office-based surgery in general.

Much of the knowledge related to anesthesia safety in the ambulatory setting stems from the American Society of Anesthesiologists' (ASA) Closed Claims Database. The ASA Closed Claims Project is described in a subsequent section of this report.

### **Pediatric Dental Anesthesia Safety Research**

The subcommittee's search identified only a handful of studies of anesthesia safety related to pediatric dentistry. One of the best known studies addressed complications of pediatric sedation through critical incident analysis. This study reported that 29% of adverse events were related to dental treatment.<sup>43</sup> The study utilized a panel of four physicians who reviewed 118 reports of adverse sedation events from the FDA adverse event reporting system accumulated between 1969 and 1996, which yielded 51 reports of deaths, 9 cases of permanent neurological injury, and 21 cases of prolonged hospitalization without injury. Additional data was collected from USP adverse events and surveys of pediatric anesthesiologists, intensivists and emergency specialists. Patients were age < 20 years. Cases in which general anesthesia or MAC (sedation) was performed by an anesthesiologist were excluded. Inadequate resuscitation, death and permanent neurological injury were more frequent in non-hospital based facilities. As with other studies, presenting events included respiratory events such as desaturation, apnea and laryngospasm with cardiac arrest occurring as a second or third event. The majority of patients were age 6 or less. Causes or contributing factors included drug related events, inadequate monitoring, inadequate resuscitation, and inadequate medical evaluation. The authors recommend improved insurance coverage for dental anesthesia, better training for dentists who use sedation, development of specialty independent guidelines and better regulation of facilities.

This report does not include an estimate of the incidence or prevalence of dental sedation/anesthesia morbidity and mortality. It includes data from a period approximately 27 years. During this time period there have been significant improvements in anesthesia safety and the results may not indicate outcomes from more recent practice.

Lee<sup>44</sup> reported a review of media reports of pediatric deaths related to dental treatment of 44 patients between 1980 and 2011 for patients up to age 21. The majority of deaths occurred

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<sup>43</sup> Cote, C. J., Notterman, D. A., Karl, H. W., Weinberg, J. A., & McCloskey, C. (2000). "Adverse sedation events in pediatrics: a critical incident analysis of contributing factors." *Pediatrics*, 105(4 Pt 1), 805–814.

<sup>44</sup> Lee, H. H., Milgrom, P., Starks, H., & Burke, W. (2013). "Trends in death associated with pediatric dental sedation and general anesthesia." *Paediatr Anaesth*, 23(8), 741–746. <http://doi.org/10.1111/pan.12210s>

between ages 2-5 (46.7%) and 13-21 (29.6%). The majority of deaths occurred in the office setting, the most common treatment location for general dentists, with the majority (45.5%) being related to moderate sedation, 22.7% relate to general anesthesia and 22.7% not reported. The authors comment that it is not possible to evaluate the incidence and prevalence of pediatric sedation adverse outcomes without establishing an appropriate database.

The dental profession has published numerous studies of outcomes from sedation and anesthesia. Early epidemiological reports were based primarily on retrospective data, voluntary surveys of professional association members, with small sample sizes making them of limited value. These studies are well known and will not be repeated here. Other studies we reviewed were reports of specific drug combinations and techniques that utilized sample sizes of a few hundred patients from a single site. Again, we felt these were of limited value.

Perrott<sup>45</sup> et al reported results from a prospective cohort study of 34,191 consecutive patients of whom 71.9% received office based deep sedation/general anesthesia, 15.5% received conscious sedation, and 12.6% received local anesthesia. Study methods included an audit of data collection to reduce selection bias and ensure cases were entered consecutively. Data was collected from 79 oral surgeons between January 2001 and December 2001 at 58 study sites between located in six geographical regions of the United States. Most complications were minor and self limiting and two patients required hospitalization. There were no deaths.

Lee<sup>46</sup> et al published a prospective comparison study of the safety of anesthetic outcomes of propofol and methohexital anesthesia administered to 47,710 consecutively assigned patients between January 2001 and December 2007. 0.7% experienced adverse events, mostly post operative nausea and vomiting without aspiration, laryngospasm in the methohexital group, and syncope or prolonged emergence. Nine patients required hospitalization due to allergic reaction to antibiotics and minor surgical complications such as persistent pain or wound problems (three patients) to prolonged emergence with delirium and one case of bronchospasm with aspiration, one due to new onset dysrhythmia and two were not described. The study reported no deaths or brain damage. The study included 2,404 patients who received anesthesia from a physician anesthesiologist or CRNA. This arm of the study was underpowered but reported no significant difference between providers.

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<sup>45</sup> Perrott, D. H., Yuen, J. P., Andresen, R. V., & Dodson, T. B. (2003). "Office-based ambulatory anesthesia: Outcomes of clinical practice of oral and maxillofacial surgeons." *Journal of Oral and Maxillofacial Surgery*, 61(9), 983–995. [http://doi.org/10.1016/S0278-2391\(03\)00668-2](http://doi.org/10.1016/S0278-2391(03)00668-2)

<sup>46</sup> Lee, J. S., Gonzalez, M. L., Chuang, S. K., & Perrott, D. H. (2008). "Comparison of Methohexital and Propofol Use in Ambulatory Procedures in Oral and Maxillofacial Surgery." *Journal of Oral and Maxillofacial Surgery*, 66(10), 1996–2003. <http://doi.org/10.1016/j.joms.2008.06.028>.

Inverso et al<sup>47</sup> compared the complications of moderate sedation with deep sedation/general anesthesia for 29,548 adolescent patients with average age of 17.3 undergoing third molar surgery between January 2001 and December 2010. Prospective data was collected from 79 surgeons at 58 sites across the U.S. As with previous studies, the most common complications were post operative nausea and vomiting, prolonged recovery, syncope, and laryngospasm with a complication rate of 0.8% overall. There were no reports of new neurologic impairment and apparently no deaths. Patients receiving moderate sedation had a nominally lower rate of complications but this was not statistically significant.

Other investigators of anesthesia outcomes have utilized similar sized populations and have noted that very large populations must be studied to fully evaluate the occurrence of rare but serious outcomes such as brain injury or death. These studies may be underpowered to identify rare but serious outcomes such as death and brain damage. Large-scale multi-center studies are necessary, but the resources necessary to enroll populations of sufficient size and to maintain adequate controls are significant. High quality studies of pediatric dental sedation outcomes might be accomplished through a well established national outcomes registry.

### **Closed Claims Data**

In a 1999 landmark study, Cheney et al<sup>48</sup> describes how the study of insurance company closed claims provides a cost-effective approach to data collection with extensive data on injuries that occurred in many different institutions gathered in a centralized location. Typically, a closed claim file consists of the hospital record, the anesthesia record, and narrative statements of the involved healthcare personnel, expert and peer reviews, deposition summaries, outcome reports, and the cost of settlement or jury awards. These files provide a collection of information on the relatively rare events leading to anesthesia-related injury.

Although the use of closed claims circumvents the problem of gaining access to low-frequency adverse events, this approach has inherent limitations that must be considered when interpreting the data. For example, closed claims review does not provide information as to how many anesthetics were administered. Therefore, closed claims data does not provide a denominator for calculating the risk of anesthetic injury. In addition, some injured patients do not file claims, whereas others without any apparent injury do file claims. Closed claims analysis provides a snapshot of anesthesia liability, but is not a comprehensive picture of all anesthetic

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<sup>47</sup> Inverso, G., Dodson, T. B., Gonzalez, M. L., & Chuang, S.-K. (2016). "Complications of Moderate Sedation Versus Deep Sedation/General Anesthesia for Adolescent Patients Undergoing Third Molar Extraction." *Journal of Oral and Maxillofacial Surgery*, 74(3), 474–479. <http://doi.org/10.1016/j.joms.2015.10.009>

<sup>48</sup> Cheney, F. W. (1999). "The American Society of Anesthesiologists Closed Claims Project: what have we learned, how has it affected practice, and how will it affect practice in the future?" *Anesthesiology*, 91(2), 552–556. Retrieved from <http://anesthesiology.pubs.asahq.org/article.aspx?articleid=1946221>

injury. Injuries leading to claims are not a random sample of all injuries, and we do not know how closely this snapshot resembles the whole picture of anesthetic injury. Another limitation of closed claims analysis is the retrospective nature of data collection. The information was gathered by the insurance companies for the purpose of resolving the claims, not for patient safety research. Data from different sources may be conflicting, and some data may be missing. In addition, it takes an average of five years for cases to become available for review due to the time necessary for them to be resolved. Closed claims analysis is useful for generating hypotheses about the mechanism and prevention of anesthetic injury, but cannot be used for testing of those hypotheses. As a retrospective study, it cannot establish a cause-and effect relationship of previous events, nor of changes in claim experience.

Closed claims data also provides information about risk related to the location in which sedation and anesthesia is administered. Domino's<sup>49</sup> original report indicated that the severity of injury was greater for office based claims than for other ambulatory settings, with 40% for death compared to 25% for other ambulatory claims. Respiratory events, airway obstruction, bronchospasm, inadequate oxygenation-ventilation and esophageal intubation were the most common complications (29%). These adverse events were deemed preventable through better monitoring.

Monitored anesthesia care (MAC) accounted for 50% of out of operating room claims. Respiratory depression from MAC accounted for 21% of claims and death or permanent brain damage accounted for 40% of MAC claims. Although this proportion is similar to general anesthesia claims and suggests that MAC and general anesthesia have similar risk profiles, Bhananker's study<sup>50</sup> includes outcomes from MAC in both inpatient and outpatient facilities making it difficult to draw conclusions about the safety of MAC in outpatient facilities.

Jimenez<sup>51</sup> et al reported a study of closed pediatric claims between the 1970s and the 1990s. Death and brain damage were the most common reason for claims in the 16 or younger age group. Seventy-seven percent of cases involved relatively healthy patients with ASA PS 1 or 2, and the most common procedures involved the airway. The proportion of claims assessed as preventable by better monitoring decreased from an average of 63% in the 1970s to 16% in the 1990s, possibly due to better monitoring, however, cardiovascular events (26%) joined

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<sup>49</sup> Domino, K. B. (n.d.). "Office-Based Anesthesia : Lessons Learned from the Closed Claims Project, 9–12." *ASA Newsletter* 65 (6) 2001.

<sup>50</sup> Sanjay M. Bhananker, M.D., F.R.C.A.,\* Karen L. Posner, Ph.D.,† Frederick W. Cheney, M.D.,‡ Robert A. Caplan, M. D., & Lorri A. Lee, M.D., Karen B. Domino, M.D., M. P. H. (2006). "Injury and Liability Associated with Monitored Anesthesia." *Anesthesiology*, 104(2), 228–234.

<sup>51</sup> Jimenez, N., Posner, K. L., Cheney, F. W., Caplan, R. A., Lee, L. A., & Domino, K. B. (2007). "An update on pediatric anesthesia liability: A closed claims analysis." *Anesthesia and Analgesia*, 104(1), 147–153. <http://doi.org/10.1213/01.ane.0000246813.04771.03>

respiratory events as being most important. The authors indicate that the policy implications of the data are unclear; including whether pediatric anesthesia specialists provide safer care for younger, higher-risk patients and what type of case should be performed in what type of facility.

Closed claims review has also been utilized as a data source to study dental sedation/anesthesia related morbidity and mortality. Jastak and Peskin<sup>52</sup> evaluated 13 claims that occurred between 1974 and 1989 from patients of all ages. Adverse outcomes were most often due to airway obstruction or respiratory depression resulting in hypoxia and 10 of 13 cases were judged to be avoidable through the use of better monitoring. The majority of patients had pre existing medical conditions and were rated as ASA II or III. The authors conclude that the very old and very young are at greatest risk.

Deegan<sup>53</sup> reported 136 claims from the American Association of Oral and Maxillofacial Surgeons National Insurance Company accumulated between 1988 and 1999. At that time, AAOMS National insured approximately 55% of the oral surgeons practicing in the U.S. Thirty-seven claims involved serious injury or hypoxic brain damage as the result of both office and inpatient anesthesia. The authors state that there were equal numbers of claims from both conscious sedation and general anesthesia. Unlike most other closed claims studies, the authors provide an estimate of the total number of cases performed and an estimate of the incidence of office deaths as 1: 747,000 administrations. There were 23 deaths and one brain damage case from office anesthesia and 11 deaths and 4 brain damage cases from inpatient anesthesia provided by anesthesiologists or nurse anesthetists.

Nkansah<sup>54</sup> et al published a report of anesthesia outcomes for oral and maxillofacial surgeons from the Canadian province of Ontario, utilizing claims data from the regional professional liability program that covers all claims originating from Ontario between 1973 and 1995. The Canadian model of anesthesia delivery is similar to that utilized in the U.S., with the OMS administering the anesthesia and performing the surgery with trained assistants. The authors provide an estimate of total cases performed during the study interval via survey of members of the professional association. Four deaths occurred, with one administered by a dentist anesthesiologist and three by oral and maxillofacial surgeons. A single case involving anesthesia

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<sup>52</sup> Jastak, J. T., & Peskin, R. M. (1991). "Major morbidity or mortality from office anesthetic procedures: a closed-claim analysis of 13 cases." *Anesthesia Progress*, 38(2), 39–44.

<sup>53</sup> Deegan, a E. (2001). "Anesthesia morbidity and mortality, 1988-1999: claims statistics from AAOMS National Insurance Company." *Anesthesia Progress*, 48(3), 89–92. Retrieved from <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2007373&tool=pmcentrez&rendertype=abstract>

<sup>54</sup> Nkansah, P. J., Haas, D. A., & Saso, M. A. (1997). "Mortality incidence in outpatient anesthesia for dentistry in Ontario." *Oral Surgery, Oral Medicine, Oral Pathology*, 83(6), 646–651.

administered by a physician anesthesiologist was excluded. The author estimates an incidence of mortality of 1.4 per 1,000,000.

A more recent closed claims review by Chicka<sup>55</sup> et al evaluated adverse events during pediatric dental sedation. This study reviewed 17 claims accumulated between 1993 and 2007 from two major insurance carriers. Reports were limited to pediatric cases age <13 with 78% age 5 or less. Thirteen claims involved sedation, three involved local anesthesia alone, and one involved general anesthesia. The average age of the patient was 3.6 years and only one case involved the use of physiologic monitoring. The study included only claims from office based treatment. Over half (53%) were claims from a death or permanent brain damage.

Bennett et al published the most recent closed claims study of dental cases, reporting information from 113 closed claims cases from the files of a national insurance carrier for approximately 80% of oral and maxillofacial surgeons practicing in the United States.<sup>56</sup> This company tracks the number of anesthetics performed annually. Claims were for cases that resulted in death or brain injury collected over 14 years, between 2000-2013. The authors do not provide details that indicate specific adverse events or contributing factors, but indicate that the majority of adverse outcomes are related to respiratory events. This study did not provide patient age related data. Unlike most other closed claims studies, this report provides an estimate of the overall number of cases performed and an estimate of the incidence of anesthesia morbidity and mortality as one per 348,602 cases.

### **State Board Data**

Investigators have attempted to gather information from state dental boards; however collection and storage of data varies state to state which limits the value of this data. State board outcomes data has the potential to inform policy decisions. State laws specify mandatory reporting of patient deaths or hospitalization. This improves the reliability of dental board data compared to closed claims reports or self reporting by the members of professional associations. The total number of patients treated, however, remains unknown. This makes accurate calculation of the incidence and prevalence of adverse events impossible because, as with closed claims data, there is no “denominator.” Death and serious injury cases often involve lengthy legal proceedings that require 3 or more years to elapse before information can be made available. Dental boards collect information to manage enforcement actions, not for

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<sup>55</sup> Chicka, M. C., Dembo, J. B., Mathu-Muju, K. R., Nash, D. A., & Bush, H. M. (2012). “Adverse events during pediatric dental anesthesia and sedation: a review of closed malpractice insurance claims.” *Pediatr Dent*, 34(3), 231–238.

<sup>56</sup> Bennett, J. D., Kramer, K. J., & Bosack, R. C. (2015). “How safe is deep sedation or general anesthesia while providing dental care?” *J Am Dent Assoc*, 146(9), 705–708. <http://doi.org/10.1016/j.adaj.2015.04.005>

clinical research, and state records retention and disclosure policies may conflict with data collection. Standardization of data collection across state dental boards has the potential to provide meaningful information, however this has yet to occur.

Krippaehne and Montgomery requested morbidity and mortality information from dental boards in all 50 states and Puerto Rico related to either general anesthesia or sedation in dental offices. The information requested included the formal complaint, the formal order and judgment by the board, expert opinions, and the medical examiner's report. They received responses from all states and Puerto Rico; however, most states had not kept records on such cases and hence could not contribute to the data base. Forty-three cases were reported by nine states, with mortality comprising 81% of the cases.<sup>57</sup>

Dental board data provides important details of adverse outcomes from sedation and anesthesia that may not be available from other sources. As with closed claims data, dental board data is retrospective, but is still useful in generating a hypothesis about the mechanism of injury and how it might be prevented in the future.

## **DENTAL SEDATION AND ANESTHESIA OUTCOMES REPORTS**

### **The Pediatric Sedation Research Consortium**

The Pediatric Sedation Research Consortium (PSRC) has made significant contributions to pediatric sedation research, demonstrating a remarkable safety record for sedation provided by highly motivated and skilled practitioners from a variety of specialties functioning outside the operating room. The PSRC collected data from 37 participating institutions within large children's hospitals, children's hospitals within hospitals, and general/community hospitals.<sup>58</sup> The Consortium has published a series of prospective observational studies that have demonstrated many of the concepts important to the safe administration of pediatric sedation. Over time the PSRC has accumulated a large database of children up to age 21.

The authors of the PSRC studies describe the limitations of their studies. Reporting institutions are self selected for voluntarily reporting of their outcomes, and represent a highly motivated

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<sup>57</sup> Krippaehne, J. A., & Montgomery, M. T. (1992). "Morbidity and mortality from pharmacosedation and general anesthesia in the dental office." *Journal of Oral and Maxillofacial Surgery*. [http://doi.org/10.1016/0278-2391\(92\)90099-L](http://doi.org/10.1016/0278-2391(92)90099-L)

<sup>58</sup> Cravero, J. P., Blike, G. T., Beach, M., Gallagher, S. M., Hertzog, J. H., Havidich, J. E., & Gelman, B. (2006). "Incidence and nature of adverse events during pediatric sedation/anesthesia for procedures outside the operating room: report from the Pediatric Sedation Research Consortium." *Pediatrics*, *118*(3), 1087–1096. <http://doi.org/10.1542/peds.2006-0313>

and organized systems that would outperform other, less controlled systems and may represent “best practice.” The practice patterns and outcomes of the PSRC represent a highly competent cohort that may not generalize to other clinical settings in which sedation care is provided.<sup>59</sup>

Although the PSRC studies include data from a wide variety of providers, dentists are significantly underrepresented in this series. Only 0.80%, or 397 of nearly 50,000 cases, were dental cases. Dentists are grouped in the “other” category with pediatric residents or fellows, radiologists, surgeons, advanced practice nurses, certified registered nurse anesthetists, and registered nurses. In addition, the PSRC data was accumulated from inpatient facilities such as pediatric hospitals and community hospitals with pediatric sedation services that are not usually utilized for dentistry. As a result, it is impossible to generalize results from the PSRC studies to community dental practices. Nevertheless, the “best practices” utilized at PSRC facilities have broad application to pediatric sedation in all settings.

Coulores et al reported the results of an analysis of 133,941 procedural sedation records from the PSRC that evaluated a comparison of the major complication frequency of sedation performed by pediatric specialists outside of the operating room. There was no statistical difference between different sedation providers’ major complication rates.<sup>60</sup>

Langhan et al reported the results a study of physiologic monitoring practices during pediatric sedation from the PSRC.<sup>61</sup> Data from 114,855 subjects were collected and analyzed. The frequency of use of each physiologic monitoring modality by health care provider type, medication used, and procedure performed varied significantly. The largest difference in frequency of monitoring use was seen between providers using electrocardiography (13%-95%); the smallest overall differences were seen in monitoring use based on the American Society of Anesthesiologists classifications (1%-10%). Guidelines published by the American Academy of Pediatrics, the American College of Emergency Physicians, and the American Society of Anesthesiologists for non anesthesiologists were adhered to for only 52% of subjects.

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<sup>59</sup> Cravero, J. P., Blike, G. T., Beach, M., Gallagher, S. M., Hertzog, J. H., Havidich, J. E., & Gelman, B. (2006). “Incidence and nature of adverse events during pediatric sedation/anesthesia for procedures outside the operating room: report from the Pediatric Sedation Research Consortium.” *Pediatrics*, *118*(3), 1087–1096. <http://doi.org/10.1542/peds.2006-0313>

<sup>60</sup> Couloures, K. G., Beach, M., Cravero, J. P., Monroe, K. K., & Hertzog, J. H. (2011). “Impact of provider specialty on pediatric procedural sedation complication rates.” *Pediatrics*, *127*(5), e1154–60. <http://doi.org/10.1542/peds.2010-2960>

<sup>61</sup> Langhan, M. L., Mallory, M., Hertzog, J., Lowrie, L., & Cravero, J. (2012). “Physiologic monitoring practices during pediatric procedural sedation: a report from the Pediatric Sedation Research Consortium.” *Arch Pediatr Adolesc Med*, *166*(11), 990–998. <http://doi.org/10.1001/archpediatrics.2012.1023>

Despite the variability in monitoring, serious adverse outcomes during procedural sedation were uncommon. The authors conclude that further research is needed to develop evidence-based guidelines regarding the appropriateness of various monitoring modalities and their effect on adverse outcomes that are associated with sedation.

Cravero, et al reported the results of a study of data from thirty seven locations that submitted data on 49,836 propofol sedation.<sup>62</sup> The authors state that given the potency of propofol and the nature of pediatric patients, essentially all children administered propofol would clearly be categorized as being deeply sedated or anesthetized. Despite varying guidelines, propofol sedation/anesthesia is delivered to children for procedures in emergency departments, intensive care units, and sedation/anesthesia units all over the United States (and around the world) by pediatric generalists and subspecialists every day.

The authors stress that the results of their study should not reassure providers that propofol sedation/anesthesia of children is safe, but it helps define the competencies required to deliver this care.

#### **SUMMARY OF LITERATURE REVIEW**

Review articles identify very few high-quality published reports and clinical trials related to pediatric sedation for dentistry. This may be due to the practical difficulties of enrolling sufficient number of children into adequately controlled and blinded studies.

Because significant anesthesia injury is a relatively rare occurrence, it is difficult to study prospectively or by retrospective medical record review, even when data is collected from multiple institutions.

The effect that provider type or personnel type has on outcomes has received little study, particularly as related to pediatric dentistry.

There is no standardized definition of anesthesia related mortality, and this determination often relies on subjective interpretation. Differences in methodology make it difficult to compare mortality rates among different studies because the mortality rate may depend on the surgical population being studied. Available studies do not support a firm conclusion, but suggest that anesthesia related mortality for ASA I and II patients treated in inpatient facilities is in the range of 1:250,000.

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<sup>62</sup> Cravero, J. P., Beach, M. L., Blike, G. T., Gallagher, S. M., & Hertzog, J. H. (2009). "The incidence and nature of adverse events during pediatric sedation/anesthesia with propofol for procedures outside the operating room: a report from the pediatric sedation research consortium." *Anesthesia and Analgesia*, 108(3), 795–804. <http://doi.org/10.1213/ane.0b013e31818fc334>

Several studies indicate that the most common complications of pediatric sedation include respiratory events such as desaturation, apnea and laryngospasm with cardiac arrest occurring as a second or third event. Complications may be more frequent under age 6, with younger patients and higher ASA physical status classification III or IV at greater risk. Causes or contributing factors include drug related events, inadequate monitoring, inadequate resuscitation, and inadequate medical evaluation.

Although pediatric sedation has an excellent safety record, adverse outcomes sometimes occur in apparently healthy patients indicating that there is inherent risk in sedation and general anesthesia.

### **Board Statistics**

The subcommittee developed an estimate of the number of patients treated under sedation and general anesthesia in California each year. This information would establish a “denominator” that is used to determine the incidence of adverse anesthesia outcomes. Studies of adverse outcomes from closed claims data, dental board reports, and media reports do not include a denominator. Unfortunately, there is no reliable estimate of the number of cases due to the lack of a national reporting database for adverse anesthesia outcomes.

California is a very large state, with a population over 39 million as of 2015. Approximately 23% of the population is age 18 or under, or approximately 9 million children. With a population this large, a significant number of children undoubtedly receive treatment under sedation or general anesthesia. For example if only 1.5% of this population required anesthesia for dental treatment this would result in 135,000 administrations per year.

In an effort to provide utilization statistics, the subcommittee obtained the incidence of billing code utilization for general anesthesia by Denti Cal providers. This reveals that approximately 25,000 patients under age 17 receive general anesthesia through the Denti Cal program each year. Approximately 2.5 million children are currently enrolled in Denti Cal, and approximately half of those enrolled receive services. Based on these assumptions, the anesthesia utilization rate for Denti Cal patients is approximately 1%.

The subcommittee reviewed the medical and dental literature to determine the number of cases of sedation and anesthesia performed. Chicka, et al<sup>63</sup> indicate in their study of pediatric dental anesthesia morbidity and mortality that approximately 100,000-250,000 cases were performed annually as of 2005.

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<sup>63</sup> Chicka, M. C., Dembo, J. B., Mathu-Muju, K. R., Nash, D. A., & Bush, H. M. (2012). “Adverse events during pediatric dental anesthesia and sedation: a review of closed malpractice insurance claims.” *Pediatr Dent*, 34(3), 231–238.

There are several published estimates of the number of cases performed under anesthesia by oral and maxillofacial surgeons. These studies report that an average oral and maxillofacial surgeon performs approximately 480-505<sup>64</sup> <sup>65</sup> general anesthetics per year. This figure does not include cases performed utilizing moderate sedation or cases performed by other dental sedation practitioners such as pediatric dentists, periodontists, or dentist anesthesiologists. Assuming that 40% of patients treated by the 675 actively practicing oral and maxillofacial surgeons in California are under age 21, this yields an estimate of 133,000 anesthetics per year.

The California Association of Oral and Maxillofacial Surgeons (CALAOMS) recently conducted a survey of their membership based on data obtained from electronic records. Results of this survey are included in their comments submitted to the Dental Board. CALAOMS estimates that approximately 48% of cases performed under anesthesia were for patients age 21 or under. Their current active membership is 675 oral surgeons.

Based on this data, for the study period January 1, 2010 to December 31, 2015, the subcommittee therefore estimates that approximately 800,000 cases utilizing general anesthesia were performed.

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<sup>64</sup> D'Eramo, E. M., Bontempi, W. J., & Howard, J. B. (2008). "Anesthesia Morbidity and Mortality Experience Among Massachusetts Oral and Maxillofacial Surgeons." *Journal of Oral and Maxillofacial Surgery*, 66(12), 2421–2433. <http://doi.org/10.1016/j.joms.2008.06.095>

<sup>65</sup> Nkansah, P. J., Haas, D. A., & Saso, M. A. (1997). "Mortality incidence in outpatient anesthesia for dentistry in Ontario." *Oral Surgery, Oral Medicine, Oral Pathology*, 83(6), 646–651.

### **Part 3: DENTAL BOARD OF CALIFORNIA - DATA RELATED TO PEDIATRIC SEDATION AND ANESTHESIA**

Part III of this study will address the review of all incident reports related to pediatric sedation/anesthesia in California for a certain time. In the context of this study, “incident report” is defined as the notification the Board received from a licensee in accordance with reporting requirements of Business & Professions Code (BPC) Section 1680(z) relating to (1) the death of a patient during the performance of any dental or dental hygiene procedure; (2) the discovery of the death of a patient whose death is related to a dental or dental hygiene procedure performed by the dentist; and (3) the removal to a hospital or emergency center for medical treatment for a period exceeding 24 hours of any patient to whom oral conscious sedation, conscious sedation, or general anesthesia was administered, or any patient as a result of dental or dental hygiene treatment. While some notifications provide specific details of the incident, other notifications have minimal information. The regulation does not specify what information is required to be included in the notification to the Board.

This report will, therefore, reflect data related to incident reports of death and hospitalizations related to use of local anesthetic, oral conscious sedation, conscious sedation, general anesthesia, and “other” incidents NOT related to sedation for pediatric patients reported over a six year period, January 1, 2010 – December 31, 2015. For the purposes of this report, the age of a pediatric patient is defined as 21 years and younger.

In order to identify instances of pediatric hospitalizations and deaths reported to the Board, reports from the Consumer Affairs System (CAS) database were pulled for cases tracked with specific violation codes related to the Board’s reporting requirements under BPC Section 1680(z). Reports pulled from the database were based on coding entered by complaint intake staff upon initial receipt of the notification and/or complaint.

Eight Board staff, including two dental consultants, and four investigative staff, reviewed the available incident reports, investigative files, and cases identified and recorded in the Board’s database. There is no mechanism to sort data by age, therefore approximately 325 records and investigative files were reviewed in order to determine the number of pediatric hospitalizations and deaths reported or investigated by the Board in relation to dental treatment.

A portion of the cases identified in the database were not able to be reviewed as the files were not able to be located, or were purged pursuant to the Board’s records retention schedule.

#### **NOTIFICATION OF PEDIATRIC DEATHS**

Review of the incident reports combined with additional information obtained during the course of the Board’s investigations revealed that, during the six-year period identified as January 1, 2010 through December 31, 2015, the Board received notice of nine pediatric deaths, four of which involved general anesthesia. A summary of the findings by year follows:

Review of records indicated that in 2010 the Board received no notification of pediatric deaths.

In 2011, three cases were received. Board review indicated the following:

- Investigation into the treatment of a three-year-old child under oral conscious sedation resulted in a referral to the Office of the Attorney General and an accusation was filed; the accusation was subsequently withdrawn.

The patient was treated in a dental office for restorations of 20 teeth under oral conscious sedation on December 9, 2011. During the procedure, the patient was awake and crying; additional sedation was administered by the provider. The patient was discharged to parent at 11:30 a.m., and did not wake after the procedure. 9-1-1 was called at 3:00 p.m.; the patient was pronounced dead the following evening.

- Investigation into the treatment of a four-year-old patient under general anesthesia on November 11, 2011, indicated insufficient evidence to proceed with disciplinary action.

The patient was treated under general anesthesia, administered by a medical anesthesiologist at a hospital, for dental caries and gingivitis. The patient had a complex cardiac history and treatment was rendered at a large children's hospital. The dental procedures were completed uneventfully, and the patient was extubated. In the recovery room, the patient experienced cardiac arrest, and expired after 45 minutes of resuscitation efforts. A coroner's report and review by six corner bureau staff concluded it was a natural death.

- Investigation related to the treatment of a nine-year-old child under local anesthetic (xylocaine) on December 5, 2011, indicated no violation.

On December 5, 2011, a severely compromised nine-year-old patient was treated for extractions of six primary teeth under local anesthetic, at a sub-acute care facility. The patient's health history was significant for spinal muscular atrophy type 1, global delay, reactive airway disease, asthma, osteopenia, chronic respiratory failure, anemia, aspiration pneumonia, constipation, failure to thrive, g-tube, gastric hypo motility, gerd, osteoporosis, quadriplegic, bed ridden, and nonverbal.

The patient was transported by paramedics to a university dental school subacute facility to treat dental pain. Treatment was provided under the supervision of the patient's accompanying paramedics who provided transport; the patient experienced a medical emergency. The paramedics declined the offer of the dental school's emergency medical assistance and took the patient to the ER. The patient expired at the hospital after cardiac arrest in the sub-acute care facility.

Review of records indicated that in 2012 the Board received no notification of pediatric deaths.

The Board received four notifications related to pediatric death in the year 2013. Of the four notifications received, three notifications were related to the treatment of a single patient by multiple providers, thereby reflecting only two incidents for this year.

- Investigation was initiated upon receipt of notification related to the treatment of an 11-year-old child on May 22, 2013. The investigation found no violation occurred related to the treatment.

The patient had a history of mucopolysaccharidosis Type VII, and behavioral issues, and required treatment of decay under general anesthesia. Treatment of tooth #3 was initiated at a university health clinic for children with anesthesia administered by an anesthesiologist. During the treatment, irregular cardiac patterns were detected, and treatment was halted. The medical team attempted to stabilize the patient without success.

- Investigation was initiated upon receipt of notification related to the death of a 19-year-old patient. Three investigations were initiated as three dental providers were involved in the treatment. Two investigations resulted in referral to the Office of the Attorney General, and one investigation resulted in a closure with no violation.

Provider #1 saw patient on January 14, 2014, February 1, 2013, February 28, 2013, and March 6, 2013, for issues related to pain. Provider #1 placed a MODLB onlay on tooth #30 on February 1, 2013. Patient was seen by provider #1 an additional two times; February 28, 2013, and March 6, 2013 (#30 bite adjustment), for continued issues with pain. On March 16, 2013, patient's mother called as patient continued to have pain, and spoke to provider #1 who felt patient had discomfort from grinding and recommended a night guard.

A second opinion was requested from provider #2, who attempted to fix the crown at #30 two times (March 20, 2013, March 22, 2013) without success. Provider #2 referred patient to provider #3, an endodontist, on March 22, 2013, who on the same day performed a partial root canal treatment on tooth #30, and prescribed antibiotics, pain pills, and made a follow-up appointment. The patient accompanied her mother to the pharmacy to fill the prescriptions. When the mother returned to the car, the patient was unresponsive. 9-1-1 was called, the patient passed four days later; the cause of death is listed as sepsis, clinical dental infection with multiple dental procedures, clinical.

Review of records indicated that in 2014 the Board received no notification of pediatric deaths.

The Board received four notifications related to pediatric death in the year 2015.

- Investigation was conducted upon receipt of notification related to treatment rendered to a 17-year-old patient under general anesthesia on April 1, 2015. The investigation indicated insufficient evidence to proceed with disciplinary action.

The 17-year-old patient had history significant for cerebral palsy, seizure disorder, 1P36 chromosomal deletion syndrome, chronic constipation, and thrombocytopenia secondary to valproic acid. Medical consultations were obtained from the patient's neurologist, hematologist, and GI doctor prior to treatment under general anesthesia for decay, prophy, x-rays, and dental pain. Treatment was performed at a pediatric children's hospital by two dental providers. X-rays were taken, the prophy was performed, and one primary over retained tooth and four permanent teeth were extracted, without issue.

Patient was transferred to post anesthesia care unit, but was not able to be removed from the respirator. Five days later, the patient suffered complications involving pneumonia and the parents asked the patient be removed from life support.

- Investigation was conducted upon notification of the death of a six-year-old patient, who was placed under general anesthesia for dental treatment. The investigation resulted in referral to the Office of the Attorney General; outcome is pending.

The six-year-old patient presented to a dental office for the extraction of a mesiodens in the area of #9 under general anesthesia on March 13, 2015. Following the administration of a local anesthetic, the provider reported not being able to hear the patient breathing. Oxygen/mask bag was applied, and 911 was called; the oxygen/mask bag was unsuccessful. While waiting for EMS, the provider unsuccessfully attempted to intubate patient; the provider continued with mask/bag ventilation until EMT arrived. After two days of treatment, MD ordered compassionate withdrawal of care. Cause of death listed as hypoxic encephalopathy due to cardiac arrest.

- Investigation was conducted upon notification of the death of a three-year-old patient after treatment in a pediatric dental office. The investigation resulted in the referral to the Office of the Attorney General; outcome is pending.

The three-year-old patient presented to a pediatric dental office for restorative treatment in all four quadrants under oral sedation, with a papoose board on February 25, 2015. The patient was in treatment for four hours and was in recovery for two hours when he became tachycardic and his oxygen saturation decreased. Patient was given oxygen and was monitored, about one hour later (3 hours after treatment), 9-1-1 was called. Patient was transported to the hospital and expired four days later; cause of death listed a malignant hyperthermia, with cerebral edema and hypoglycemia as underlying causes.

- Investigation related to the treatment of a three-year-old child under local anesthetic (lidocaine, septocaine, and nitrous oxide) on July 30, 2015, is ongoing.

On July 30, 2015, the three-year-old patient was undergoing dental treatment under nitrous oxide and local anesthetic, and became non-responsive. CPR was initiated, and paramedics were called. Patient was transported to the hospital and passed on August 1, 2015. The cause of death was not known at the time the report was submitted to the Board.

A simplified summary of the Board’s findings related to pediatric deaths for the years 2011, 2013, and 2015 follows. There were no reported pediatric deaths in 2010, 2012, or 2014.

| YEAR OF OCCURRENCE | AGE                | TYPE(S) OF ANESTHESIA OR ANESTHETIC ADMINISTERED | TREATMENT/SETTING                | DISCIPLINE  |
|--------------------|--------------------|--|----------------------------------|---|
| 2010               | NO DEATHS REPORTED |  |                                  |   |
| 2011               | 3                  | Oral Conscious sedation                          | Dental office                    | Accusation withdrawn 8/21/15                                      |
| 2011               | 4                  | General anesthesia                               | Hospital with Anesthesiologist   | Closed insufficient evidence                                      |
| 2011               | 9                  | Local anesthetic                                 | Sub-acute care facility/Hospital | No violation  |
| 2012               | NO DEATHS REPORTED |  |                                  |   |
| 2013               | 11                 | General anesthesia                               | Hospital with Anesthesiologist   | No violation  |
| 2013               | 19                 | Local anesthetic                                 | Dental offices                   | 2 Accusations filed 12/28/15<br>(and one finding of no violation) |
| 2014               | NO DEATHS REPORTED |  |                                  |   |
| 2015               | 3                  | Pediatric oral sedation                          | Pediatric dental office          | Accusation 9/30/15  |
| 2015               | 3                  | Local anesthetic and nitrous oxide               | Hospital                         | Pending   |
| 2015               | 6                  | General anesthesia                               | Dental office                    | Accusation filed 2/24/2016  |
| 2015               | 17                 | General anesthesia                               | Hospital                         | No violation  |

**NOTIFICATION OF PEDIATRIC HOSPITALIZATIONS**

Board staff conducted additional review of hospitalizations of pediatric patients from January 1, 2010 through December 31, 2015. The following chart summarizes the number of instances; and breaks down incidents by the year of occurrence, the patient’s age, and the type of sedation used, if applicable.

| Summary of Pediatric Hospitalization by Year and Patient Age, 2010-2015 |     |                    |                    |                  |         |             |
|---|-----|--------------------|--------------------|------------------|---------|-------------|
| Year  | Age | Conscious Sedation | General Anesthesia | Local Anesthetic | Unknown | Grand Total |
| 2010  | 3   |                    | 1                  |                  |         | 1           |
|   | 18  |                    |                    | 1                |         | 1           |
| 2010 Total  |     |                    | 1                  | 1                |         | 2           |
| 2011  | 17  |                    |                    |                  | 1       | 1           |
| 2011 Total  |     |                    |                    |                  | 1       | 1           |
| 2012  | 3   |                    | 1                  |                  |         | 1           |
|   | 6   |                    | 1                  | 1                |         | 2           |
|   | 14  |                    | 1                  |                  |         | 1           |
|   | 18  |                    | 1                  | 1                |         | 2           |
| 2012 Total  |     |                    | 4                  | 2                |         | 6           |
| 2013  | 1.5 |                    |                    | 1                |         | 1           |
|   | 1.7 |                    | 1                  |                  |         | 1           |
|   | 3   | 1                  | 1                  |                  |         | 2           |
|   | 4   |                    |                    |                  | 1       | 1           |
|   | 15  |                    | 1                  |                  |         | 1           |
|   | 17  | 2                  | 1                  | 1                |         | 4           |
|   | 18  |                    | 1                  |                  |         | 1           |
|   | 20  | 1                  |                    |                  |         | 1           |
| unknown   |     |                    |                    |                  | 1       | 1           |
| 2013 Total  |     | 4                  | 5                  | 2                | 2       | 13          |
| 2014  | 2.5 |                    | 1                  |                  |         | 1           |
|   | 3   | 1                  | 1                  |                  |         | 2           |
|   | 4   | 1                  | 2                  | 2                |         | 5           |
|   | 5   |                    | 1                  |                  |         | 1           |
|   | 6   | 1                  | 1                  |                  |         | 2           |
|   | 7   |                    |                    |                  | 1       | 1           |
|   | 14  |                    | 1                  |                  |         | 1           |
|   | 17  |                    | 1                  |                  |         | 1           |
| 19  |     |                    |                    | 1                | 1       |             |
| 2014 Total  |     | 3                  | 8                  | 4                |         | 15          |
| 2015  | 2   | 1                  | 2                  |                  |         | 3           |
|   | 3.5 | 1                  |                    |                  |         | 1           |
|   | 8   |                    | 1                  |                  |         | 1           |
|   | 14  |                    | 1                  |                  |         | 1           |
|   | 15  |                    | 1                  |                  |         | 1           |
| 21  |     | 1                  |                    |                  | 1       |             |
| 2015 Total  |     | 2                  | 6                  |                  |         | 8           |
| Grand Total   |     | 9                  | 24                 | 9                | 3       | 45          |

For the purpose of this inquiry, the Board has examined all identified notifications and investigations of pediatric deaths and hospitalizations. During the course of an investigation, the Board gathers information and evidence, and conducts investigations with the intent to determine if dental treatment was rendered within the community standard of care.

Any notifications of potential violations are initially received and reviewed by the Complaint and Compliance Unit (CCU). CCU staff initially review and enter the complaint in the database. The matter is then referred to an analyst within the CCU to determine priority, gather records, and prepare for review by an in-house dental consultant. The in-house dental consultant determines at a general level, if the treatment was within the community standard of care. If the in-house consultant finds a deviation from the community standard of care, the matter is referred to investigation.

Of note, each case has different factors and components, and depending on the circumstances of the investigation, the matter may be identified as a priority matter. Reports of patient death are immediately referred to investigation, and are handled and investigated as a priority matter.

Upon initial receipt by investigative staff, the case is reviewed and evaluated for potential Dental Practice Act (DPA) and community standard of care violations. Matters are reviewed by investigative staff upon first receipt for prioritization. Upon investigation of each individual case, evidence is obtained, records are gathered, and interviews are conducted.

The investigative evidence gathered is then forwarded to a subject matter expert (SME) in the area of treatment, for review and determination of violation(s) of the community standard of care and the DPA. The SME prepares a report of his or her findings, and based on the findings, the Board will proceed accordingly; i.e., referral to the Office of the Attorney General, case closure; with no violation or insufficient evidence, a citation and fine, etc.

Cases are referred to the Office of the Attorney General for consideration of disciplinary action, including revocation, suspension, or probation. Matters closed with no violation are a result of a finding that the treatment rendered did not deviate from the community standard of care. A case closed with insufficient evidence, did not support that a violation occurred to the degree that charges can successfully be filed with the Office of the Attorney General.

Because of the broad range of complaint types, information gathered is specific to each case, and varies widely from investigation to investigation. The information obtained during the course of the investigation is germane to the specific case and allegations. The Board does not have the ability to maintain detailed scientific research data through its tracking mechanisms for investigations conducted.

In conclusion, there were nine major complications, and all resulted in death of the patient. There were no reports of serious permanent sequelae such as brain damage or permanent disability following hospitalization, with most patients discharged after a brief hospital stay. Of the nine major complications, three involved office sedation/anesthesia, three occurred in hospital, and three involved local anesthesia or local + nitrous oxide/oxygen. Of the three cases that involved office sedation or anesthesia, two involved the use of oral conscious sedation and one involved the use of general anesthesia.

The data available from published studies and board statistics for California do not support a statistical analysis due to the small number of serious adverse outcomes, but do not indicate that any type of provider or sedation delivery model has better outcomes.

Although pediatric dental sedation has an excellent safety record, adverse outcomes sometimes occur in apparently healthy patients, indicating that there may be inherent risk in sedation and general anesthesia. Nevertheless, it is important to continue efforts to improve outcomes for all patients who receive sedation and general anesthesia for dental treatment.

A record of the public comments received by the Dental Board of California during the workshops and meetings held to discuss the pediatric anesthesia study can be found at the following link: <http://www.dbc.ca.gov/formspubs/pedanesthesiastudy.pdf>

## APPENDIX 1

### **Dental advanced educational programs that include training in moderate sedation, deep sedation, and general anesthesia**

#### **Commission on Dental Accreditation Advanced Educational Programs**

The Commission on Dental Accreditation (CODA) was established in 1975 and is nationally recognized by the United States Department of Education (USDE) as the sole agency to accredit dental and dental-related education programs conducted at the post-secondary level. CODA accreditation is a non-governmental, voluntary peer review process by which educational institutions or programs may be granted public recognition for compliance with accepted standards of quality and performance. Accreditation standards are developed in consultation with those affected who represent broad communities of interest. A comparison table of education for training in various levels of sedation is included as Appendix 2, Table 1.

#### **Postgraduate CODA-approved residencies that require deep sedation-general anesthesia training.**

##### **Oral and Maxillofacial Surgery (OMS) (48-72 months of Post Graduate Education)<sup>1</sup>**

OMs complete, at a minimum, a post-graduate, CODA-approved residency of 48 months (single degree-DDS). Approximately half of those trained complete a 72-month residency (dual degree-DDS, MD).

The following CODA-approved, post-graduate residency training programs (after dental school-four years) require 36 months for dental anesthesiology, 30 months for periodontics, 24 months for pediatric dentistry, and 12-24 months for general practice (GPR).

##### *OMS Sedation / General Anesthesia Training During Residency Training*

- During OMS training, a resident completes the equivalency of a PGY1 year of anesthesia training.
- During the four- or six-year residency, each resident receives didactic education in subjects related to anesthesia including anatomy, pharmacology, and physiology, patient evaluation, risk assessment, anesthesia and sedation techniques, patient monitoring, and diagnosis and management of emergency complications. They also complete a structured course in physical diagnosis including patient evaluation and risk assessment.

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<sup>1</sup> CODA. (2012). "Accreditation Standards for Advanced Specialty Education Programs in Oral and Maxillofacial Surgery." Retrieved from <https://www.ada.org/~media/CODA/Files/oms.pdf?la=en>

- The clinical training currently includes five months on the hospital medical anesthesia service functioning at an anesthesia resident (PGY1) level with responsibility for patient evaluation, risk assessment, anesthesia and sedation techniques, patient monitoring, and diagnosis and management of complications.
- Clinical experience shall also include training to competency in airway management (simple, direct/ fiber optic intubation, emergency tracheotomy).
- CODA training requirements require the resident to perform 300 cases of general anesthesia of which 50 are pediatric patients and 150 of the 300 must be ambulatory anesthesia for OMS. Pediatric patients are defined as under age 18.
- CODA-approved training also requires hospital based rotations with the resident functioning at a PGY1 level: two months on the medicine service (for non-M.D. programs); four months on the general or a sub-specialty surgery service; and a rotation on the hospital emergency service.
- In addition, the OMS resident is required to complete the following certifications: Advanced Trauma Life Support (ATLS); Certification and currency in Advanced Cardiac Life Support (ACLS); and Pediatric Advanced Life Support (PALS).

### **Dental Anesthesiology<sup>2</sup> (36 months Post-Graduate Education)**

**Note:** until recently, a CODA-approved residency in dental anesthesiology was 24 months. The current residents in dental anesthesiology must receive didactic instruction at an advanced in-depth level for applied biomedical sciences foundational to dental anesthesiology, physical diagnosis and evaluation, methods of anxiety and pain control, complications and emergencies, and pain management.

The clinical requirements must include a minimum of 24 months in anesthesia with a minimum of this period of 6 months devoted to dental anesthesiology. Twelve months over the 36-month period must be assigned full-time to a hospital anesthesia service. They must complete 800 total cases of deep sedation/general anesthesia: 300 cases must be intubated general anesthetics including 50 nasal intubations and 25 advanced airway management techniques; 125 children age 0-7seven; and 75 patients with special needs. At least 100 of 800 cases must be outpatient anesthesia for dentistry and the resident must be the provider. Additionally, the resident must participate in four months of clinical medical rotations of internal medicine; intensive care; pain medicine; pediatrics; or pulmonary medicine.

**Postgraduate CODA-approved residencies that include moderate sedation training.**

**Periodontics (30 months Post-Graduate Education)**

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<sup>2</sup> CODA. (2012). “Accreditation Standards For Advanced General Dentistry Education Programs in Dental Anesthesiology.” Retrieved from [https://www.ada.org/~media/CODA/Files/anes.pdf?la=en](https://www.ada.org/~/media/CODA/Files/anes.pdf?la=en)

The periodontics training standards state the program must provide training in the methods of pain control and sedation. They must achieve knowledge in all areas of minimal, moderate, and deep sedation and be trained to a level of competency in adult minimal enteral and moderate parenteral sedation.

**Pediatric Dentistry<sup>3</sup>** (24 months Post-Graduate Education)

The pediatric dentistry training standards require education in anatomy, pharmacology, and principles and objectives of sedation and general anesthesia as behavioral guidance techniques including indications and contraindications for their use in accordance with the ADA Standards for Teaching of Pain Control and Sedation to Dentists and Dental Students. Clinical experience must include infants, children, adolescents, and patients with special needs for inhalation analgesia (nitrous oxide/oxygen) and sedation. Therefore they must perform 20 inhalation analgesia cases as primary operator, 50 patient encounters in which sedative agents (other than nitrous oxide/oxygen) by any route are used and must act as the operator in a minimum of 25 sedation cases.

**General Practice Residency** (12-24 months Post-Graduate Training)

The general practice residency standards require the resident to receive education and training beyond pre-doctoral training including pain and anxiety control utilizing behavioral and/or pharmacological techniques. For clinical experience, residents must be assigned to an anesthesia rotation for a minimum 70 hours to gain experience in preoperative evaluation, assessment of the effects of behavioral and pharmacologic techniques, venipuncture technique, patient monitoring, airway management, understanding of the use of pharmacologic agents, recognition and treatment of anesthetic emergencies, and assessment of patient recovery from anesthesia. Additional clinical experience includes interpreting clinical and other diagnostic data from other health care providers, using the services of clinical medicine and pathology, and performing a history and physical evaluation and collecting other data necessary to establish a medical assessment.

**American Society of Anesthesiologists Training recommended for non-anesthesiologists seeking privileges to administer deep sedation<sup>4</sup>**

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<sup>3</sup> CODA. (2015). “Accreditation Standards for Advanced Specialty Education Programs in Pediatric Dentistry.” Retrieved from <https://www.ada.org/~media/CODA/Files/ped.pdf?la=en>

<sup>4</sup> American Society of Anesthesiologists. (2010). “Advisory on granting privileges for deep sedation to non-anesthesiologist sedation practitioners.” Retrieved from <http://www.asahq.org/~media/Sites/ASAHQ/Files/Public/Resources/standards-guidelines/advisory-on-granting-privileges-for-deep-sedation-to-non-anesthesiologist.pdf>

## EDUCATION AND TRAINING

The non-anesthesiologist sedation practitioner will have satisfactorily completed a formal training program in (1) the safe administration of sedative and analgesic drugs used to establish a level of deep sedation, and (2) rescue of patients who exhibit adverse physiologic consequences of a deeper-than-intended level of sedation. This training may be a formally recognized part of a recently completed Accreditation Council for Graduate Medical Education (ACGME) residency or fellowship training (e.g., within two years), or may be a separate deep sedation educational program that is accredited by Accreditation Council for Continuing Medical Education (ACCME) or equivalent providers recognized for dental, oral surgical and podiatric continuing education, and that includes the didactic and performance concepts below. A knowledge-based test is necessary to objectively demonstrate the knowledge of concepts required to obtain privileges.

The following subject areas will be included:

- 3.1** Contents of the following ASA documents (or their more current version if subsequently modified) that will be understood by practitioners who administer sedative and analgesic drugs to establish a level of deep sedation.
  - 3.1.1 Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists. *Anesthesiology* 2002: 96; 1004-1017.
  - 3.1.2 Continuum of Depth of Sedation; Definition of General Anesthesia and Levels of Sedation/Analgesia (ASA HOD 2004, amended 2009)
  - 3.1.3 Standards for Basic Anesthetic Monitoring (Approved by the ASA House of Delegates on October 21, 1986, and last amended on October 25, 2005)
  - 3.1.4 Practice Guidelines for Preoperative Fasting and the Use of Pharmacologic Agents to Reduce the Risk of Pulmonary Aspiration: Application to Healthy Patients Undergoing Elective Procedures (Approved by ASA House of Delegates on October 21, 1998, and effective January 1, 1999)
- 3.2** Appropriate methods for obtaining informed consent through pre-procedure counseling of patients regarding risks, benefits and alternatives to the administration of sedative and analgesic drugs to establish a level of deep sedation.
- 3.3** Skills for obtaining the patient's medical history and performing a physical examination to assess risks and co-morbidities, including assessment of the airway for anatomic and mobility characteristics suggestive of potentially difficult airway management. The non-anesthesiologist sedation practitioner will be able to recognize those patients whose medical condition requires that sedation needs to be provided by an anesthesia professional, such as morbidly obese patients, elderly patients, pregnant patients, patients with severe systemic disease, patients with obstructive sleep apnea, or patients with delayed gastric emptying.

- 3.4 Assessment of the patient's risk for aspiration of gastric contents as described in the ASA Practice Guidelines for Preoperative Fasting. In urgent, emergent or other situations where gastric emptying is impaired, the potential for pulmonary aspiration of gastric contents must be considered in determining
  - 3.4.1 The target level of sedation
  - 3.4.2 Whether the procedure should be delayed
  - 3.4.3 Whether the sedation care should be transferred to an anesthesia professional for the delivery of general anesthesia with endotracheal intubation.
- 3.5 The pharmacology of
  - 3.5.1 All sedative and analgesic drugs the practitioner requests privileges to administer to establish a level of deep sedation
  - 3.5.2 Pharmacological antagonists to the sedative and analgesic drugs
  - 3.5.3 Vasoactive drugs and antiarrhythmics.
- 3.6 The benefits and risks of supplemental oxygen.
- 3.7 Recognition of adequacy of ventilatory function: This will include experience with patients whose ventilatory drive is depressed by sedative and analgesic drugs as well as patients whose airways become obstructed during sedation. This will also include the ability to perform capnography and understand the results of such monitoring. Non-anesthesiologist practitioners will demonstrate competency in managing patients during deep sedation, and understanding of the clinical manifestations of general anesthesia so that they can ascertain when a patient has entered a state of general anesthesia and rescue the patient appropriately.
- 3.8 Proficiency in advanced airway management for rescue: This training will include appropriately supervised experience to demonstrate competency in managing the airways of patients during deep sedation, and airway management using airway models as well as using high-fidelity patient simulators. The non-anesthesiologist practitioner must demonstrate the ability to reliably perform the following:
  - 3.8.1. Bag-valve-mask ventilation
  - 3.8.2. Insertion and use of oro- and nasopharyngeal airways

3.8.3. Insertion and ventilation through a laryngeal mask airway

3.8.4. Direct laryngoscopy and endotracheal intubation

This will include clinical experience on no less than 35 patients or equivalent simulator experience (See ACGME reference). The facility with oversight by the Director of Anesthesia Services will determine the number of cases needed to demonstrate these competencies, and may increase beyond the minimum recommended.

**3.9** Monitoring of physiologic variables, including the following:

3.9.1 Blood pressure.

3.9.2 Respiratory rate.

3.9.3 Oxygen saturation by pulse oximetry with audible variable pitch pulse tone.

3.9.4 Capnographic monitoring. The non-anesthesiologist practitioner shall be familiar with the use and interpretation of capnographic waveforms to determine the adequacy of ventilation during deep sedation.

3.9.5 Electrocardiographic monitoring. Education in electrocardiographic (EKG) monitoring will include instruction in the most common dysrhythmias seen during sedation and anesthesia, their causes and their potential clinical implications (e.g., hypercapnia), as well as electrocardiographic signs of cardiac ischemia.

3.9.6 Depth of sedation. The depth of sedation will be based on the ASA definitions of “deep sedation” and “general anesthesia.” (See below).

- 3.10** The importance of continuous use of appropriately set audible alarms on physiologic monitoring equipment.
- 3.11** Documenting the drugs administered, the patient’s physiologic condition and the depth of sedation at five-minute intervals throughout the period of sedation and analgesia, using a graphical, tabular or automated record which documents all the monitored parameters including capnographic monitoring. The importance of monitoring the patient through the recovery period and the inclusion of specific discharge criteria for the patient receiving sedation.
- 3.12** Regardless of the availability of a “code team” or the equivalent, the non-anesthesiologist practitioner will have advanced life support skills and current certificate such as those required for Advanced Cardiac Life Support (ACLS). When granting privileges to administer deep sedation to pediatric patients, the non-anesthesiologist practitioner will have advanced life support skills and current certificate such as those required for Pediatric Advanced Life Support (PALS). Initial ACLS and PALS training and subsequent retraining shall be obtained from the American Heart Association or another vendor that includes “hands-on” training and skills demonstration of airway management and automated external defibrillator (AED) use.
- 3.13** Required participation in a quality assurance system to track adverse outcomes and unusual events including respiratory arrests, use of reversal agents, prolonged sedation in recovery process, larger than expected medication doses, and occurrence of general anesthesia, with oversight by the Director of Anesthesia services or their designee.
- 3.14** Knowledge of the current CMS Conditions of Participation regulations and their interpretive guidelines pertaining to deep sedation, including requirements for the pre-anesthesia evaluation, anesthesia intra-operative record, and post-anesthesia evaluation.

Separate privileging is required for the care of pediatric patients. When the non-anesthesiologist practitioner is granted privileges to administer sedative and analgesic drugs to pediatric patients to establish a level of deep sedation, the education and training requirements enumerated in #1-15 above will be specifically defined to qualify the practitioner to administer sedative and analgesic drugs to pediatric patients.

#### **4. LICENSURE**

- 4.1** The non-anesthesiologist sedation practitioner will have a current active, unrestricted medical, osteopathic, or dental license in the state, district or territory of practice. (Exception: practitioners employed by the federal government may have a current active license in any U.S. state, district or territory.)
- 4.2** The non-anesthesiologist sedation practitioner will have a current unrestricted Drug Enforcement Administration (DEA) registration (Schedules II-V).
- 4.3** The privileging process will require disclosure of any disciplinary action (final judgments) against any medical, osteopathic or dental license by any state, district or territory of

practice and of any sanctions by any federal agency, including Medicare/Medicaid, in the last five years.

- 4.4 Before granting or renewing privileges to administer or supervise the administration of sedative and analgesic drugs to establish a level of deep sedation, the health care organization shall search for any disciplinary action recorded in the National Practitioner Data Bank (NPDB) and take appropriate action regarding any Adverse Action Reports.

## 5. PERFORMANCE EVALUATION

- 5.1 Before granting initial privileges to administer or supervise administration of sedative and analgesic drugs to establish a level of deep sedation, a process will be developed to evaluate the practitioner's performance and competency. For recent graduates (e.g., within two years), this may be accomplished through letters of recommendation from directors of residency or fellowship training programs that include deep sedation as part of the curriculum. For those who have been in practice since completion of their training, performance evaluation may be accomplished through specific documentation of performance evaluation data transmitted from department heads or supervisors at the institution where the individual previously held privileges to administer deep sedation. Alternatively, the non-anesthesiologist sedation practitioner could be proctored or supervised by a physician or dentist who is currently privileged to administer sedative and analgesic agents to provide deep sedation. The Director of Anesthesia Services with oversight by the facility governing body will determine the number of cases that need to be performed in order to determine independent competency in deep sedation.
- 5.2 Before granting ongoing privileges to administer or supervise administration of sedative and analgesic drugs to establish a level of deep sedation, a process will be developed to re-evaluate the practitioner's performance at regular intervals. Re-evaluation of competency in airway management will be part of this performance evaluation. For example, the practitioner's performance could be reviewed by an anesthesiologist or a non-anesthesiologist sedation practitioner who is currently privileged to administer deep sedation. The facility will establish an appropriate number of procedures that will be reviewed.

## 6. PERFORMANCE IMPROVEMENT

Privileging in the administration of sedative and analgesic drugs to establish a level of deep sedation will require active participation in an ongoing process that evaluates the practitioner's clinical performance and patient care outcomes through a formal facility program of continuous performance improvement. The facility's deep sedation performance improvement program will be developed with advice from and with outcome review by the Director of Anesthesia Services.

- 6.3 The organization in which the practitioner practices will conduct peer review of its clinicians.

- 6.4 The performance improvement program will assess up-to-date knowledge as well as ongoing competence in the skills outlined in the educational and training requirements described above.
- 6.5 Continuing medical education in the delivery of anesthesia services is required for renewal of privileges.
- 6.6 The performance improvement program will monitor and evaluate patient outcomes and adverse or unusual events.
- 6.7 Any of the following events will be referred to the facility quality assurance committee for evaluation and performance evaluation:
  - 6.5.1 Unplanned admission
  - 6.5.2 Cardiac arrest
  - 6.5.3 Use of reversal agents
  - 6.5.4 Use of assistance with ventilation requiring bag-valve-mask ventilation or laryngeal or endotracheal airways.
  - 6.5.5 Prolonged periods of oxygen desaturation (<85% for 3 minutes)
  - 6.5.6 Failure of the patient to return to 20% of pre-procedure vital signs

## **7. DEFINITIONS**

Anesthesia Professional: An anesthesiologist, anesthesiologist assistant (AA), or certified registered nurse anesthetist (CRNA).

Non-anesthesiologist Sedation Practitioner: A licensed physician (allopathic or osteopathic); or dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under state law; who has not completed postgraduate training in anesthesiology but is specifically trained to administer personally or to supervise the administration of deep sedation.



## APPENDIX 2

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### Comparison of California requirements for minimal, moderate and deep sedation/general anesthesia with American Dental Association Guidelines<sup>1</sup> and American Academy of Pediatrics – American Academy of Pediatric Dentistry Guidelines<sup>2</sup>

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1 American Dental Association. (2012). Guidelines for the Use of Sedation and General Anesthesia by Dentists. In *Society* (Vol. 80, pp. 75–106). <http://doi.org/10.1112/S0024611500012132>

2 Coté, C. J., & Wilson, S. (2016). Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016. *Pediatrics*, 138(1), 1–87. <http://doi.org/10.1542/peds.2016-1212>



**TABLE 1**  
**California Definitions Compared to ADA<sup>1</sup> and ADA-AAPD Guidelines<sup>2</sup>**

| <p><b>California requirements for minimal sedation, moderate sedation and general anesthesia</b></p> <p><b>California law has specific requirements for pediatric patients for oral (moderate) conscious sedation only (under age 13).</b></p> | <p><b>ADA Guidelines for use of sedation and general anesthesia by dentists; For pediatric patients ADA supports AAP-AAPD Guidelines (age 12 and under)</b></p>   | <p><b>AAP-AAPD Guidelines for monitoring and management of pediatric patients (age 21 and under)</b></p>   |
|--|---|--|
| <p><b>Minimal Sedation</b></p>   |   |  |
| <p>Minimal sedation not defined in CA Law. See BPC 1647, Conscious Sedation, BPC 1647.10, Use of Oral Conscious Sedation for Pediatric patients, and 1647.18, Use of Oral Conscious Sedation for Adult Patients.</p>                           | <p>“A minimally depressed level of consciousness produced by a pharmacological method, that retains the patient’s ability to independently and continuously maintain an airway and respond normally to tactile stimulation and verbal command.”</p> <p>“Although cognitive function and coordination may be modestly impaired, ventilatory and cardiovascular functions are unaffected.”</p> <p>“The drug(s) and/or techniques used should carry a margin of safety wide enough never to render unintended loss of consciousness. Further, patients whose only response is reflex withdrawal from repeated painful stimuli would not be considered to be in a state of minimal sedation.”</p> <p>The ADA Guidelines add a definition of “combination inhalation-enteral conscious sedation” for when the intent is anxiolysis only. When the intent is conscious (moderate) sedation that definition applies.</p> | <p>Minimal sedation (old terminology anxiolysis): a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.</p> |

## Oral Conscious Sedation

Oral conscious sedation (pediatric and adult) See BPC 1674.10

Oral conscious sedation means “a minimally depressed level of consciousness produced by oral medication that retains the patient’s ability to maintain independently and continuously an airway, and respond appropriately to physical stimulation or verbal command.”

“The drugs and techniques used in oral conscious sedation shall have a margin of safety wide enough to render unintended loss of consciousness unlikely. Further, patients whose only response is reflex withdrawal from painful stimuli would not be considered to be in a state of oral conscious sedation.”

Author’s note: The ADA Guidelines include definitions of both conscious sedation and moderate sedation, and give clinical guidelines for both terms. However, the preferred term appears to be moderate sedation because it is accompanied by clinical guidelines.

## Moderate Sedation

CA term is “conscious sedation”  
See BPC 1647.1

Conscious sedation means “a minimally depressed level of consciousness produced by a pharmacologic or nonpharmacologic method, or a combination thereof, that retains the patient’s ability to maintain independently and continuously an airway, and respond appropriately to physical stimulation or verbal command.”

Conscious sedation does not include that administration of oral medication or the administration of a mixture of nitrous oxide and oxygen, whether alone or with each other.

The drugs and techniques used in conscious sedation shall have a margin of safety wide enough to render unintended loss of consciousness unlikely.

For the very young or handicapped, incapable of the usual verbal response, a minimally depressed level of consciousness should be maintained.

Further, patients whose only response is reflex withdrawal from painful stimuli shall not be considered to be in a state of conscious sedation.

The term “conscious sedation” has been replaced by the ADA with the term “moderate sedation,” defined as “a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation.”

“No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.”

“Drugs or techniques should maintain a margin of safety wide enough to render unintended loss of consciousness unlikely.”

“Repeated dosing of an agent before the effects of previous dosing can be fully appreciated may result in a greater alteration of the state of consciousness than is the intent of the dentist.”

“A patient whose only response is reflex withdrawal from a painful stimulus is not considered to be in a state of moderate sedation.”

The ADA Guidelines also include the following cautionary statement:

“Because sedation and general anesthesia are a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to diagnose and manage the physiologic consequences (rescue) for patients whose level of sedation becomes deeper than initially intended.”

For all levels of sedation, the practitioner must have the training, skills, drugs and equipment to identify and manage such an occurrence until either assistance arrives (emergency medical service) or the patient returns to the intended level of sedation without airway or cardiovascular complications.

Moderate sedation (old terminology conscious sedation or sedation/analgesia): a drug-induced depression of consciousness during which patients respond purposefully to verbal commands (e.g., open your eyes either alone or accompanied by light tactile stimulation—a light tap on the shoulder or face, not a sternal rub). For older patients, this level of sedation implies an interactive state; for younger patients, age-appropriate behaviors (e.g., crying) occur and are expected. Reflex withdrawal, although a normal response to a painful stimulus, is not considered as the only age-appropriate purposeful response (e.g., it must be accompanied by another response, such as pushing away the painful stimulus so as to confirm a higher cognitive function). With moderate sedation, no intervention is required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained. However, in the case of procedures that may themselves cause airway obstruction (eg, dental or endoscopic), the practitioner must recognize an obstruction and assist the patient in opening the airway. If the patient is not making spontaneous efforts to open his/her airway so as to relieve the obstruction, then the patient should be considered to be deeply sedated.

### Deep sedation

|  |  |  |
|--|--|--|
| <p>Deep sedation in California is described in BPC 1647 (c) as part of a continuum for which the educational standards for general anesthesia should be applied. Deep sedation is not otherwise defined in the California law.</p> | <p>The ADA defines deep sedation as “a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.</p> | <p>Deep sedation (deep sedation/analgesia): a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully (see discussion of reflex withdrawal above) after repeated verbal or painful stimulation (e.g., purposefully pushing away the noxious stimuli). The ability to independently maintain ventilator function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. A state of deep sedation may be accompanied by partial or complete loss of protective airway reflexes.</p> |
|--|--|--|

### General Anesthesia

|   |   |   |
|---|---|---|
| <p>BPC 1646 defines deep sedation as a “controlled state of depressed consciousness or unconsciousness, accompanied by a partial or complete loss of protective reflexes, produced by pharmacologic or non-pharmacologic method, or a combination thereof.”</p> | <p>A drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.</p> | <p>General anesthesia: a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive-pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.</p> |
| <p>CA requires a pediatric oral (moderate) conscious sedation permit for children 13 or under.</p>  | <p>Pediatrics<br/><br/>For children 12 years of age and under, the American Dental Association supports the use of the American Academy of Pediatrics/American Academy of Pediatric Dentistry Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures.</p>   |   |

(Endnotes)

- 1 American Dental Association. (2012). Guidelines for the Use of Sedation and General Anesthesia by Dentists. In *Society* (Vol. 80, pp. 75–106). <http://doi.org/10.1112/S0024611500012132>
- 2 Coté, C. J., & Wilson, S. (2016). Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016. *Pediatrics*, 138(1), 1–87. <http://doi.org/10.1542/peds.2016-1212>

**TABLE 2**  
**Educational Requirements for Minimal, Moderate, Deep Sedation and General Anesthesia**

| California Requirements for Moderate Sedation and General Anesthesia   | ADA Guidelines for use of Sedation and General Anesthesia by Dentists <sup>1</sup>  | AAP-AAPD Guidelines for Monitoring and Management of Pediatric Patients <sup>2</sup>   |
|--|---|--|
|  | <b>Educational Requirements</b>   |  |
|  | <b>Minimal Sedation</b>   |  |
| <p>Minimal sedation is not specifically defined in California sedation laws.</p> <p>Training in minimal sedation, including the administration of a mixture of nitrous oxide and oxygen, either alone or in combination with minimal oral sedation, may be taught to the level of basic competency at the predoctoral (dental school) level.</p> <p>(see ADA Educational Guidelines)</p> | <p>The predoctoral curriculum should provide instruction, exposure and/or experience in anxiety and pain control, including minimal and moderate sedation. The predoctoral program must also provide the knowledge and skills to enable students to recognize and manage any emergencies that might arise as a consequence of treatment. Predoctoral dental students must complete a course in Basic Life Support for including a “hands on” component. Such courses should be AHA or ARC approved.</p> <p><b>Minimal sedation requires</b></p> <p>a. Training to the level of competency in minimal sedation consistent with that prescribed in the ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students, or a comprehensive training program in moderate sedation that satisfies the requirements described in the Moderate Sedation section of the ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students at the time training was commenced, or</p> <p>b. An equivalent advanced education program accredited by the ADA Commission on Dental Accreditation.</p> <p><b>Enteral and/or Combination Inhalation-Enteral Minimal Sedation Course Duration:</b></p> <p>Current certification in Basic Life Support for Healthcare Providers</p> <ol style="list-style-type: none"> <li>1. Completion of a nitrous oxide competency course.</li> <li>2. While length of a course is only one of many factors, the course should include a minimum of 16 hours, plus clinically-oriented experiences during which competency in enteral and/or combined inhalation-enteral minimal sedation techniques is demonstrated.</li> </ol> <p style="text-align: right;"><i>continued on next page</i></p> | <p>No specific educational requirements are provided in these guidelines, however, personnel qualifications are described.</p> <p>“The practitioner responsible for the treatment of the patient and/or the administration of drugs for sedation must be competent to use such techniques, to provide the level of monitoring provided in this guideline, and to manage complications of these techniques (ie, to be able to rescue the patient). Because the level of intended sedation may be exceeded, the practitioner must be sufficiently skilled to provide rescue should the child progress to a level of deep sedation. The practitioner must be trained in, and capable of providing, at the minimum, bag-valve-mask ventilation so as to be able to oxygenate a child who develops airway obstruction or apnea. Training in, and maintenance of, advanced pediatric airway skills is required; regular skills reinforcement is strongly encouraged.”</p> <p>The practitioner is responsible for life support measures while awaiting EMS arrival. Rescue techniques require specific training and skills. The maintenance of the skills needed to rescue a child with apnea, laryngospasm, and/or airway obstruction include the ability to open the airway, suction secretions, provide continuous positive airway pressure (CPAP), perform successful bag-valve-mask ventilation, insert an oral airway, a nasopharyngeal airway, or a laryngeal mask airway (LMA), and, rarely, perform tracheal intubation.</p> <p style="text-align: right;"><i>continued on next page</i></p> |

|  | <b>Minimal Sedation (continued)</b>   |   |
|--|---|---|
|  | <p>Clinically-oriented experiences may include group observations on patients undergoing enteral and/or combination inhalation-enteral minimal sedation.</p> <p>Clinical experience in managing a compromised airway is critical to the prevention of life-threatening emergencies.</p> <p>The faculty should schedule participants to return for additional clinical experience if competency has not been achieved in the time allotted.</p> <p>The educational course may be completed in a predoctoral dental education curriculum or a postdoctoral continuing education competency course.</p> <p>Not intended for the management of sedation in children, which requires additional course content and clinical learning experience.</p> | <p>These skills are likely best maintained with frequent simulation and team training for the management of rare events. Competency with emergency airway management procedure algorithms is fundamental for safe sedation practice and successful patient rescue.</p> <p>Practitioners should have an in-depth knowledge of the agents they intend to use and their potential complications.</p> |

|   | Moderate Sedation  |  |
|---|--|--|
| California Moderate Enteral Sedation Courses for Adults and Minors  | Moderate Enteral Sedation  |  |
| <p>Completion of approved post doctoral or residency training; or a board-approved course that includes 25 hours of instruction including a clinical component utilizing at least one age-appropriate patient; training for either adult patients or minor patients (13 or younger); training requirements reference ADA, AAPD definitions of levels of sedation. (See BPC 1647.12; CCR 1044–1044.5.)</p> | <p>A minimum of <i>24 hours</i> of instruction, plus management of <i>at least 10 adult case experiences</i> by the enteral and/or enteral-nitrous oxide/oxygen route are required to achieve competency. These ten cases must include at least three live clinical dental experiences managed by participants in groups no larger than five. The remaining cases may include simulations and/or video presentations, but must include one experience in returning (rescuing) a patient from deep to moderate sedation. Participants combining enteral moderate sedation with nitrous oxide-oxygen must have first completed a nitrous oxide competency course.</p> <p>Participants should be provided supervised opportunities for clinical experience to demonstrate competence in airway management. Clinical experience will be provided in managing healthy adult patients; <b>this course in moderate enteral sedation is not designed for the management of children (aged 12 and under)</b>. Additional supervised clinical experience is necessary to prepare participants to manage medically compromised adults and special needs patients. This course in moderate enteral sedation does not result in competency in moderate parenteral sedation. The faculty should schedule participants to return for additional didactic or clinical exposure if competency has not been achieved in the time allotted.</p> | <p>No specific educational requirements are provided in these guidelines, however personnel qualifications are described.</p> <p>See description below.</p> <p>High-fidelity patient simulators are now available that allow physicians, dentists, and other healthcare providers to practice managing a variety of programmed adverse events, such as apnea, bronchospasm, and laryngospasm. The use of such devices is encouraged to better train medical professionals and teams to respond more effectively to rare events. One study that simulated the quality of cardiopulmonary resuscitation compared standard management of ventricular fibrillation versus rescue with the EZ-IO for the rapid establishment of intravenous access and placement of an LMA for establishing a patent airway in adults; the use of these devices resulted in more rapid establishment of vascular access and securing of the airway.</p> |

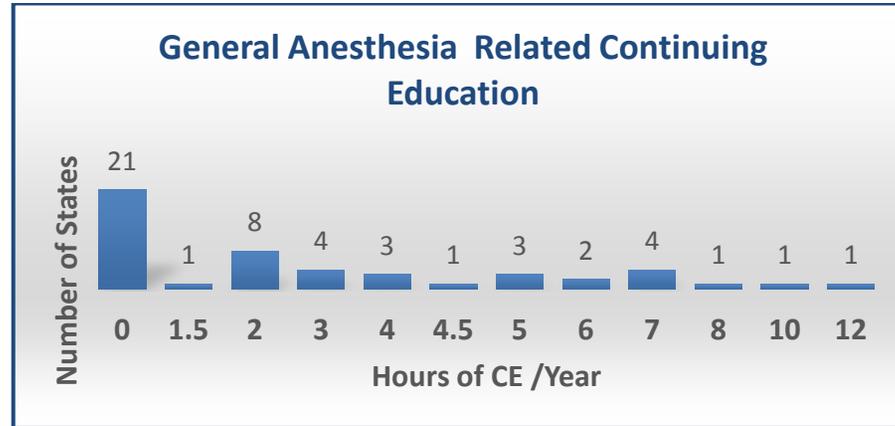
| <b>Conscious Sedation<br/>(Moderate IV Sedation)</b>  | <b>Moderate Parenteral Sedation</b>  | <b>Moderate Sedation</b>   |
|---|--|--|
| <p>At least 60 hours of instruction. Satisfactory completion of at least 20 cases of administration of conscious sedation for a variety of dental procedures.</p> <p>Course must comply with the requirements of the Guidelines for Teaching the Comprehensive Control of Anxiety and Pain in Dentistry of the American Dental Association (see BPC 1647.3)</p> | <p>A minimum of 60 hours of instruction plus management of at least 20 patients using the intravenous route; clinical experience in managing a compromised airway is critical to prevention of emergencies.</p> <p>Management of children and medically compromised adults requires additional experience; course completion does not result in clinical competency.</p> | <p>The practitioner must be competent to use such techniques to provide the level of monitoring provided in this guideline, and to manage complications of these techniques (ie, to be able to rescue the patient).<br/>(ed. Specific educational requirements are not described.)</p> <p>The use of moderate sedation shall include the provision of a person, in addition to the practitioner, whose responsibility is to monitor appropriate physiologic parameters and to assist in any supportive or resuscitation measures, if required. This individual may also be responsible for assisting with interruptible patient-related tasks of short duration, such as holding an instrument or troubleshooting equipment. This individual should be trained in and capable of providing advanced airway skills (eg, PALS). The support person shall have specific assignments in the event of an emergency and current knowledge of the emergency cart inventory. The practitioner and all ancillary personnel should participate in periodic reviews, simulation of rare emergencies, and practice drills of the facility's emergency protocol to ensure proper function of the equipment and coordination of staff roles in such emergencies. It is recommended that at least one practitioner be skilled in obtaining vascular access in children.</p> |

| General Anesthesia   | Deep Sedation or General Anesthesia  | Deep Sedation  |
|--|--|--|
| <p>Completion of a residency program in general anesthesia of not less than one calendar year, that is approved by the board; or a graduate program in oral and maxillofacial surgery which has been approved by the Commission on Dental Accreditation. (CCR 1043)</p> <p>A dentist who orders administration of anesthesia by a nurse anesthetist must meet the requirements for California general anesthesia permit. (BPC 2827).</p> | <p><b>C. Deep Sedation or General Anesthesia</b></p> <ol style="list-style-type: none"> <li>1. Completion of an advanced education program accredited by the ADA Commission on Dental Accreditation that affords comprehensive and appropriate training necessary to administer and manage deep sedation or general anesthesia, commensurate with these guidelines; and</li> <li>2. Administration of deep sedation or general anesthesia by another qualified dentist or independently practicing qualified anesthesia healthcare provider requires the operating dentist and his/her clinical staff to maintain current certification in Basic Life Support (BLS) Course for the Healthcare Provider.</li> </ol> | <p>Ed. Specific educational requirements are not addressed in this document.</p> <p>During deep sedation, there must be one person whose only responsibility is to constantly observe the patient's vital signs, airway patency, and adequacy of ventilation and to either administer drugs or direct their administration. This individual must, at a minimum, be trained in PALS and capable of assisting with any emergency event. At least one individual must be present who is trained in and capable of providing advanced pediatric life support and who is skilled to rescue a child with apnea, laryngospasm, and/or airway obstruction. Required skills include the ability to open the airway, suction secretions, provide CPAP, insert supraglottic devices (oral airway, nasal trumpet, LMA), and perform successful bag-valve-mask ventilation, tracheal intubation, and cardiopulmonary resuscitation.</p> |

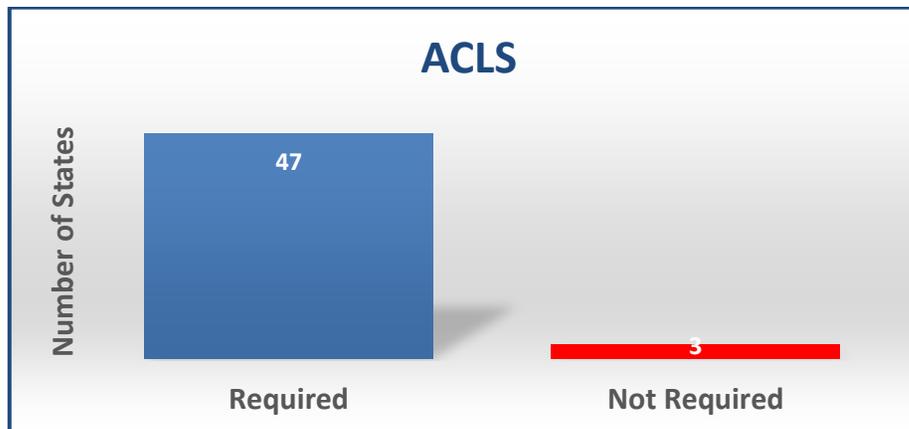
(Footnotes)

- 1 American Dental Association. (2012). Guidelines for the Use of Sedation and General Anesthesia by Dentists. In *Society* (Vol. 80, pp. 75–106). <http://doi.org/10.1112/S0024611500012132>
- 2 Coté, C. J., & Wilson, S. (2016). Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016. *Pediatrics*, *138*(1), 1–87. <http://doi.org/10.1542/peds.2016-1212>

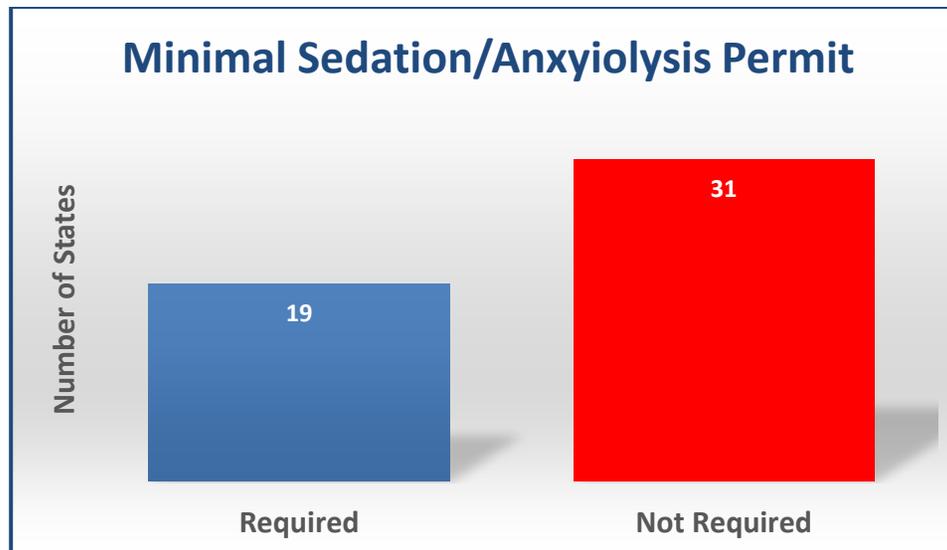
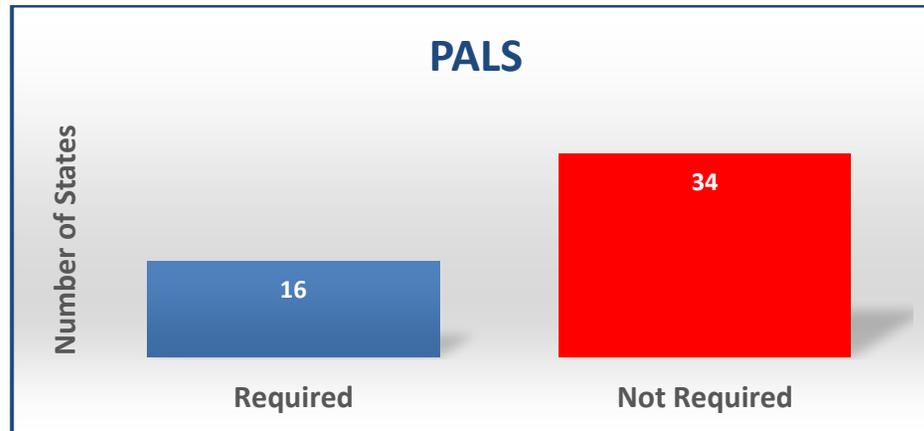
## Continuing Education – State Requirements



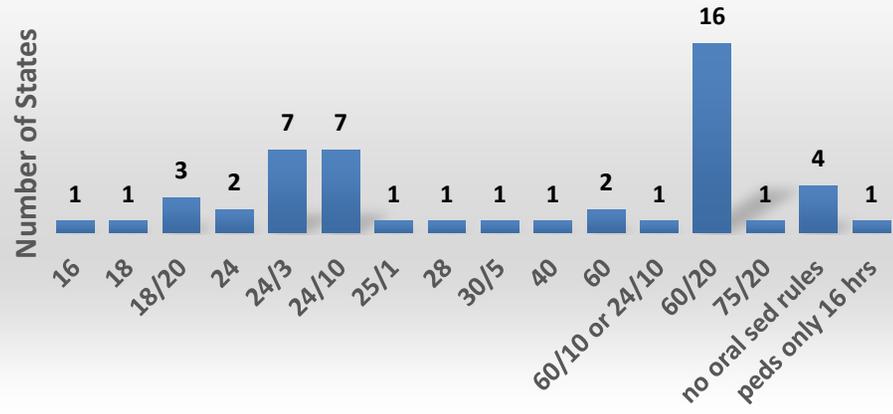
### ACLS for General Anesthesia Permits



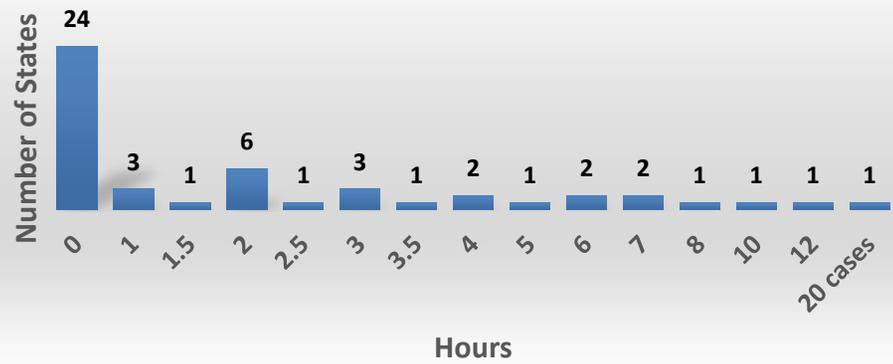
## Pediatric Advanced Life Support for General Anesthesia Permit Holders



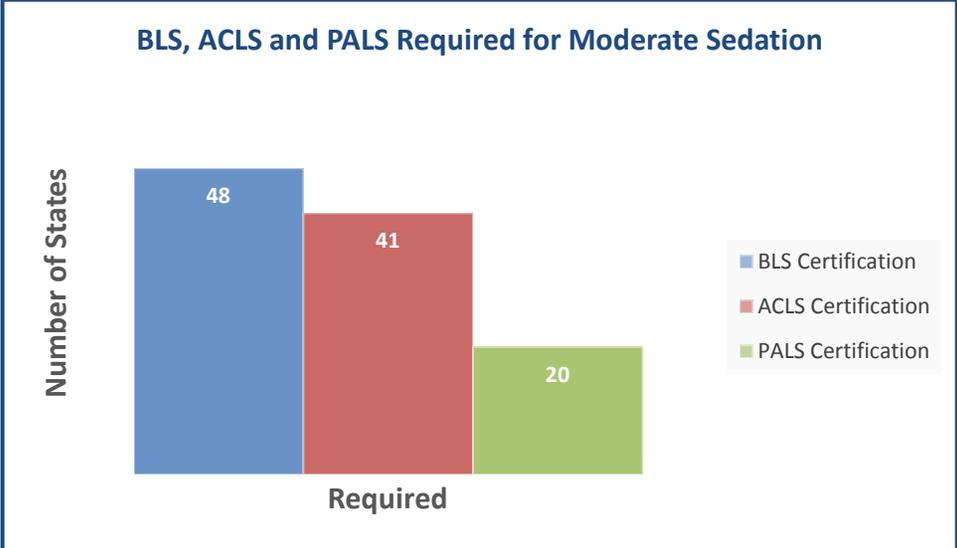
### Moderate Oral Sedation Course Requirements hours/cases

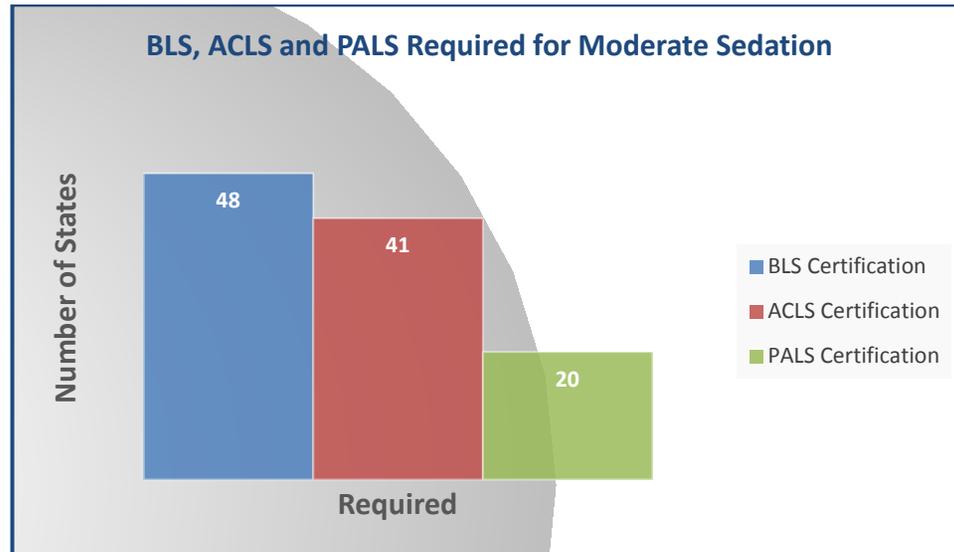


### Sedation Related Continuing Education Hours/Year



**BLS, ACLS and PALS Required for Moderate Sedation**





**TABLE 3**  
**Pre-operative Evaluation for Minimal Sedation, Moderate Sedation, Deep Sedation, and General Anesthesia**

| California Requirements  | ADA Guidelines   | AAP-AAPD Guidelines   |
|--|--|---|
| <p>The term minimal sedation is not used in CA. Laws related to oral moderate sedation apply (CCR Sec. 1044)</p>   | <p>Minimal sedation</p>  | <p>General guidelines are provided for all levels of sedation</p>   |
| <p><b>Pre-operative evaluation</b><br/> Adequate medical history and physical evaluation records updated prior to each administration of oral conscious sedation. Such records shall include, but are not limited to, an assessment including at least visual examination of the airway, the age, sex, weight, physical status (American Society of Anesthesiologists Classification), and rationale for sedation of the minor or adult patient. (CCR 1043.3 (i))</p> <p>Written informed consent must be obtained for all patients undergoing general anesthesia or conscious sedation, or as appropriate, from the parent or legal guardian of the patient. (BPC 1682 (d))</p> <p>There is no specific requirement for preoperative dietary precautions.</p> | <p><b>Pre-operative evaluation and preparation</b></p> <ol style="list-style-type: none"> <li>In healthy or medically stable individuals (ASA I, II) a review of their current medical history and medication use. However, patients with significant medical considerations (ASA III, IV) may require consultation with their primary care physician or consulting medical specialist.</li> <li>Pre-operative preparation <ul style="list-style-type: none"> <li>The patient, parent, guardian, or caregiver must be advised regarding the procedure associated with the delivery of any sedative agents and informed consent for the proposed sedation must be obtained.</li> <li>Determination of adequate oxygen supply and equipment necessary to deliver oxygen under positive pressure must be completed.</li> <li>Baseline vital signs must be obtained unless the patient's behavior prohibits such determination.</li> <li>A focused physical evaluation must be performed as deemed appropriate.</li> <li>Pre-operative dietary restrictions must be considered based on the sedative technique prescribed.</li> <li>Pre-operative verbal and written instructions must be given to the patient, parent, escort, guardian, or caregiver.</li> </ul> </li> </ol> | <p><b>Health evaluation</b></p> <p><b>Age and weight.</b></p> <ul style="list-style-type: none"> <li>Health history, including: 1) allergies and previous allergic or adverse drug reactions, 2) medication/drug history, 3) relevant diseases, physical abnormalities, and neurologic impairment that might increase the potential for airway obstruction, such as a history of snoring or obstructive sleep apnea, 4) pregnancy status, 5) a summary of previous relevant hospitalizations, 6) history of sedation or general anesthesia and any complications or unexpected responses, and 7) relevant family history, particularly related to anesthesia.</li> <li>Review of systems with a special focus on abnormalities of cardiac, pulmonary, renal, or hepatic function. Vital signs, including heart rate, blood pressure, respiratory rate, and temperature.</li> <li>Physical examination, including a focused evaluation of the airway (tonsillar hypertrophy, abnormal anatomy).</li> <li>Physical status evaluation [ASA classification].</li> <li>Name, address, and telephone number of the child's medical home.</li> </ul> <p><b>Dietary precautions:</b><br/> Before sedation, the practitioner should evaluate preceding food and fluid intake. It is likely that the risk of aspiration during procedural sedation differs from that during general anesthesia involving tracheal intubation or other airway manipulation. However, because the absolute risk of aspiration during procedural sedation is not yet known, guidelines for fasting periods before elective sedation generally should follow those used for elective general anesthesia. For emergency procedures in children who have not fasted, the risks of sedation and the possibility of aspiration must be balanced against the benefits of performing the procedure promptly. Further research is needed to better elucidate the relationships between various fasting intervals and sedation complications.</p> |

| Conscious (Moderate) Sedation  | Moderate Sedation  | Moderate Sedation<br>(See above section) |
|--|--|--|
| <p>Adequate medical history and physical evaluation records updated prior to each administration of general anesthesia or conscious sedation. Such records shall include, but are not limited to the recording of the age, sex, weight, physical status (American Society of Anesthesiologists Classification), medication use, any known or suspected medically compromising conditions, rationale for sedation of the patient, and visual examination of the airway, and, for general anesthesia only, auscultation of the heart and lungs as medically required. (CCR 1043.3 (i))</p> <p>There are no specific requirements for preoperative dietary restrictions.</p> <p>A written informed consent must be signed by the patient or guardian. See BPC 1682 (d).</p> | <p><b>Patient Evaluation</b></p> <p>In healthy or medically stable individuals (ASA I, II) evaluation should consist of at least a review of their current medical history and medication use. However, patients with significant medical considerations (e.g., ASA III, IV) may require consultation with their primary care physician or consulting medical specialist.</p> <p>2. Pre-operative preparation</p> <ul style="list-style-type: none"> <li>• The patient, parent, guardian, or caregiver must be advised regarding the procedure associated with the delivery of any sedative agents and informed consent for the proposed sedation must be obtained.</li> <li>• Determination of adequate oxygen supply and equipment necessary to deliver oxygen under positive pressure must be completed.</li> <li>• Baseline vital signs must be obtained unless the patient's behavior prohibits such determination.</li> <li>• A focused physical evaluation must be performed as deemed appropriate.</li> <li>• Pre-operative dietary restrictions must be considered based on the sedative technique prescribed.</li> <li>• Pre-operative verbal or written instructions must be given to the patient, parent, escort, guardian, or caregiver.</li> </ul> |  |

| General Anesthesia   | Deep Sedation or General Anesthesia   | Deep Sedation   |
|--|---|---|
| <p>No specific dietary restrictions.</p> <p>Equipment for an IV must be available, but does not need to be established. Dentist discretion advised for cases where it may be difficult or impossible to establish IV access.</p> | <p><b>Patient Evaluation</b></p> <p>In healthy or medically stable individuals (ASA I, II), at least a review of their current medical history and medication use and NPO status. However, patients with significant medical considerations (e.g., ASA III, IV) may require consultation with their primary care physician or consulting medical specialist.</p> <p>2. Pre-operative preparation</p> <ul style="list-style-type: none"> <li>• The patient, parent, guardian, or caregiver must be advised regarding the procedure associated with the delivery of any sedative or anesthetic agents and informed consent for the proposed sedation/anesthesia must be obtained.</li> <li>• Determination of adequate oxygen supply and equipment necessary to deliver oxygen under positive pressure must be completed.</li> <li>• Baseline vital signs must be obtained unless the patient's behavior prohibits such determination.</li> <li>• A focused physical evaluation must be performed as deemed appropriate.</li> <li>• Pre-operative dietary restrictions must be considered based on the sedative/anesthetic technique prescribed.</li> <li>• Pre-operative verbal and written instructions must be given to the patient, parent, escort, guardian, or caregiver.</li> <li>• An intravenous line, which is secured throughout the procedure, must be established except as provided in part IV. C.6. Pediatric and Special Needs Patients.</li> </ul> | <p>Ed. See above section for health evaluation. This applies to all levels of sedation.</p> |



**TABLE 4**  
**Personnel Requirements – Clinical Guidelines – Comparison of CA, ADA, and AAP-AAPD Guidelines (updated Sept. 2016)**

| California   | ADA Guidelines  | AAP-AAPD Guidelines   |
|--|---|---|
| <b>Minimal Sedation</b>  |   |   |
|  | At least one additional person trained in BLS + dentist.    | Children who have received minimal sedation generally will not require more than observation and intermittent assessment of their level of sedation. Some children will become moderately sedated despite the intended level of minimal sedation; should this occur, then the guidelines for moderate sedation apply.   |
| <b>Moderate Sedation</b>   |   |   |
| <p>BPC 1682</p> <p>Each patient is continuously monitored on a one-to-one ratio while sedated by either the dentist or another licensed health professional authorized by law to administer conscious sedation or general anesthesia.</p> <p>The patient must be closely monitored by licensed health professionals experienced in the care and resuscitation of patients recovering from conscious sedation or general anesthesia.</p> <p>If one licensed professional is responsible for the recovery care of more than one patient at a time, all of the patients shall be physically in the same room to allow continuous visual contact with all patients and the patient to recovery staff ratio should not exceed three to one.</p> <p>Staff must be certified in basic cardiac life support (CPR) and recertified.</p> | At least one person trained in BLS for providers + dentist. | <p>The use of moderate sedation shall include provision of a person, in addition to the practitioner, whose responsibility is to monitor appropriate physiologic parameters and to assist in any supportive or resuscitation measures, if required. This individual may also be responsible for assisting with interruptible patient-related tasks of short duration, such as holding an instrument or troubleshooting equipment. This individual should be trained in and capable of providing advanced airway skills (eg, PALS). The support person shall have specific assignments in the event of an emergency and current knowledge of the emergency cart inventory.</p> <p>The practitioner and all ancillary personnel should participate in periodic reviews, simulation of rare emergencies, and practice drills of the facility’s emergency protocol to ensure proper function of the equipment and coordination of staff roles in such emergencies.</p> <p>It is recommended that at least one practitioner be skilled in obtaining vascular access in children.</p> |

### Moderate Sedation (continued)

A qualified dentist administering moderate sedation must remain in the operatory room to monitor the patient continuously until the patient meets the criteria for recovery. When active treatment concludes and the patient recovers to a minimally sedated level, a qualified auxiliary may be directed by the dentist to remain with the patient and continue to monitor them as explained in the guidelines until they are discharged from the facility. The dentist must not leave the facility until the patient meets the criteria for discharge and is discharged from the facility.

A dedicated and properly equipped recovery area is recommended (see Appendices 3 and 4). The time and condition of the child at discharge from the treatment area or facility shall be documented, which should include documentation that the child's level of consciousness and oxygen saturation in room air have returned to a state that is safe for discharge by recognized criteria. Patients receiving supplemental oxygen before the procedure should have a similar oxygen need after the procedure.

Because some sedation medications are known to have a long half-life and may delay a patient's complete return to baseline or pose the risk of re-sedation and because some patients will have complex multiorgan medical conditions, a longer period of observation in a less intense observation area (e.g., a step-down observation area) before discharge from medical/dental supervision may be indicated. Several scales to evaluate recovery have been devised and validated. A simple evaluation tool may be the ability of the infant or child to remain awake for at least 20 minutes when placed in a quiet environment.

### Deep Sedation/General Anesthesia

Same as moderate sedation

A minimum of three (3) individuals must be present.

- A dentist qualified in accordance with Part III. C. of these Guidelines to administer the deep sedation or general anesthesia.
- Two additional individuals who have current certification of successfully completing a Basic Life Support (BLS) Course for the Healthcare Provider.
- When the same individual administering the deep sedation or general anesthesia is performing the dental procedure, one of the additional appropriately trained team members must be designated for patient monitoring.

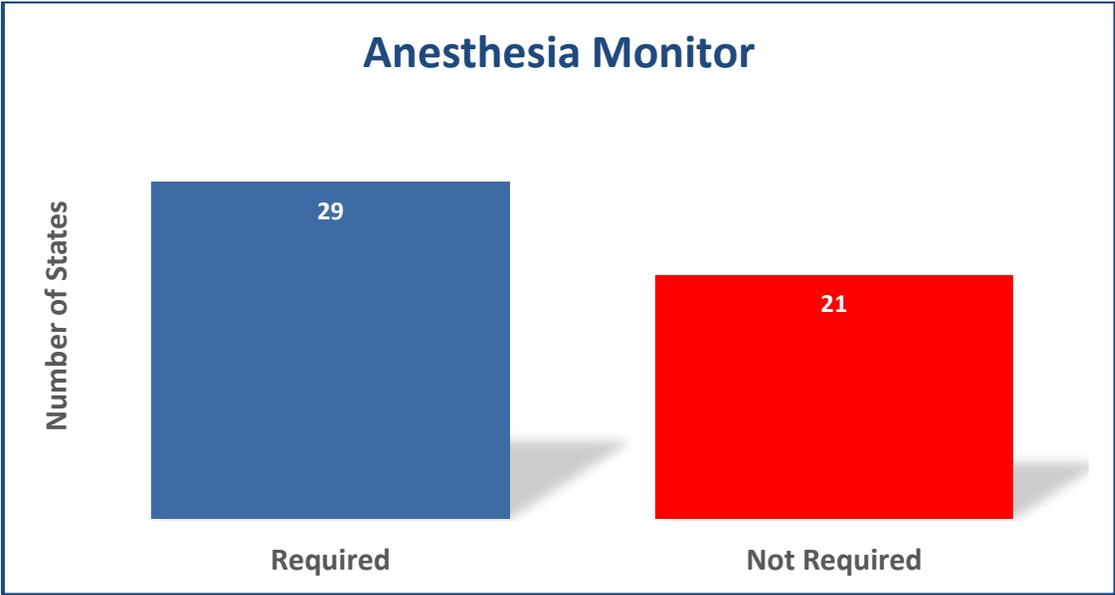
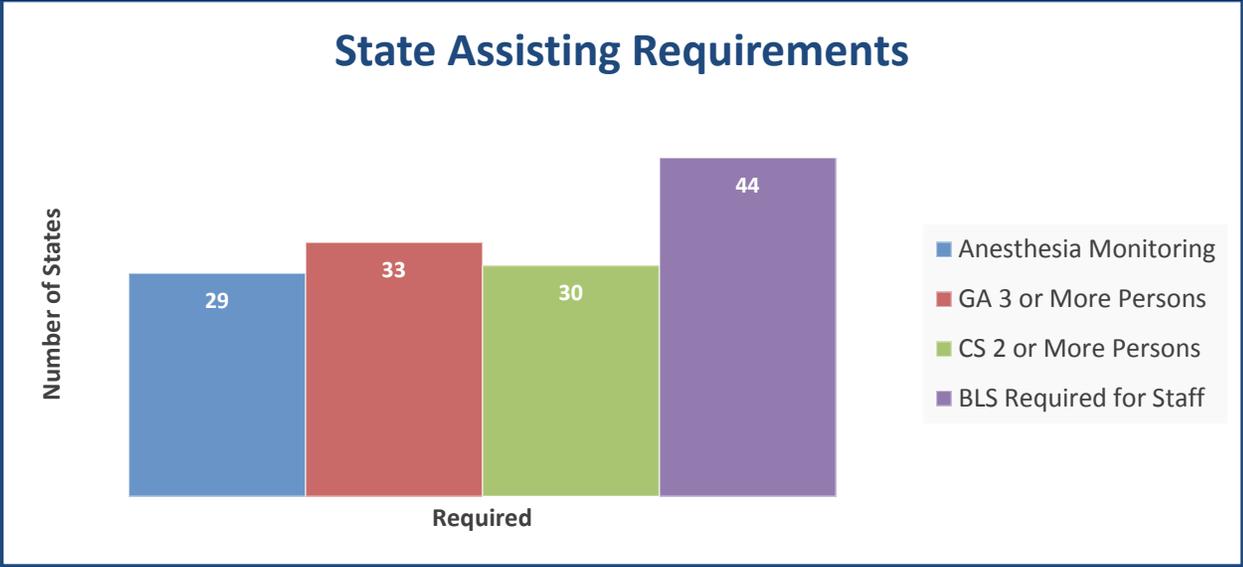
A qualified dentist administering deep sedation or general anesthesia must remain in the operatory room to monitor the patient continuously until the patient meets the criteria for recovery. The dentist must not leave the facility until the patient meets the criteria for discharge and is discharged from the facility.

During deep sedation, there must be one person whose only responsibility is to constantly observe the patient's vital signs, airway patency, and adequacy of ventilation and to either administer drugs or direct their administration. This individual must, at a minimum, be trained in PALS and capable of assisting with any emergency event. At least one individual must be present who is trained in and capable of providing advanced pediatric life support and who is skilled to rescue a child with apnea, laryngospasm, and/or airway obstruction.

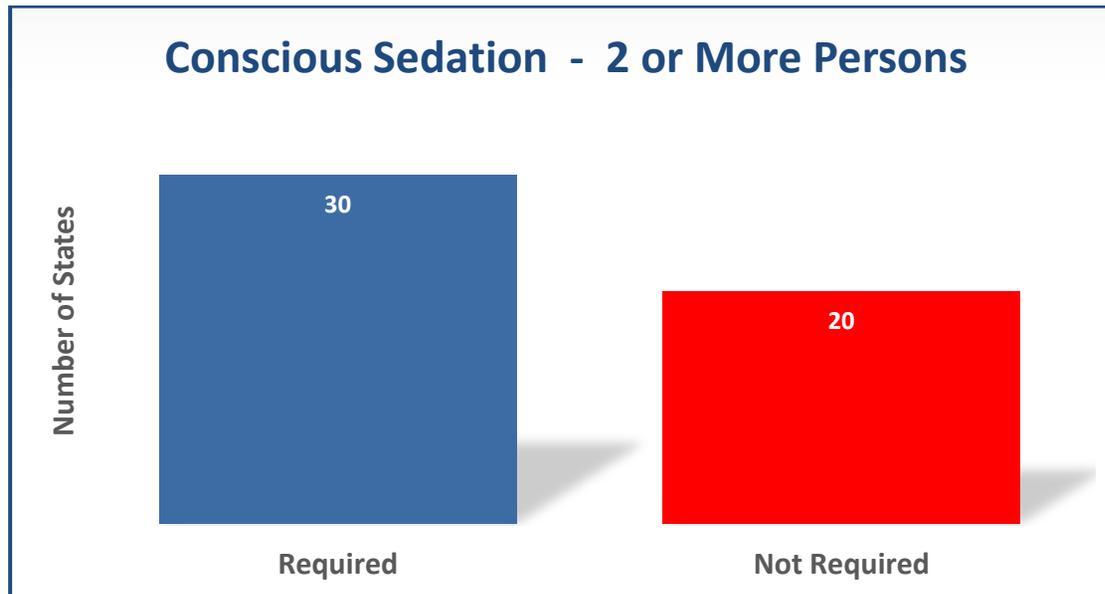
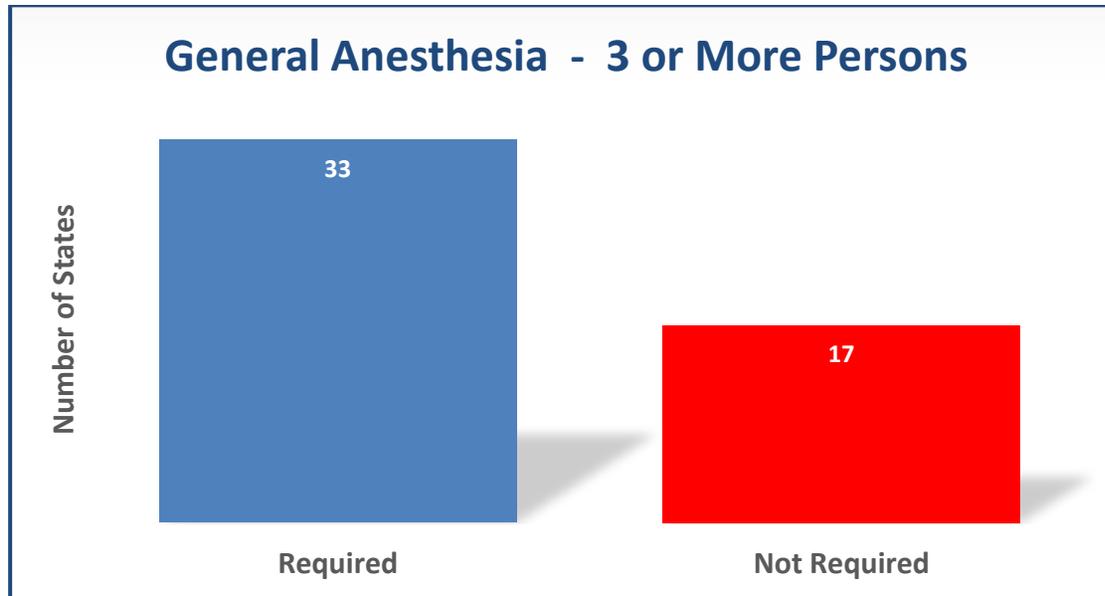
Required skills include the ability to open the airway, suction secretions, provide CPAP, insert supraglottic devices (oral airway, nasal trumpet, LMA), and perform successful bag-valve-mask ventilation, tracheal intubation, and cardiopulmonary resuscitation.

(updated to 2016 Guidelines)

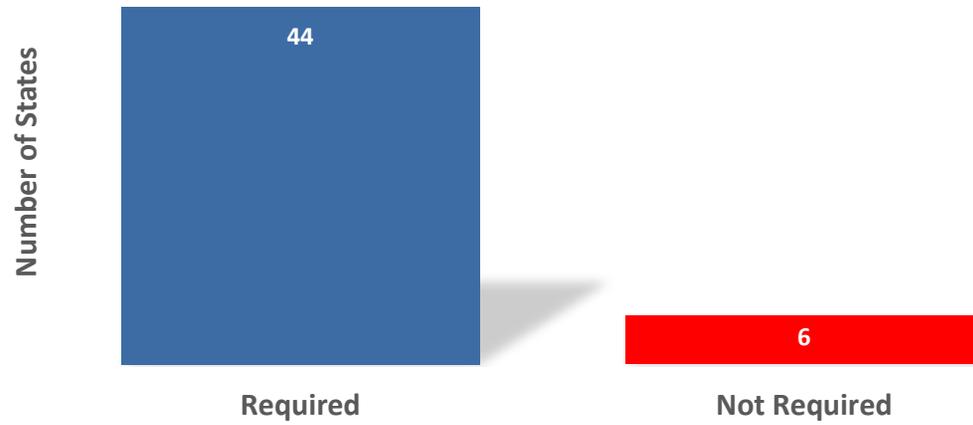
# Sedation and Anesthesia Assisting Requirements in the 50 States



# Sedation and Anesthesia Assisting Requirements in the 50 States



## BLS Required For Staff





**TABLE 5**  
**Facility Requirements — Clinical Guidelines — Comparison of California, ADA and AAP-AAPD Guidelines**

| California Requirements   | ADA Guidelines  | AAP-AAPD Guidelines   |
|---|---|---|
| <p><b>Facilities</b><br/>           See CCR 1044.5 Facility and Equipment Standards – these are the same for all levels of sedation and anesthesia.</p> <p>(a) Office Facilities and Equipment. The following office facilities and equipment shall be available and shall be maintained in good operating condition:</p> <ol style="list-style-type: none"> <li>(1) An operating theater large enough to adequately accommodate the patient on a table or in an operating chair and permit an operating team consisting of at least three individuals to freely move about the patient.</li> <li>(2) An operating table or chair which permits the patient to be positioned so the operating team can maintain the airway, quickly alter patient position in an emergency, and provide a firm platform for the management of cardiopulmonary resuscitation.</li> <li>(3) A lighting system which is adequate to permit evaluation of the patient’s skin and mucosal color and a backup lighting system which is battery powered and of sufficient intensity to permit completion of any operation underway at the time of general power failure.</li> <li>(4) Suction equipment which permits aspiration of the oral and pharyngeal cavities. A backup suction device which can operate at the time of general power failure must also be available.</li> <li>(5) An oxygen delivery system with adequate full face masks and appropriate connectors that is capable of allowing the administering of greater than 90% oxygen at a 10 liter/minute flow at least sixty minutes (650 liter “E” cylinder) to the patient under positive pressure, together with an adequate backup system which can operate at the time of general power failure.</li> <li>(6) A recovery area that has available oxygen, adequate lighting, suction, and electrical outlets. The recovery area can be the operating theater.</li> </ol> | <p>Facility requirements not specifically stated, except as listed under equipment requirements below.</p> <p>A positive-pressure oxygen delivery system suitable for the patient being treated must be immediately available.</p> <ul style="list-style-type: none"> <li>• When inhalation equipment is used, it must have a fail-safe system that is appropriately checked and calibrated. The equipment must also have either (1) a functioning device that prohibits the delivery of less than 30% oxygen or (2) an appropriately calibrated and functioning in-line oxygen analyzer with audible alarm.</li> <li>• An appropriate scavenging system must be available if gases other than oxygen or air are used.</li> </ul> | <p><b>Facilities</b><br/>           The practitioner who uses sedation must have immediately available facilities, personnel, and equipment to manage emergency and rescue situations. The most common serious complications of sedation involve compromise of the airway or depressed respirations resulting in airway obstruction, hypoventilation, hypoxemia, and apnea. Hypotension and cardiopulmonary arrest may occur, usually from inadequate recognition and treatment of respiratory compromise. Other rare complications may also include seizures and allergic reactions. Facilities providing pediatric sedation should monitor for, and be prepared to treat, such complications.</p> |



**TABLE 6**

**Monitoring and Equipment — Clinical Guidelines for Minimal Sedation, Moderate Sedation, Deep Sedation, and General Anesthesia**

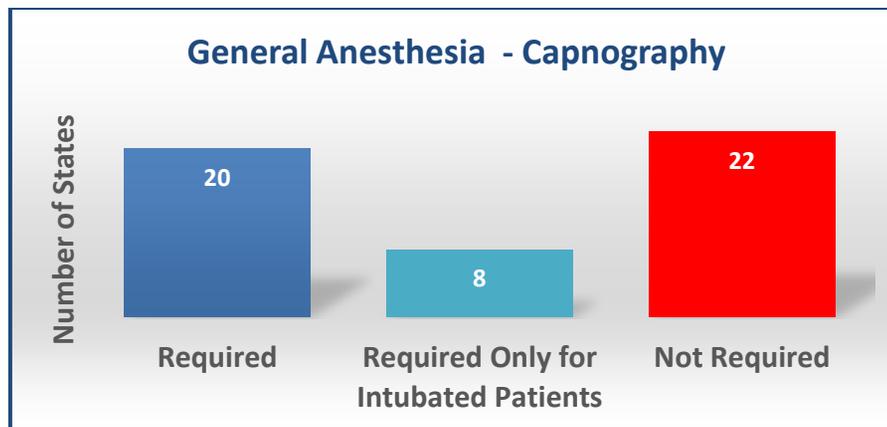
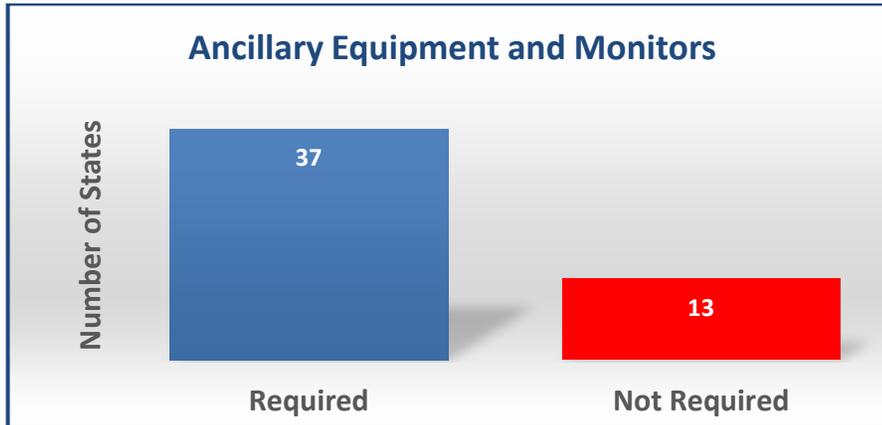
| California Requirements  | ADA Guidelines  | AAP-AAPD Guidelines  |
|--|---|--|
| Oral Conscious Sedation  | Minimal Sedation  | All Levels of Sedation   |
| <p>CCR 1044: An emergency cart or kit shall be available and readily accessible and shall include the necessary and appropriate drugs and age- and size-appropriate equipment to resuscitate a nonbreathing and unconscious patient and provide continuous support while the patient is transported to a medical facility. There must be documentation that all emergency equipment and drugs are checked and maintained on a prudent and regularly scheduled basis.</p> <p>Ancillary equipment, which must include the following, and be maintained in good operating condition:</p> <ol style="list-style-type: none"> <li>(1) Age-appropriate oral airways capable of accommodating patients of all sizes.</li> <li>(2) An age-appropriate sphygmomanometer with cuffs of appropriate size for patients of all sizes.</li> <li>(3) A precordial/pretracheal stethoscope.</li> <li>(4) A pulse oximeter</li> </ol> | <p><b>Monitoring:</b><br/>A dentist, or at the dentist’s direction an appropriately trained individual, must remain in the operatory during active dental treatment to monitor the patient continuously until the patient meets the criteria for discharge to the recovery area. The appropriately trained individual must be familiar with monitoring techniques and equipment. Monitoring must include:</p> <p><b>Oxygenation:</b></p> <ul style="list-style-type: none"> <li>• Color of mucosa, skin or blood must be evaluated continually.</li> <li>• Oxygen saturation by pulse oximetry may be clinically useful and should be considered.</li> </ul> <p><b>Ventilation:</b></p> <ul style="list-style-type: none"> <li>• The dentist and/or appropriately trained individual must observe chest excursions continually.</li> <li>• The dentist and/or appropriately trained individual must verify respirations continually.</li> </ul> <p><b>Circulation:</b></p> <ul style="list-style-type: none"> <li>• Blood pressure and heart rate should be evaluated pre-operatively, post-operatively and intra-operatively as necessary (unless the patient is unable to tolerate such monitoring).</li> </ul> | <p><b>On-site monitoring and rescue equipment</b><br/>An emergency cart or kit must be immediately accessible. This cart or kit must contain equipment to provide the necessary age- and size-appropriate drugs and equipment to resuscitate a non breathing and unconscious child. The contents of the kit must allow for the provision of continuous life support while the patient is being transported to a medical facility or to an-other area within a medical facility.</p> <p>All equipment and drugs must be checked and maintained on a scheduled basis (see Appendices C and D for suggested drugs and emergency life support equipment to consider before the need for rescue occurs). Monitoring devices, such as electrocardiography (ECG) machines, pulse oximeters (with size-appropriate oximeter probes), end-tidal carbon dioxide monitors, and defibrillators (with size-appropriate defibrillator paddles), must have a safety and function check on a regular basis as required by local or state regulation.</p> |

| Conscious Sedation   | Moderate Sedation  |  |
|--|--|--|
| <p>BPC 1682(c) Acts constituting unprofessional conduct:</p> <p>Any dentist with patients who are undergoing conscious sedation to fail to have these patients continuously monitored during the dental procedure with a pulse oximeter or similar or superior equipment required by the board.</p> <p>BPC 1043.3</p> <p>(7) Ancillary equipment, which must include the following maintained in good operating condition:</p> <p>(A) Laryngoscope complete with adequate selection of blades and spare batteries and bulb. (This equipment is not required for conscious sedation.)</p> <p>(B) Endotracheal tubes and appropriate connectors. (This equipment is not required for conscious sedation.)</p> <p>(C) Emergency airway equipment (oral airways, laryngeal mask airways or combitubes, cricothyrotomy device).</p> <p>(D) Tonsillar or pharyngeal type suction tip adaptable to all office outlets.</p> <p>(E) Endotracheal tube forcep. (This equipment is not required for conscious sedation.)</p> <p>(F) Sphygmomanometer and stethoscope.</p> <p>(G) Electrocardioscope and defibrillator. (This equipment is not required for conscious sedation.)</p> <p>(H) Adequate equipment for the establishment of an intravenous infusion.</p> <p>(I) Precordial/pretracheal stethoscope.</p> <p>(J) Pulse oximeter.</p> <p>(K) Capnograph and temperature device. A capnograph and temperature measuring device are required for the intubated patient receiving general anesthesia. (This equipment is not required for conscious sedation.)</p> | <p><b>Monitoring:</b></p> <p>A qualified dentist administering moderate sedation must remain in the operating room to monitor the patient continuously until the patient meets the criteria for recovery. When active treatment concludes and the patient recovers to a minimally sedated level a qualified auxiliary may be directed by the dentist to remain with the patient and continue to monitor them as explained in the guidelines until they are discharged from the facility. The dentist must not leave the facility until the patient meets the criteria for discharge and is discharged from the facility. Monitoring must include:</p> <p><b>Consciousness:</b></p> <ul style="list-style-type: none"> <li>• Level of consciousness (e.g., responsiveness to verbal command) must be continually assessed.</li> </ul> <p><b>Oxygenation:</b></p> <ul style="list-style-type: none"> <li>• Color of mucosa, skin or blood must be evaluated continually.</li> <li>• Oxygen saturation must be evaluated by pulse oximetry continuously.</li> </ul> <p><b>Ventilation:</b></p> <ul style="list-style-type: none"> <li>• The dentist must observe chest excursions continually.</li> <li>• The dentist must monitor ventilation. This can be accomplished by auscultation of breath sounds, monitoring end-tidal CO<sub>2</sub> or by verbal communication with the patient.</li> </ul> <p><b>Circulation:</b></p> <ul style="list-style-type: none"> <li>• The dentist must continually evaluate blood pressure and heart rate (unless the patient is unable to tolerate and this is noted in the time-oriented anesthesia record).</li> <li>• Continuous ECG monitoring of patients with significant cardiovascular disease should be considered.</li> </ul> | <p>There shall be continuous monitoring of oxygen saturation and heart rate; when bidirectional verbal communication between the provider and patient is appropriate and possible (ie, patient is developmentally able and purposefully communicates), monitoring of ventilation by (1) capnography (preferred) or (2) amplified, audible pretracheal stethoscope (eg, Bluetooth technology) or precordial stethoscope is strongly recommended. If bidirectional verbal communication is not appropriate or not possible, monitoring of ventilation by capnography (preferred), amplified, audible pretracheal stethoscope, or precordial stethoscope is required.</p> <p>S = Size-appropriate suction catheters and a functioning suction apparatus (eg, Yankauer-type suction).</p> <p>O = An adequate oxygen supply and functioning flow meters/other devices to allow its delivery.</p> <p>A = Airway: size-appropriate airway equipment [nasopharyngeal and oropharyngeal airways, LMA, laryngoscope blades (checked and functioning), endotracheal tubes, stylets, face mask, bag-valve-mask or equivalent device (functioning).</p> <p>P = Pharmacy: all the basic drugs needed to support life during an emergency, including antagonists as indicated.</p> <p>M = Monitors: functioning pulse oximeter with size-appropriate oximeter probes and other monitors as appropriate for the procedure (eg, noninvasive blood pressure, end-tidal carbon dioxide, ECG, stethoscope).</p> <p>E = Special equipment or drugs for a particular case (e.g., defibrillator).</p> <p><b>Intravenous Equipment</b></p> <p>Assorted IV catheters (eg, 24-, 22-, 20-, 18-, 16-gauge)</p> <p>Tourniquets</p> <p>Alcohol wipes</p> <p>Adhesive tape</p> <p>Assorted syringes (eg, 1-, 3-, 5-, 10-mL)</p> <p>IV tubing</p> <p>Pediatric drip (60 drops/mL)</p> <p>Pediatric burette</p> <p>Adult drip (10 drops/mL)</p> <p>Extension tubing</p> <p>3-way stopcocks</p> <p>IV fluid</p> <p>Lactated Ringer solution</p> <p>Normal saline solution</p> <p>D5 0.25 normal saline solution</p> <p>Pediatric IV boards</p> |

| Conscious Sedation | Moderate Sedation |   |
|--------------------|-------------------|---|
|                    |                   | <p><b>Intravenous Equipment (continued)</b><br/> Assorted IV needles (eg, 25-, 22-, 20-, and 18-gauge)<br/> Intraosseous bone marrow needle<br/> Sterile gauze pads</p> <p><b>Airway Management Equipment</b><br/> Face masks (infant, child, small adult, medium adult, large adult)<br/> Breathing bag and valve set<br/> Oropharyngeal airways (infant, child, small adult, medium adult, large adult)<br/> Nasopharyngeal airways (small, medium, large)<br/> Laryngeal mask airways (1, 1.5, 2, 2.5, 3, 4, and 5)<br/> Laryngoscope handles (with extra batteries)<br/> Laryngoscope blades (with extra light bulbs)<br/> Straight (Miller) No. 1, 2, and 3<br/> Curved (Macintosh) No. 2 and 3<br/> Endotracheal tubes (2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5, and 6.0 uncuffed and 6.0, 7.0, and 8.0 cuffed)<br/> Stylettes (appropriate sizes for endotracheal tubes)<br/> Surgical lubricant<br/> Suction catheters (appropriate sizes for endotracheal tubes) Yankauer-type suction<br/> Nasogastric tubes<br/> Nebulizer with medication kits<br/> Gloves (sterile and nonsterile, latex free)</p> <p>† The choice of emergency equipment may vary according to individual or procedural needs.</p> <p>‡ The practitioner is referred to the SOAPME acronym describe</p> |

| Conscious (Moderate) Sedation and General Anesthesia  | Deep Sedation or General Anesthesia  | Deep Sedation  |
|---|--|--|
| <p>BPC 1682(c) Acts constituting unprofessional conduct: Any dentist with patients who are undergoing conscious sedation to fail to have these patients continuously monitored during the dental procedure with a pulse oximeter or similar or superior equipment required by the board.</p> <p>BPC 1043.3 Onsite inspections</p> <p>The following office facilities and equipment shall be available and shall be maintained in good operating condition:</p> <p>Ancillary equipment, which must include the following maintained in good operating condition:</p> <p>Ancillary Equipment:</p> <ul style="list-style-type: none"> <li>(K) Laryngoscope complete with adequate selection of blades and spare batteries and bulb. (This equipment is not required for conscious sedation.)</li> <li>(L) Endotracheal tubes and appropriate connectors. (This equipment is not required for conscious sedation.)</li> <li>(M) Emergency airway equipment (oral airways, laryngeal mask airways or combitubes, cricthyrotomy device).</li> <li>(N) Tonsillar or pharyngeal type suction tip adaptable to all office outlets.</li> <li>(O) Endotracheal tube forcep. (This equipment is not required for conscious sedation.)</li> <li>(P) Sphygmomanometer and stethoscope.</li> <li>(Q) Electrocardioscope and defibrillator. (This equipment is not required for conscious sedation.)</li> <li>(R) Adequate equipment for the establishment of an intravenous infusion.</li> <li>(S) Precordial/pretracheal stethoscope.</li> <li>(T) Pulse oximeter.</li> <li>(K) Capnograph and temperature device. A capnograph and temperature measuring device are required for the intubated patient receiving general anesthesia. (This equipment is not required for conscious sedation.)</li> </ul> | <p><b>Monitoring:</b></p> <p>A qualified dentist administering deep sedation or general anesthesia must remain in the operatory room to monitor the patient continuously until the patient meets the criteria for recovery. The dentist must not leave the facility until the patient meets the criteria for discharge and is discharged from the facility. Monitoring must include:</p> <p><b>Oxygenation:</b></p> <ul style="list-style-type: none"> <li>• Color of mucosa, skin or blood must be continually evaluated.</li> <li>• Oxygenation saturation must be evaluated continuously by pulse oximetry.</li> </ul> <p>Ventilation:</p> <ul style="list-style-type: none"> <li>• Intubated patient: End-tidal CO2 must be continuously monitored and evaluated.</li> <li>• Non-intubated patient: Breath sounds via auscultation and/or end-tidal CO2 must be continually monitored and evaluated.</li> <li>• Respiration rate must be continually monitored and evaluated.</li> </ul> <p><b>Circulation:</b></p> <ul style="list-style-type: none"> <li>• The dentist must continuously evaluate heart rate and rhythm via ECG throughout the procedure, as well as pulse rate via pulse oximetry.</li> <li>• The dentist must continually evaluate blood pressure.</li> </ul> <p><b>Temperature:</b></p> <ul style="list-style-type: none"> <li>• A device capable of measuring body temperature must be readily available during the administration of deep sedation or general</li> </ul> <p><b>Anesthesia:</b></p> <ul style="list-style-type: none"> <li>• The equipment to continuously monitor body temperature should be available and must be performed whenever triggering agents associated with malignant hyperthermia are administered</li> </ul> <p>An intravenous line, which is secured throughout the procedure, must be established except as provided in part IV. C.6. Pediatric and Special Needs Patients.</p> | <p><b>Equipment</b></p> <p>In addition to the equipment previously cited for moderate sedation, an electrocardiographic monitor and a defibrillator for use in pediatric patients should be readily available.</p> <p>Monitoring shall include all parameters described for moderate sedation.</p> <p>Vital signs, including heart rate, respiratory rate, blood pressure, oxygen saturation, and expired carbon dioxide, must be documented at least every 5 minutes in a time-based record. Capnography should be used for almost all deeply sedated children because of the increased risk of airway/ventilation compromise. Capnography may not be feasible if the patient is agitated or uncooperative during the initial phases of sedation or during certain procedures, such as bronchoscopy or repair of facial lacerations, and this circumstance should be documented. For uncooperative children, the capnography monitor may be placed once the child becomes sedated. Note that if supplemental oxygen is administered, the capnograph may underestimate the true expired carbon dioxide value; of more importance than the numeric reading of exhaled carbon dioxide is the assurance of continuous respiratory gas exchange (ie, continuous waveform).</p> <p>Patients should have intravenous access established at the beginning of the procedure or have someone available who can do this.</p> |

## State Requirements



## Incremental Monitoring Requirements

Number of States



VS Reorded at 5  
min. Intervals



Time Interval Not  
Specified



Time Recording Not  
Specified

**TABLE 7**

**Record Requirements — Clinical Guidelines for Minimal Sedation, Moderate Sedation, Deep Sedation, and General Anesthesia**

| California Record Requirements   | ADA Guidelines   | AAP-AAPD Guidelines   |
|--|--|---|
| <b>Oral (Moderate) Conscious Sedation</b>  | <b>Minimal Sedation</b>  | <b>All Levels of Sedation</b>   |
| <p>Oral conscious sedation records shall include baseline vital signs. If obtaining baseline vital signs is prevented by the patient’s physical resistance or emotional condition, the reason or reasons must be documented. The records shall also include intermittent quantitative monitoring and recording of oxygen saturation, heart and respiratory rates, blood pressure as appropriate for specific techniques, the name, dose, and time of administration of all drugs administered including local and inhalation anesthetics, the length of the procedure, any complications of oral sedation, and a statement of the patient’s condition at the time of discharge. (CCR 1044.5)</p> | <p><b>Documentation:</b><br/>An appropriate sedative record must be maintained, including the names of all drugs administered, including local anesthetics, dosages, and monitored physiological parameters.</p> | <p><b>Documentation prior to treatment — see pre-operative evaluation</b></p> <p><b>Documentation during treatment</b><br/>The patient’s chart shall contain a time-based record that includes the name, route, site, time, dosage, and patient effect of administered drugs. Before sedation, a “time out” should be performed to confirm the patient’s name, procedure to be performed, and site of the procedure.</p> <p>During administration, the inspired concentrations of oxygen and inhalation sedation agents and the duration of their administration shall be documented. Before drug administrations, special attention must be paid to calculation of dosage (ie, mg/kg).</p> <p>The patient’s chart shall contain documentation at the time of treatment that the patient’s level of consciousness and responsiveness, heart rate, blood pressure, respiratory rate, and oxygen saturation were monitored until the patient attained predetermined discharge criteria. A variety of sedation scoring systems are available and may aid this process. Adverse events and their treatment shall be documented.</p> <p><b>Documentation after treatment</b><br/>The time and condition of the child at discharge from the treatment area or facility shall be documented; this should include documentation that the child’s level of consciousness and oxygen saturation in room air have returned to a state that is safe for discharge by recognized criteria. Patients receiving supplemental oxygen before the procedure should have a similar oxygen need after the procedure. Because some sedation medications are known to have a long half-life and may delay the patient’s complete return to baseline of pose the risk of resedation, some patients might benefit from a longer period of less-intense observation (e.g., a step-down observation area) before discharge from medical supervision.<sup>133</sup> Several scales to evaluate recovery have been devised and validated. A recently described and simple evaluation tool may be the ability of the infant or child to remain awake for at least 20 minutes when placed in a quiet environment.</p> |

| Conscious Sedation and General Anesthesia  | Moderate Sedation   |  |
|--|---|--|
| <p>The following records shall be maintained:</p> <p>(2) General anesthesia and/or conscious sedation records, which shall include a time-oriented record with preoperative, multiple intraoperative pulse oximetry (every 5 minutes intraoperatively and every 15 minutes postoperatively for general anesthesia) and blood pressure and pulse readings, (both every 5 minutes intraoperatively for general anesthesia) drugs, amounts administered and time administered, length of the procedure, any complications of anesthesia or sedation and a statement of the patient's condition at time of discharge. (CCR 1043.3)</p> | <p><b>Documentation:</b><br/>Appropriate time-oriented anesthetic record must be maintained, including the names of all drugs, dosages, and their administration times, including local anesthetics, dosages, and monitored physiological parameters. (See Additional Sources of Information for sample of a time-oriented anesthetic record.)</p> <ul style="list-style-type: none"> <li>• Pulse oximetry, heart rate, respiratory rate, blood pressure and level of consciousness must be recorded continually.</li> </ul>                    |  |
|  | Deep Sedation or General Anesthesia   |  |
|  | <p><b>Documentation:</b><br/>Appropriate time-oriented anesthetic record must be maintained, including the names of all drugs, dosages and their administration times, including local anesthetics and monitored physiological parameters. (See Additional Sources of Information for sample of a time-oriented anesthetic record.)</p> <ul style="list-style-type: none"> <li>• Pulse oximetry and end-tidal CO<sub>2</sub> measurements (if taken), heart rate, respiratory rate, and blood pressure must be recorded continually.</li> </ul> |  |

**TABLE 8**

**Emergency drugs — California sedation laws compared to ADA and ADA-AAPD Guidelines**

| California — Required Emergency Drugs  | ADA Guidelines  | AAP-AAPD Guidelines   |
|--|---|---|
| <p><b>Pediatric and Adult Oral Conscious Sedation (CCR 1044.5)</b></p>   | <p><b>Minimal Sedation</b></p>  | <p><b>All Levels of Sedation</b></p>  |
| <p>An emergency cart or kit shall be available and readily accessible and shall include the necessary and appropriate drugs and age- and size-appropriate equipment to resuscitate a nonbreathing and unconscious patient and provide continuous support while the patient is transported to a medical facility. There must be documentation that all emergency equipment and drugs are checked and maintained on a prudent and regularly scheduled basis. Emergency drugs of the following types shall be available:</p> <ul style="list-style-type: none"> <li>(1) Epinephrine</li> <li>(2) Bronchodilator</li> <li>(3) Appropriate drug antagonists</li> <li>(4) Antihistaminic</li> <li>(5) Anticholinergic</li> <li>(6) Anticonvulsant</li> <li>(7) Oxygen</li> <li>(8) Dextrose or other antihypoglycemic</li> </ul> | <p>The qualified dentist is responsible for the sedative management, adequacy of the facility and staff, diagnosis and treatment of emergencies related to the administration of minimal sedation and providing the equipment and protocols for patient rescue.</p> | <p>Appendix C. Drugs That May Be Needed to Rescue a Sedated Patient*</p> <ul style="list-style-type: none"> <li>Albuterol for inhalation</li> <li>Ammonia spirits</li> <li>Atropine</li> <li>Diphenhydramine</li> <li>Diazepam</li> <li>Epinephrine (1:1000, 1:10 000)</li> <li>Flumazenil</li> <li>Glucose (25 percent or 50 percent)</li> <li>Lidocaine (cardiac lidocaine, local infiltration)</li> <li>Lorazepam</li> <li>Methylprednisolone</li> <li>Naloxone</li> <li>Oxygen</li> <li>Fosphenytoin</li> <li>Racemic epinephrine</li> <li>Rocuronium</li> <li>Sodium bicarbonate</li> <li>Succinylcholine</li> </ul> <p>* The choice of emergency drugs may vary according to individual or procedural needs</p> |

| <b>Conscious Sedation<br/>and General Anesthesia (CCR 1043.3)</b>  | <b>Moderate Sedation</b>  |  |
|--|---|--|
| <p><b>Drugs:</b><br/>Emergency drugs of the following types shall be available:</p> <ul style="list-style-type: none"> <li>(1) Epinephrine</li> <li>(2) Vasopressor (other than epinephrine)</li> <li>(3) Bronchodilator</li> <li>(4) Muscle relaxant (This is not required for conscious sedation.)</li> <li>(5) Intravenous medication for treatment of cardiopulmonary arrest (This is not required for conscious sedation.)</li> <li>(6) Appropriate drug antagonist</li> <li>(7) Antihistaminic</li> <li>(8) Anticholinergic</li> <li>(9) Antiarrhythmic (This is not required for conscious sedation.)</li> <li>(10) Coronary artery vasodilator</li> <li>(11) Antihypertensive (This is not required for conscious sedation.)</li> <li>(12) Anticonvulsant</li> <li>(13) Oxygen</li> <li>(14) 50% dextrose or other antihypoglycemic</li> </ul> | <ul style="list-style-type: none"> <li>• The qualified dentist is responsible for the sedative management, adequacy of the facility and staff, diagnosis and treatment of emergencies related to the administration of moderate sedation and providing the equipment, drugs and protocol for patient rescue.</li> </ul> |  |
|  | <b>Deep Sedation General Anesthesia</b>   |  |
|  | <ul style="list-style-type: none"> <li>• The qualified dentist is responsible for the sedative management, adequacy of the facility and staff, diagnosis and treatment of emergencies related to the administration of moderate sedation and providing the equipment, drugs and protocol for patient rescue.</li> </ul> |  |

## **Table 9.**

### **State Mandated Office Inspection Requirement**

#### **California laws related to office inspections**

#### **Tables summarizing requirements in 50 states**

#### **California office inspection laws**

##### **General Anesthesia**

1646.4. (a) Prior to the issuance or renewal of a permit for the use of general anesthesia, the board may, at its discretion, require an onsite inspection and evaluation of the licentiate and the facility, equipment, personnel, and procedures utilized by the licentiate. The permit of any dentist who has failed an onsite inspection and evaluation shall be automatically suspended 30 days after the date on which the board notifies the dentist of the failure, unless within that time period the dentist has retaken and passed an onsite inspection and evaluation. Every dentist issued a permit under this article shall have an onsite inspection and evaluation at least once every five years. Refusal to submit to an inspection shall result in automatic denial or revocation of the permit.

(b) The board may contract with public or private organizations or individuals expert in dental outpatient general anesthesia to perform onsite inspections and evaluations. The board may not, however, delegate its authority to issue permits or to determine the persons or facilities to be inspected.

##### **Conscious Sedation**

1647.7. (a) Prior to the issuance or renewal of a permit to administer conscious sedation, the board may, at its discretion, require an onsite inspection and evaluation of the licentiate and the facility, equipment, personnel, and procedures utilized by the licentiate. The permit of any dentist who has failed an onsite inspection and evaluation shall be automatically suspended 30 days after the date on which the board notifies the dentist of the failure unless, within that time period, the dentist has retaken and passed an onsite inspection and evaluation. Every dentist issued a permit under this article shall have an onsite inspection and evaluation at least once in every six years. Refusal to submit to an inspection shall result in automatic denial or revocation of the permit.

(b) An applicant who has successfully completed the course required by Section 1647.3 may be granted a one-year temporary permit

by the board prior to the onsite inspection and evaluation. Failure to pass the inspection and evaluation shall result in the immediate and automatic termination of the temporary permit.

(c) The board may contract with public or private organizations or individuals expert in dental outpatient conscious sedation to perform onsite inspections and evaluations. The board may not, however, delegate its authority to issue permits or to determine the persons or facilities to be inspected.

#### **16 CCR § 1043.3**

### **§ 1043.3. Onsite Inspections.**

Also see CCR 1043, 1043.2, 1043.4, 1043.5, 1043.6, 1043.7, 1043.8

All offices in which general anesthesia or conscious sedation is conducted under the terms of this article shall, unless otherwise indicated, meet the standards set forth below. In addition, an office may in the discretion of the board be required to undergo an onsite inspection. For the applicant who administers in both an outpatient setting and at an accredited facility, the onsite must be conducted in an outpatient setting. The evaluation of an office shall consist of three parts:

(a) Office Facilities and Equipment. The following office facilities and equipment shall be available and shall be maintained in good operating condition:

(1) An operating theatre large enough to adequately accommodate the patient on a table or in an operating chair and permit an operating team consisting of at least three individuals to freely move about the patient.

(2) An operating table or chair which permits the patient to be positioned so the operating team can maintain the airway, quickly alter patient position in an emergency, and provide a firm platform for the management of cardiopulmonary resuscitation.

(3) A lighting system which is adequate to permit evaluation of the patient's skin and mucosal color and a backup lighting system which is battery powered and of sufficient intensity to permit completion of any operation underway at the time of general power failure.

(4) Suction equipment which permits aspiration of the oral and pharyngeal cavities. A backup suction device which can operate at the time of general power failure must also be available.

(5) An oxygen delivery system with adequate full face masks and appropriate connectors that is capable of allowing the administering of greater than 90% oxygen at a 10 liter/minute flow at least sixty minutes (650 liter "E" cylinder) to the patient under positive pressure, together with an adequate backup system which can operate at the time of general power failure.

(6) A recovery area that has available oxygen, adequate lighting, suction, and electrical outlets. The recovery area can be the operating theatre.

(7) Ancillary equipment:

(A) Laryngoscope complete with adequate selection of blades and spare batteries and bulb. (This equipment is not required for conscious sedation.)

(B) Endotracheal tubes and appropriate connectors. (This equipment is not required for conscious sedation.)

(C) Emergency airway equipment (oral airways, laryngeal mask airways or combitubes, cricothyrotomy device).

(D) Tonsillar or pharyngeal type suction tip adaptable to all office outlets.

(E) Endotracheal tube forcep. (This equipment is not required for conscious sedation.)

(F) Sphygmomanometer and stethoscope.

(G) Electrocardioscope and defibrillator. (This equipment is not required for conscious sedation.)

(H) Adequate equipment for the establishment of an intravenous infusion.

(I) Precordial/pretracheal stethoscope.

(J) Pulse oximeter.

(K) Capnograph and temperature device. A capnograph and temperature measuring device are required for the intubated patient receiving general anesthesia. (This equipment is not required for conscious sedation.)

(b) Records. The following records shall be maintained:

(1) Adequate medical history and physical evaluation records updated prior to each administration of general anesthesia or conscious sedation. Such records shall include, but are not limited to the recording of the age, sex, weight, physical status (American Society of Anesthesiologists Classification), medication use, any known or suspected medically compromising conditions, rationale for sedation of the patient, and visual examination of the airway, and for general anesthesia only, auscultation of the heart and lungs as medically required.

(2) General Anesthesia and/or conscious sedation records, which shall include a time-oriented record with preoperative, multiple intraoperative, and postoperative pulse oximetry (every 5 minutes intraoperatively and every 15 minutes postoperatively for general anesthesia) and blood pressure and pulse readings, (both every 5 minutes intraoperatively for general anesthesia) drugs, amounts administered and time administered, length of the procedure, any complications of anesthesia or sedation and a statement of the patient's condition at time of discharge.

(3) Written informed consent of the patient or if the patient is a minor, his or her parent or guardian.

(c) Drugs. Emergency drugs of the following types shall be available:

(1) Epinephrine

- (2) Vasopressor (other than epinephrine)
  - (3) Bronchodilator
  - (4) Muscle relaxant (This is not required for conscious sedation.)
  - (5) Intravenous medication for treatment of cardiopulmonary arrest (This is not required for conscious sedation.)
  - (6) Appropriate drug antagonist
  - (7) Antihistaminic
  - (8) Anticholinergic
  - (9) Antiarrhythmic (This is not required for conscious sedation.)
  - (10) Coronary artery vasodilator
  - (11) Antihypertensive (This is not required for conscious sedation.)
  - (12) Anticonvulsant
  - (13) Oxygen
  - (14) 50% dextrose or other antihypoglycemic
- (d) Prior to an onsite inspection and evaluation, the dentist shall provide a complete list of his/her emergency medications to the evaluator.
- Note: Authority cited: Section 1614, Business and Professions Code. Reference: Sections 1646.2, 1646.3, 1647.3 and 1647.6, Business and Professions Code.

#### HISTORY

- 1. Amendment filed 4-1-91; operative 5-1-91 (Register 91, No. 18).
  - 2. Editorial correction of subsection (a)(4) (Register 95, No. 16).
  - 3. Amendment filed 2-27-2006; operative 3-29-2006 (Register 2006, No. 9).
- This database is current through 7/1/16 Register 2016, No. 27  
 16 CCR § 1043.3, 16 CA ADC § 1043.3

### Oral Conscious Sedation

16 CCR § 1044.5

See also CCR sections 1044, 1044.1, 1044.2, 1043.3, 1044.4

#### § 1044.5. Facility and Equipment Standards.

A facility in which oral conscious sedation is administered to patients pursuant to this article shall meet the standards set forth below.

(a) Facility and Equipment.

- (1) An operatory large enough to adequately accommodate the patient and permit a team consisting of at least three individuals to freely move about the patient.
  - (2) A table or dental chair which permits the patient to be positioned so the attending team can maintain the airway, quickly alter patient position in an emergency, and provide a firm platform for the management of cardiopulmonary resuscitation.
  - (3) A lighting system which is adequate to permit evaluation of the patient's skin and mucosal color and a backup lighting system which is battery powered and of sufficient intensity to permit completion of any treatment which may be underway at the time of a general power failure.
  - (4) An appropriate functional suctioning device that permits aspiration of the oral and pharyngeal cavities. A backup suction device that can function at the time of general power failure must also be available.
  - (5) A positive-pressure oxygen delivery system capable of administering greater than 90% oxygen at a 10 liter/minute flow for at least sixty minutes (650 liter "E" cylinder), even in the event of a general power failure. All equipment must be age-appropriate and capable of accommodating the patients being seen at the permit-holder's office.
  - (6) Inhalation sedation equipment, if used in conjunction with oral sedation, must have the capacity for delivering 100%, and never less than 25%, oxygen concentration at a flow rate appropriate for an age appropriate patient's size, and have a fail-safe system. The equipment must be maintained and checked for accuracy at least annually.
- (b) Ancillary equipment, which must include the following, and be maintained in good operating condition:
- (1) Age-appropriate oral airways capable of accommodating patients of all sizes.
  - (2) An age-appropriate sphygmomanometer with cuffs of appropriate size for patients of all sizes.
  - (3) A precordial/pretracheal stethoscope.
  - (4) A pulse oximeter.
- (c) The following records shall be maintained:
- (1) An adequate medical history and physical evaluation, updated prior to each administration of oral conscious sedation. Such records shall include, but are not limited to, an assessment including at least visual examination of the airway, the age, sex, weight, physical status (American Society of Anesthesiologists Classification), and rationale for sedation of the minor patient as well as written informed consent of the patient or, as appropriate, parent or legal guardian of the patient.

(2) Oral conscious sedation records shall include baseline vital signs. If obtaining baseline vital signs is prevented by the patient's physical resistance or emotional condition, the reason or reasons must be documented. The records shall also include intermittent quantitative monitoring and recording of oxygen saturation, heart and respiratory rates, blood pressure as appropriate for specific techniques, the name, dose and time of administration of all drugs administered including local and inhalation anesthetics, the length of the procedure, any complications of oral sedation, and a statement of the patient's condition at the time of discharge.

(d) An emergency cart or kit shall be available and readily accessible and shall include the necessary and appropriate drugs and age- and size-appropriate equipment to resuscitate a nonbreathing and unconscious patient and provide continuous support while the patient is transported to a medical facility. There must be documentation that all emergency equipment and drugs are checked and maintained on a prudent and regularly scheduled basis. Emergency drugs of the following types shall be available:

- (1) Epinephrine
- (2) Bronchodilator
- (3) Appropriate drug antagonists
- (4) Antihistaminic
- (5) Anticholinergic
- (6) Anticonvulsant
- (7) Oxygen
- (8) Dextrose or other antihypoglycemic

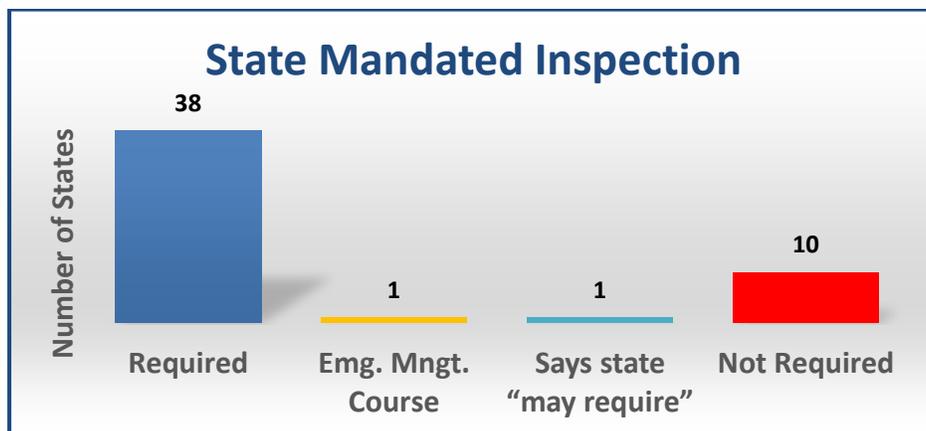
Note: Authority cited: Section 1614, Business and Professions Code. Reference: Sections 1647.10, 1647.16, 1647.22 and 1647.24, Business and Professions Code.

#### HISTORY

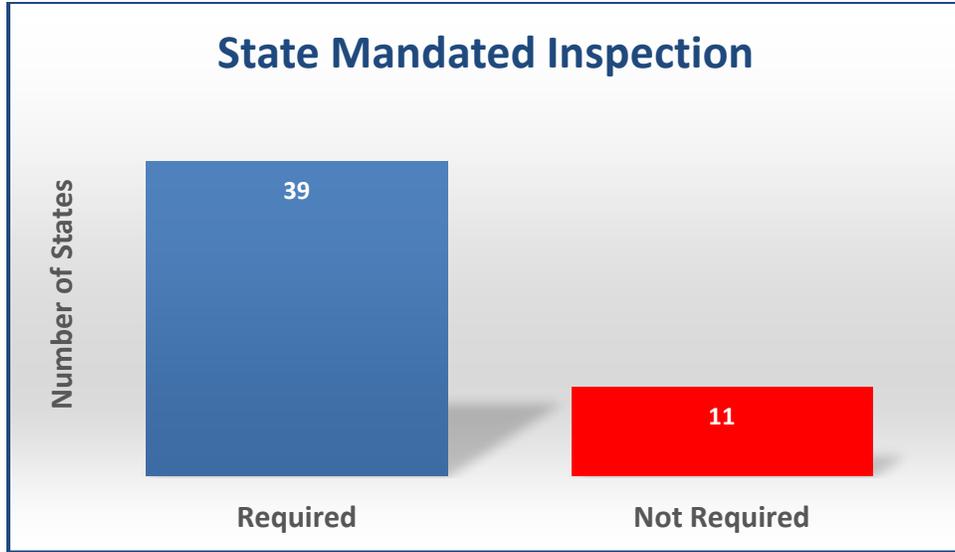
1. New section and new forms OCS-5 and OCS-3 filed 3-14-2000; operative 4-13-2000 (Register 2000, No. 11).
  2. Amendment of section and Note and repealer of printed forms (this action incorporates applicable forms within article 5.5 by reference) filed 12-13-2007; operative 12-13-2007 pursuant to Government Code section 11343.4 (Register 2007, No. 50). This database is current through 7/1/16 Register 2016, No. 27
- 16 CCR § 1044.5, 16 CA ADC § 1044.5

## Summary of Requirements in 50 states

### General Anesthesia Permits



## Moderate (Parenteral) Sedation Permit





**Table 10.**

**Pediatric Sedation Laws for the 50 States – Summary**

**Pediatric sedation requirements**

Individual states have taken different approaches to the regulation of pediatric sedation. Twenty five states, including California have special requirements for young patients. California requirements apply to patients age 13 or under. An increasing number of states have adopted pediatric sedation educational requirements, equipment requirements, and permits over the past 10 years. All states regulate moderate sedation and deep sedation/GA , regardless of route of administration.

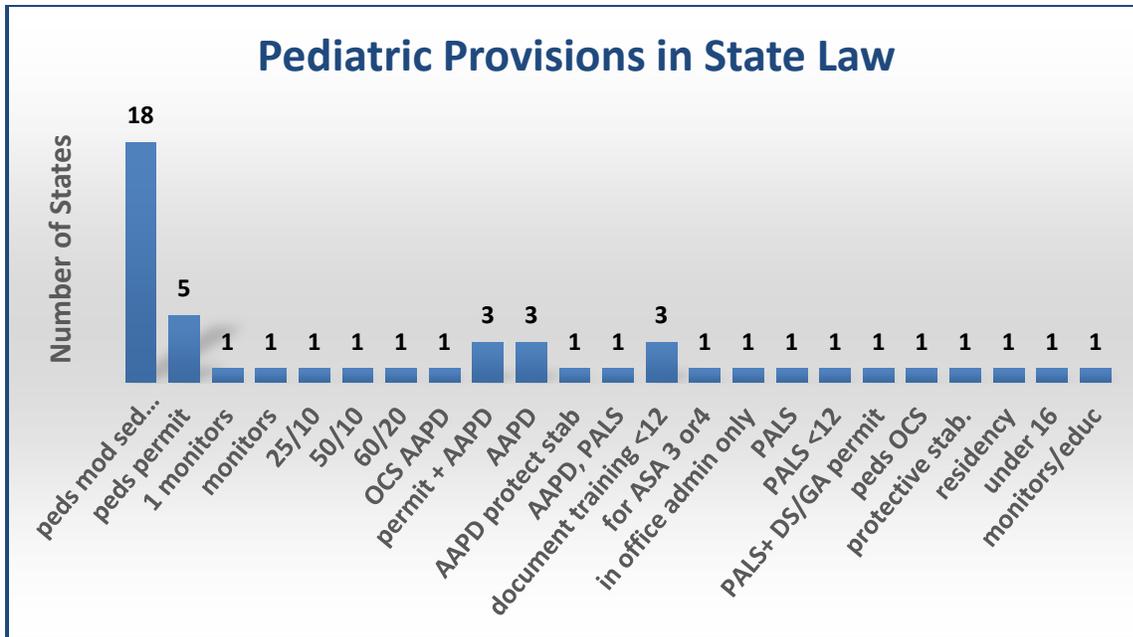
Ten states (California, Colorado, Florida, Georgia, Kentucky, Louisiana, Missouri, Mississippi, North Carolina and Oklahoma ) require permits for sedating pediatric patients.

Sixteen states require specific training, some in addition to adult sedation training, to administer moderate/conscious sedation to pediatric patients.

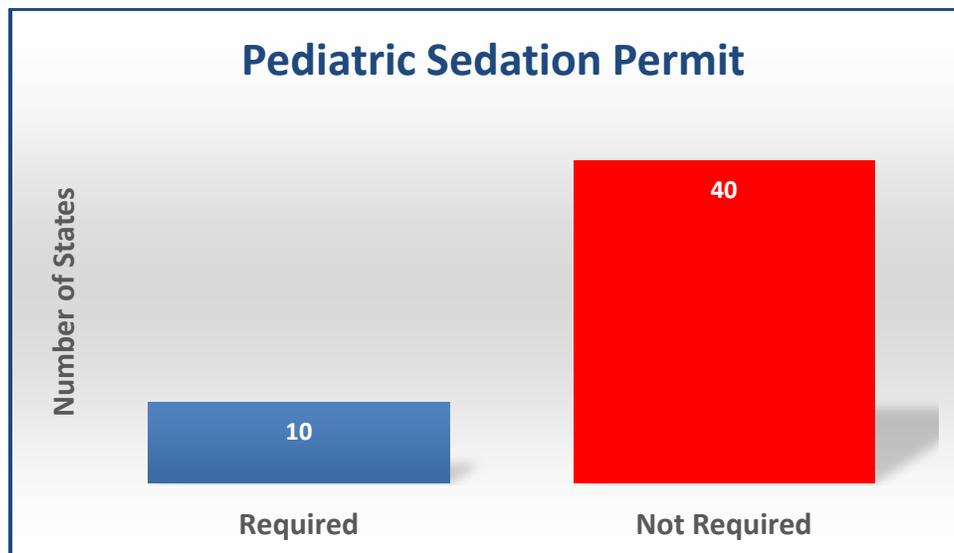
Approximately twenty nine states have specific requirements for pediatric sedation administered by the oral route.

States differ in their definition of the pediatric patient. Several states define the pediatric patient as being under the age of 12 consistent with ADA Guidelines; however other states use 13, 14, 16 and 18 years of age. Most states, including California, specify that the practitioner must have appropriately sized equipment for pediatric patients. In some states ACLS certification is deemed sufficient for treating pediatric patients; Twenty states currently require PALS certification. California does not presently require certification in PALS.

Although ten states have adopted the AAP-AAPD Guidelines, these usually apply to minimal and moderate sedation. Most states do not have specific requirements for the administration of deep sedation/general anesthesia to children.



OCS = oral conscious sedation; 25/10 etc. = classroom hours/supervised cases; PALS= pediatric advanced life support course; all numbers are approximate.







STATE OF CALIFORNIA



DEPARTMENT OF CONSUMER AFFAIRS

**BOARD OF CALIFORNIA**

**REPORT ON THE ELECTIVE FACIAL COSMETIC  
SURGERY PERMIT PROGRAM AS PROVIDED BY  
BUSINESS AND PROFESSIONS CODE SECTION 1638.1**

**SUBMITTED TO:**

**THE SENATE BUSINESS, PROFESSIONS AND  
ECONOMIC DEVELOPMENT COMMITTEE**

**JANUARY 1, 2017**

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## Introduction

The Dental Board of California (Board) is submitting this report on the Elective Facial Cosmetic Surgery (EFCS) Permit Program pursuant to Business and Professions Code (Code) Section 1638.1 (Senate Bill 438, Chapter 909, Statutes of 2006). The last report was submitted in January 2013, and statute requires additional reports to be submitted every four years thereafter.

On September 30, 2006, Governor Arnold Schwarzenegger signed Senate Bill 438, enacting Code Section 1638.1, which took effect on January 1, 2007. This statute authorizes Oral and Maxillofacial Surgeons licensed by the Board, who are not also licensed as physicians and surgeons by the Medical Board of California, to perform elective facial cosmetic surgery. Additionally, this statute specifies the application requirements for an EFCS permit and establishes a Credentialing Committee (Committee) to review the qualifications of each applicant for a permit.

Code Section 1638.1(e) provides for the establishment of a Committee to be appointed by the Board and specifies that the Committee be comprised of five members consisting of one (1) physician and surgeon with a specialty in plastic and reconstructive surgery, one (1) physician and surgeon with a specialty in otolaryngology, and three (3) oral and maxillofacial surgeons licensed by the Board who are board certified by the American Board of Oral and Maxillofacial Surgeon, all of whom must maintain active status on the staff of a licensed general acute care hospital in California. At its February 9, 2007 meeting, the Board appointed five members to the Committee. The Committee is responsible for reviewing applications for EFCS permits in closed session during Committee meetings and providing recommendations to the Board as to whether an applicant is qualified to be issued a permit.

Code Section 1638.1 specifies the application requirements to obtain an EFCS permit from the Board to perform procedures from the following categories:

- Category I: Cosmetic contouring of the osteocartilaginous facial structure which may include, but is not limited to, rhinoplasty and otoplasty.
- Category II: Cosmetic soft tissue contouring or rejuvenation, which may include, but is not limited to, facelift, blepharoplasty, facial skin resurfacing, or lip augmentation.

The Board may grant unlimited or limited permits upon recommendation of the Committee. An unlimited permit allows the licensee to perform Category I and Category II procedures as defined in B&P code section 1638.1(c)(2)(A)(iii)(I) and (II). A limited permit would limit the procedures that may be performed by the permit holder.

The Committee may recommend permit limitations if it is not satisfied that the applicant has the training or competence necessary to perform certain procedures, or if the applicant has not requested to be permitted for all procedures authorized in the statute. Permits may also be issued for Category I only, unlimited or limited; Category II only, unlimited or limited; or a combination of any of the above.

## Report

Code Section 1638.1(k) requires the Board to provide a report to the Joint Committee on Boards, Commissions, and Consumer Protection on January 1, 2009 and every four years thereafter. The report is required to contain information on all of the following:

1. The number of persons licensed pursuant to Section 1634 who apply to receive a permit to perform elective facial cosmetic surgery from the board pursuant to subdivision (a).
2. The recommendations of the credentialing committee to the board.
3. The board's action on recommendations received by the credentialing committee.
4. The number of persons receiving a permit from the board to perform elective facial cosmetic surgery.
5. The number of complaints filed by or on behalf of patients who have received elective facial cosmetic surgery by persons who have received a permit from the board to perform elective facial cosmetic surgery.
6. Action taken by the board resulting from complaints filed by or on behalf of patients who have received elective facial cosmetic surgery by persons who have received a permit from the board to perform elective facial cosmetic surgery.

The Board respectfully submits the following information as required by Code Section 1638.1(k):

**1. The number of persons licensed pursuant to Section 1634 who apply to receive a permit to perform elective facial cosmetic surgery from the Board pursuant to subdivision (a).**

The following table describes the status of applications submitted to the Board from 2013-2017. The applications that are carried over from previous years are most commonly due to application deficiencies.

In 2013 there were five (5) new applications received; four (4) were referred to the Committee for evaluation and four (4) were granted permits. One (1) has not gone before the Committee for review due to deficiencies.

In 2014 there were three (3) new applications received. Two (2) were referred to the Committee for evaluation; one (1) was granted a permit and one (1) was deemed deficient by the committee. One (1) did not go before the Committee for review due to deficiencies.

In 2015 there were three (3) new applications received. One (1) was referred to the Committee for evaluation and was granted a permit. Two (2) did not go before the Committee for review due to deficiencies.

In 2016 there were three (3) new applications received. Two (2) were referred to the Committee for evaluation; two (2) were granted permits and one (1) application was denied due to insufficient hospital privileges, insufficient operative reports, and an unclear letter from the program director specifying the procedures the applicant intended to perform with this permit.

**Table 1: Persons Applying for an EFCS Permit**

| <b>Application Status</b>                     | <b>2013</b> | <b>2014</b> | <b>2015</b> | <b>2016</b> |
|---|-------------|-------------|-------------|-------------|
| New applications received                     | 5           | 3           | 3           | 3           |
| Referred to Committee for Evaluation          | 4           | 2           | 1           | 2           |
| Permits Granted                               | 4           | 1           | 1           | 2           |
| Have not gone before the Committee for Review | 1           | 1           | 2           | 2           |
| Found Ineligible                              | 0           | 0           | 0           | 0           |
| Denied  | 0           | 0           | 0           | 1           |
| Committee Rejected application                | 0           | 0           | 0           | 0           |

**2. The recommendations of the Committee to the Board.**

In 2013 five (5) applicants applied for permits. Three (3) applicants applied for Category I and II, unlimited permits and two (2) were recommended by the Committee for approval. One (1) application was recommended for approval of a Category I, limited permit and one (1) application was recommended for approval of a Category II, limited permit. One (1) application did not go before the Committee for review due to deficiencies.

In 2014 three (3) applicants applied for permits. Two (2) applicants applied for a Category I and II, unlimited permit. One (1) was recommended to the Board for approval and one (1) was found deficient. One (1) applicant applied for Category I, unlimited and was recommended to the Board for Category I, limited. One (1) applicant applied for Category II, unlimited and was recommended to the Board for Category II, limited. One (1) application did not go before the Committee for review due to deficiencies.

In 2015 three (3) applicants applied for permits. One (1) applicant applied for a Category I and II, unlimited permit and was recommended to the Board for approval. One (1) applicant applied for a Category II, limited permit and was found deficient. One (1) application did not go before the Committee for review due to deficiencies.

In 2016 three (3) applicants applied for permits. Three (3) applicants applied for a Category I and II, unlimited permit and two (2) were recommended to the Board for approval and one (1) applicant was found deficient.

**Table 2: Committee Recommendations to the Board**

| Permit Type  | 2013 | 2014 | 2015 | 2016 |
|--|------|------|------|------|
| Applied for Category I and Category II, Unlimited              | 2    | 1    | 1    | 2    |
| Recommended Approval for Category I and Category II, Unlimited | 2    | 1    | 1    | 2    |
| Category 1, Unlimited and Category 2, limited                  | 0    | 0    | 0    | 0    |
| Category I, Unlimited  | 0    | 0    | 0    | 0    |
| Category 1, Limited and Category 2, Unlimited                  | 0    | 0    | 0    | 0    |
| Category II, Unlimited   | 0    | 0    | 0    | 0    |
| Category I, Limited  | 1    | 0    | 0    | 1    |
| Category II, Limited   | 1    | 0    | 0    | 0    |
| Denied   | 0    | 0    | 0    | 1    |
| Rejected   | 0    | 0    | 0    | 0    |
| Not yet reviewed   | 1    | 1    | 2    | 2    |

### 3. The Board's actions on recommendations received by the Credentialing Committee.

In 2013 the Board approved four (4) applications; two (2) for Category I and Category II, unlimited permits, one (1) for Category I, limited permit one (1) for Category II, limited permit. In 2014 the Board approved one (1) application for a Category I and Category II, unlimited permit. In 2015 the Board approved one (1) application for a Category I and Category II, unlimited permit. In 2016 the Board approved two (2) applications for Category I and Category II, unlimited permits. The Board denied one (1) application, due to insufficient hospital privileges, insufficient operative reports, and an unclear letter from the program director specifying the procedures the applicant intended to perform with this permit.

**Table 3: The Boards Actions**

| Permit Type  | 2013 | 2014 | 2015 | 2016 |
|--|------|------|------|------|
| Approved for Category I and Category II, Unlimited | 2    | 1    | 1    | 2    |
| Category 1, Unlimited and Category 2, limited      | 0    | 0    | 0    | 0    |
| Category I, Unlimited                              | 0    | 0    | 0    | 0    |
| Category 1, Limited and Category 2, Unlimited      | 0    | 0    | 0    | 0    |
| Category II, Unlimited                             | 0    | 0    | 0    | 0    |
| Category I, Limited                                | 1    | 0    | 0    | 1    |
| Category II, Limited                               | 1    | 0    | 0    | 0    |
| Denied   | 0    | 0    | 0    | 1    |
| Rejected   | 0    | 0    | 0    | 0    |

**4. The number of persons receiving a permit from the Board to perform elective facial cosmetic surgery.**

In 2013 a total of four (4) permits were issued; two (2) for Category I and Category II, unlimited, one (1) for Category I, limited and one (1) for Category II, limited. In 2014 a total of one (1) permit was issued for Category I and Category II, unlimited. In 2015 a total of one (1) permit was issued for Category I and Category II, unlimited. In 2016 a total of two (2) permits were issued for Category I and Category II, unlimited. In total there were eight (8) permits issued; six (6) for Category I and Category II, unlimited, one (1) for Category I, limited, and one (1) for Category II, limited.

**Table 4: Permits Issues by the Board**

| Permit Type                                   | 2013     | 2014     | 2015     | 2016     | Total    |
|---|----------|----------|----------|----------|----------|
| Category I and Category II, Unlimited         | 2        | 1        | 1        | 2        | 6        |
| Category 1, Unlimited and Category 2, limited | 0        | 0        | 0        | 0        | 0        |
| Category I, Unlimited                         | 0        | 0        | 0        | 0        | 0        |
| Category 1, Limited and Category 2, Unlimited | 0        | 0        | 0        | 0        | 0        |
| Category II, Unlimited                        | 0        | 0        | 0        | 0        | 0        |
| Category I, Limited                           | 1        | 0        | 0        | 1        | 1        |
| Category II, Limited                          | 1        | 0        | 0        | 0        | 1        |
| <b>Total Permits Issued</b>                   | <b>4</b> | <b>1</b> | <b>1</b> | <b>2</b> | <b>8</b> |

**5. The number of complaints filed by or on behalf of patients who have received elective facial cosmetic surgery by persons who have received a permit from the Board to perform elective facial cosmetic surgery.**

There have been no complaints filed by or on behalf of patients who have received elective facial cosmetic surgery by persons who have received a permit from the board to perform elective facial cosmetic surgery as there have been no complaints filed to date.

**6. Action taken by the board resulting from complaints filed by or on behalf of patients who have received elective facial cosmetic surgery by persons who have received a permit from the Board to perform elective facial cosmetic surgery.**

No action has been taken by the Board resulting from complaints filed by or on behalf of patients who have received elective facial cosmetic surgery by persons who have received a permit from the board to perform elective facial cosmetic surgery as there have been no complaints filed to date.

## **Conclusion**

The Committee recently approved regulatory language and the EFCS Permit application at its October 19, 2016 EFCS Permit Credentialing Committee meeting and recommended the Board initiate the rulemaking process at a future meeting. The hope is that these changes will make the application process clearer for applicants therefore making the review process easier for the Committee.

The next EFCS Permit Credentialing Committee meeting is scheduled for January 25, 2017. Applications are being received, reviewed and acted upon in a timely fashion. The Credentialing Committee is reviewing the applications with a discerning eye for not all applicants are granted all of the procedures/categories requested.

# DENTAL BOARD OF CALIFORNIA

## REVIEW OF THE REGISTERED DENTAL ASSISTANT PRACTICAL EXAMINATION



OFFICE OF PROFESSIONAL EXAMINATION SERVICES



# DENTAL BOARD OF CALIFORNIA

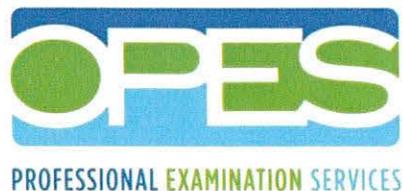
## REVIEW OF THE REGISTERED DENTAL ASSISTANT PRACTICAL EXAMINATION

This report was prepared and written by the  
Office of Professional Examination Services  
California Department of Consumer Affairs

April 6, 2017

Heidi Lincer, Ph.D., Chief

Irene L. Wong-Chi, M.A., Research Program Specialist II



## EXECUTIVE SUMMARY

The Dental Board of California (Board) requested that the Department of Consumer Affairs' Office of Professional Examination Services (OPES) complete a comprehensive review of the Registered Dental Assistant (RDA) Practical Examination. The review was conducted with the following goals: 1) to evaluate the psychometric properties of the examination (e.g., reliability, test security, standardization) in response to ongoing concerns from the Board and industry stakeholders; 2) to determine the necessity and accuracy of the examination in response to Assembly Bill (AB) 179 (2015); and 3) to evaluate the content validity of the RDA Practical Examination in relation to the 2016 RDA Occupational Analysis (OA) results.

OPES evaluated the practical examination with regard to reliability of measurement, examiner training and scoring, test administration, test security, and fairness. [REDACTED]

[REDACTED] Specifically, the inconsistencies in different test site conditions, deficiencies in scoring criteria, poor calibration of examiners, and the lack of a clear definition of minimum acceptable competence indicate that the examination does not meet critical psychometric standards.

OPES recommends that the Board immediately suspend the administration of the practical examination. OPES believes there is a relatively low risk of harm to the public from the suspension of the examination because of the other measures in place, i.e., passing a written examination and the fact that RDAs are required to be under general or direct supervision by a licensed dentist (Business and Professions Code section 1752.4.(c)). [REDACTED]

Based on OPES' experience, correcting the problems to bring the examination into compliance with technical and professional standards will require a great deal of time, staffing and fiscal resources from the Board and the industry. Therefore, OPES recommends that the Board initiate a process to thoroughly evaluate options other than a practical examination for ensuring the competency of RDAs to perform the clinical procedures identified as a necessary component of RDA licensure.

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## CHAPTER 1. INTRODUCTION

### FACTORS LEADING TO THE PRACTICAL EXAMINATION REVIEW

Licensing boards and bureaus within the California Department of Consumer Affairs (DCA) are required to ensure that examination programs used in the California licensure process comply with psychometric and legal standards. The public must be reasonably confident that an individual passing a licensing examination has the requisite knowledge and skills to competently and safely practice in the respective profession.

In March 2015, the Office of Professional Examination Services (OPES) initiated an occupational analysis (OA) of the Registered Dental Assistant (RDA) profession at the request of the Dental Board of California (Board). Business and Professions (B&P) Code section 139 requires that the boards and bureaus of DCA conduct an OA for each license classification every five to seven years.

One purpose of the OA is to develop a description of current practice in terms of the actual job tasks that entry-level licensees must be able to perform safely and competently. The results of OA research projects are also used to ensure that the content of written, practical, and law and ethics licensing examinations reflect knowledge, skills, and abilities that are critical for public protection. To become more familiar with the RDA skills and abilities, OPES staff attended the examiner training and three sessions of the August 2015 RDA Practical Examination.

During the course of the RDA OA, Assembly Bill (AB) 179 (2015) chaptered (Chapter 510, statutes of 2015), requiring that OPES “conduct a review to determine whether a practical examination is necessary to demonstrate competency of registered dental assistants, and if so, how this examination should be developed and administered.”

AB 179 also included language allowing the Board to vote to suspend the practical examination if OPES’ review “concludes that the practical examination is unnecessary or does not accurately measure the competency of registered dental assistants.”

Pursuant to AB 179, OPES initiated the review in conjunction with the OA, and in May 2016, OPES issued a Memorandum to the Board with their preliminary findings. The results of the review determined that the evaluation of candidate competency to perform specific clinical skills is a necessary component of RDA licensure; however, the review concluded that there are multiple methods the Board could employ to ensure that these skills are assessed as part of the licensure process. In the May 2016 Memorandum, OPES provided the Board with two options:

Option 1: Continue use of a Board administered practical examination. This option requires the Board’s practical examination to be updated to include the 2016 RDA OA results.

Option 2: Candidates meet initial educational and training requirements through

schools and/or on the job training, as currently allowed in statute. Once education and training requirements have been met, the candidate gains practical clinical experience under a supervising dentist. Following satisfactory acquisition of clinical skills as determined by the supervising dentist, candidates will submit an application for licensure with certification from their supervising dentist indicating the candidate can demonstrate the required RDA clinical skills.

## **PURPOSE OF THE REVIEW**

At the time of the May 2016 Board meeting, OPES had not had an opportunity to evaluate whether the practical examination accurately measured the competency of RDAs. During the Board meeting, there was a request from industry to release the grading criteria for the practical examination, which was approved by the Board and found acceptable to OPES. The Board voted not to suspend the practical examination and directed staff to work with OPES to review and update the practical examination. Subsequently, the Board entered into an intra-agency agreement with OPES to conduct a comprehensive review of the RDA practical examination.

In summary, one purpose of this review was to determine whether the Board's RDA Practical Examination meets professional guidelines and technical standards. The review was also necessary to satisfy the requirements of AB 179, and, if requested, to update the RDA Practical Examination based on the results of the 2016 OA.

## **CALIFORNIA LAW AND POLICY**

Section 139 (a) of the California B&P Code states:

The Legislature finds and declares that occupational analyses and examination validation studies are fundamental components of licensure programs. It further requires that DCA develop a policy to address the minimum requirements for psychometrically sound examination validation, examination development, and occupational analyses, including standards for the review of state and national examinations.

DCA policy, OPES 12-01, specifies the *Standards for Educational and Psychological Testing* (2014), hereinafter referred to as *Standards*<sup>1</sup>, as the most relevant technical and professional standards that should be followed to ensure that examinations used for licensure testing in California are psychometrically sound, job-related, and legally defensible.

<sup>1</sup> *Standards* references information taken from: American Educational Research Association, American Psychological Association, and National Council on Measurement in Education. (2014). *Standards for Educational and Psychological Testing*. Washington, DC: American Educational Research Association.

## FORMAT OF THE REPORT

The following chapters of this report provide the relevant standards with regard to various aspects of the RDA Practical Examination and describe the issues and findings that OPES identified during their review. [REDACTED]

## CHAPTER 2. RELIABILITY OF MEASUREMENT

### OBSERVATION OF PRACTICAL EXAMINATION

On November 5, 2016, OPES staff observed the examiner training and three sessions of the RDA Practical Examination held at the University of California, San Francisco (UCSF) School of Dentistry in San Francisco. The observation included discussions with Board staff, testing staff, and dentists who were involved with the practical examination. The purpose of the observation was to evaluate the process of the practical examination with regard to reliability of measurement, examiner training and test scoring, administration, and test security and fairness to determine if the examination meets professional guidelines and technical standards.

The standards most relevant to reliability/precision of measurement, as applied by the *Standards* to credentialing or licensing examinations, are:

### STANDARDS

#### **Standard 2.1**

The range of replications over which reliability/precision is being evaluated should be clearly stated, along with a rationale for the choice of this definition, given the testing situation. (p. 42)

Comment: For any testing program, some aspects of the testing procedure (e.g., time limits and availability of resources such as books, calculators, and computers) are likely to be fixed, and some aspects will be allowed to vary from one administration to another (e.g., specific tasks or stimuli, testing contexts, raters, and, possibly, occasions). Any test administration that maintains fixed conditions and involves acceptable samples of the conditions that are allowed to vary would be considered a legitimate replication of the testing procedure. As a first step in evaluating the reliability/precision of the scores obtained with a testing procedure, it is important to identify the range of conditions of various kinds that are allowed to vary, and over which scores are to be generalized.

#### **Standard 11.14**

Estimates of the consistency of test-based credentialing decisions should be provided in addition to other sources of reliability evidence. (p. 182)

### FINDINGS

The Board typically administers the RDA Practical Examination eight times per year in two or three different locations (i.e., UCSF School of Dentistry in San Francisco, Carrington College in Pomona, or San Joaquin Valley College, Inc. in Fresno). Each administration usually consists of two testing days, with three testing sessions per day.

At the November 5, 2016 UCSF test administration, OPES staff found that all three testing sessions were equal with regard to standardized check-in/registration

procedures, candidate instructions, administration, test security protocols, and scoring. Aspects of the test administrations did not appear to vary from one administration session to another.

**Finding 1:** The standardization of administrations with regard to replicating the administration of the test between multiple test sessions at the UCSF test administration appears to meet professional guidelines and technical standards.

## ISSUES

During the observation of the San Francisco test administration, OPES staff met with Board staff and test examiners. OPES staff was informed that all test administration procedures, policies, and protocols are standardized at each test site for each testing session and that the testing staff, proctors, and examiners are predominantly the same individuals.

However, the testing sites themselves are different from each other with regard to testing environment. The Pomona test site has a classroom/lecture-type setting, with less space between candidates compared to the San Francisco test site, which is in a dental operatory lab-type setting. Pomona candidates are reportedly heavily crowded at a table to perform their examination compared to the more open space afforded the San Francisco candidates.

**Issue 1:** The testing environments do not appear to be standardized across different test sites, thus introducing potential measurement error into the assessment process.

## RECOMMENDATIONS

**Recommendation 1:** Find alternative testing sites in Southern California that resemble the testing environment at UCSF School of Dentistry in San Francisco.

**Recommendation 2:** Continue to provide testing at Carrington College in Pomona, but afford more space between candidates. This might result in adding an extra testing room, testing day, and/or testing sessions.

## CONCLUSIONS

Although test administration appears to meet professional guidelines and technical standards with regard to replicating the test for multiple sessions at a given test site, the testing environments between test sites do not appear to be comparable to each other.

No issues were observed regarding whether individual candidates had sufficient space to work in at the UCSF test site. Regarding the Pomona test site, OPES received multiple reports of this being a material issue at this test site, (i.e., candidates experienced test conditions that offered less individual privacy and were more crowded).





Finding comparable test sites for northern and southern California test administrations appears to be one key variable in diminishing construct irrelevant variance in the RDA Practical Examination. One approach could involve keeping the UCSF test site and locating a comparable test site in Southern California.

Rearranging the seating at the Pomona test site is not an option because of the layout and fixed nature of the tables. Reducing the number of candidates being tested at the same time will reduce overcrowding but will also add more testing days and testing sessions to the Pomona site, thus substantially increasing the costs to the Board.

## CHAPTER 3. EXAMINER TRAINING AND TEST SCORING

### STANDARDS

The standards most relevant to examiner training and test scoring, as applied by the *Standards* to credentialing or licensing examinations, are:

#### **Standard 4.20**

The process for selecting, training, qualifying, and monitoring scorers should be specified by the test developer. The training materials, such as the scoring rubrics and examples of test takers' responses that illustrate the levels on the rubric score scale, and the procedures for training scorers should result in a degree of accuracy and agreement among scorers that allows the scores to be interpreted as originally intended by the test developer. Specifications should also describe processes for assessing scorer consistency and potential drift over time in raters' scoring. (p. 92)

#### **Standard 4.21**

When test users are responsible for scoring and scoring requires scorer judgement, the test user is responsible for providing adequate training and instruction to the scorers and for examining scorer agreement and accuracy. The test developer should document the expected level of scorer agreement and accuracy and should provide as much technical guidance as possible to aid test users in satisfying this standard. (p. 92)

#### **Standard 6.8**

Those responsible for test scoring should establish scoring protocols. Test scoring that involves human judgment should include rubrics, procedures, and criteria for scoring. When scoring of complex responses is done by computer, the accuracy of the algorithm and processes should be documented. (p. 118)

### ISSUES

The Board's RDA examiner manual provides information to examiners regarding preparation for grading, evaluation and grading, and grading procedures. Instructions are provided to examiners for how to perform candidate scoring and how to handle scoring anomalies.

The examiner orientation/training session at the UCSF test site included descriptions of minimum competency. [REDACTED]

Before the scoring process had begun, examiners were instructed to follow the scoring protocols and to direct questions to designated staff or to the lead examiner, as needed.

[REDACTED]

Examiners were also instructed that scoring should be performed based on the specific scoring criteria/scoring rubric and should not be based on what is "perfect" or on a given examiner's opinion.

[REDACTED]

**Issue 2:** Although the Board provides some training information, materials, and instructions to examiners for scoring the RDA Practical Examination, including a certain amount of scoring protocols, procedures, and criteria, there is a degree of inaccuracy and non-agreement among examiners. Thus, the training and scoring protocols and criteria do not appear to meet professional and technical standards and guidelines.

According to the *Standards*, calibration refers to "...procedures used during training and scoring to achieve a desired level of scorer agreement" (p. 216).

[REDACTED]

There are no standardized exercises for training examiners on scoring procedures to measure their level of anchoring/calibration.

[REDACTED]

[REDACTED]

**Issue 3:** There is no evaluation of whether examiners understand the definition and criteria associated with minimum competency and each scale point. There is also no evaluation of the degree or level of examiner calibration, (i.e., the ability of the individual examiner to consistently and accurately apply the scoring standards).

[REDACTED]

**Issue 4:** There is no measure of inter-rater reliability between examiners since examiner ratings are not tracked. [REDACTED]

Equitability in the application of the scoring criteria by an individual examiner and within the team of two examiners is a critical part of ensuring the validity and reliability of the examination results. [REDACTED]

**RECOMMENDATIONS**

**Recommendation 3:** Conduct the necessary workshops and studies to reestablish what constitutes as minimum acceptable competency for each of the procedures being evaluated in the practical examination.

**Recommendation 4:** Conduct the necessary workshops and studies to develop anchoring/calibration procedures and materials for examiner orientation/training sessions.

[REDACTED]

[REDACTED]

[REDACTED]

**Recommendation 5:** Develop procedures for tracking every examiner's ratings to assess their pass/fail scores over time and their inter-rater reliability.

## CONCLUSIONS

The procedures used to calibrate the examiners and evaluate the ability of examiners, individually and as a team of two examiners, to consistently and accurately apply the scoring standards appear to be either inconsistent [REDACTED]

Standardizing the scoring rubrics will require reestablishing the level of minimum acceptable competence for each procedure being evaluated. Once these studies and workshops have been successfully completed, the application of these findings to updating the rating scale and scale anchors must be accomplished.

Standardized training procedures and exercises will need to be developed for implementation during examiner orientation/training sessions to improve examiner calibration prior to scoring candidates and to increase inter-rater reliability.

In addition, examiner scoring and pass/fail decisions should be tracked over time to ensure that scoring is occurring consistently using the required rubrics and within the required minimum levels of examiner agreement.

## CHAPTER 4. TEST ADMINISTRATION

### STANDARDS

The most relevant standards relating to standardizing the test administration, as applied by the *Standards* to credentialing or licensing examinations, are:

#### **Standard 3.4**

Test takers should receive comparable treatment during the test administration and scoring process. (p. 65)

#### **Standard 4.15**

The directions for test administration should be presented with sufficient clarity so that it is possible for others to replicate the administration conditions under which the data on reliability, validity, and (where appropriate) norms were obtained. Allowable variations in administration procedures should be clearly described. The process for reviewing requests for additional testing variations should also be documented. (p. 90)

#### **Standard 4.16**

The instructions presented to test takers should contain sufficient detail so that test takers can respond to a task in the manner that the test developer intended. When appropriate, sample materials, practice or sample questions, criteria for scoring, and a representative item identified with each item format or major area in the test's classification or domain should be provided to the test takers prior to the administration of the test, or should be included in the testing material as part of the standard administration instructions. (p. 90)

#### **Standard 6.1**

Test administrators should follow carefully the standardized procedures for administration and scoring specified by the test developer and any instructions from the test user. (p. 114)

#### **Standard 6.3**

Changes or disruptions to standardized test administration procedures or scoring should be documented and reported to the test user. (p. 115)

#### **Standard 6.4**

The testing environment should furnish reasonable comfort with minimal distractions to avoid construct-irrelevant variance. (p. 116)

#### **Standard 6.5**

Test takers should be provided appropriate instructions, practice, and other support necessary to reduce construct-irrelevant variance. (p. 116)

## FINDINGS

### Test Administration – Directions and Instructions to Candidates

A link to the RDA Practical Examination candidate guide is provided on the Board's website. This guide provides candidates with information regarding RDA application and examination requirements, examination administration procedures, required materials, and grading/scoring criteria.

Throughout the administration process, candidates are presented with standardized instructions from testing staff. Testing staff and proctors are strategically placed in specific areas on the floor to assist candidates and to provide instructional information during candidate check-in/registration. Once all candidates are escorted into the testing area and are seated, the Chief Orientation Examiner (COE) provides a scripted orientation speech to candidates over the PA system. The COE also notifies candidates over the PA system when they have 30 minutes and 10 minutes remaining to complete the examination and when they must stop. These instructions are provided in a clear and uniform manner consistently in all testing sessions.

**Finding 2:** The directions and instructions provided to candidates appear straightforward. The information available to candidates is detailed and thorough, clearly stating the Board's policies where necessary.

### Test Administration – Standardized Procedures

Testing staff and proctors follow standardized scripts, instructions, and check lists throughout the test administration process. Check lists are utilized to evaluate site preparedness, document candidate compliance with infection control procedures (i.e., personal protection equipment [PPE]), and document candidate apparel/equipment (e.g., equipment replacement or incidences). Operating procedures are also in place, if needed, for emergency preparedness, sexual harassment/sexual misconduct, and other unprofessional conduct – including candidate and examiner/staff dismissal.

The following forms are completed by testing staff as necessary:

- Orientation Waiver Form
- RDA Incident Log Sheet
- Incident Report
- Candidate Examination Interruption Form
- RDA Examination Tracking Log

The test facility also has signage clearly directing candidates where to go, and the directions to the check-in area are clearly marked and monitored. Testing staff uphold a professional appearance and demeanor. Their roles and responsibilities are well-evidenced, as the check-in process is well-organized and includes reminders regarding prohibited items. The timing schedule for test administration is objective and standard, and candidates are able to monitor time remaining. Responses to candidate questions are standardized, where applicable.

**Finding 3:** The policies and procedures established for the test administration process appear to meet professional and technical standards and guidelines.

#### Test Administration – Testing Environment

The testing environment at UCSF is well-lit and is set at a comfortable temperature. All electronic devices are out-of-sight in the testing area. Candidate testing stations are identical for each candidate and are evenly spaced to permit confidential performance between candidates. The testing stations allow for the proper placement and anchoring of typodonts, and there is sufficient room for performing the procedures and for the placement of armamentaria. Communication between candidates can easily be monitored by testing staff, and proctors are able to walk through the testing area to make unobtrusive observations.

**Finding 4:** The testing environment at UCSF appears to meet professional guidelines and technical standards.

### **CONCLUSIONS**

Given the findings, the test administration protocols observed in the UCSF test site meet professional guidelines and technical standards. However, it was reported to OPES that in Southern California, bench mounts are pre-mounted in some rooms, but not in others. If this is the case, it could introduce unnecessary measurement error into the assessment process.

## CHAPTER 5. TEST SECURITY

### STANDARDS

The most relevant standards relating to the test security of credentialing or licensing examinations, as applied by the *Standards*, are:

**Standard 6.6**

Reasonable efforts should be made to ensure the integrity of test scores by eliminating opportunities for test takers to attain scores by fraudulent or deceptive means. (p. 116)

**Standard 6.7**

Test users have the responsibility of protecting the security of test materials at all times. (p. 117)

**Standard 8.9**

Test takers should be made aware that having someone else take the test for them, disclosing confidential test material, or engaging in any other form of cheating is unacceptable and that such behavior may result in sanctions. (p. 136)

**Standard 9.21**

Test users have the responsibility to protect the security of tests, including that of previous editions. (p. 147)

### FINDINGS

During test administration, the following security policies, procedures, and protocols are adhered to and implemented:

- Candidates must provide a current and valid government-issued photo identification for entry into test site.
- Candidates are prohibited from bringing any personal belongings into the testing rooms other than the required materials.
- Candidate identification numbers are used to designate candidates on all examination/scoring materials and testing stations.
- Areas of test facility are clearly marked, blocked, and/or monitored by staff (i.e., only candidates and designated staff are allowed in the testing area).
- Testing staff and proctors are clearly identified (i.e., badges, attire).
- Examiners remain in a separate room away from candidates during testing and do not intermingle with candidates outside the testing area.
- Area for kit renters is clearly marked on a separate floor, and they are not permitted anywhere in the testing area.
- Testing area layout permits the monitoring/observation of candidates.

- All scoring materials remain in a secure, designated area.
- Candidate score sheets are maintained in a confidential/secure manner.
- Only designated staff have access to testing and scoring materials.
- Procedures for candidate dismissal upon completion prevent sharing of information between candidates.
- Candidates are escorted to the waiting area during scoring, are monitored at all times, and then escorted back to the testing area for dismissal.
- Following administration, all test and scoring materials are accounted for, secured, and prepared for conveyance.

In addition to these security measures, the Board's *Candidate Guide for the Registered Dental Assistant Practical Examination* also provides information to candidates regarding what constitutes improper performance and unethical conduct on the part of candidates and the consequences of such actions.

**Finding 5:** The Board, through its internal test administration and security protocols, provides a robust framework of test site and examination security policies and procedures.

## CONCLUSIONS

Given the findings, the test security policies, procedures, and protocols meet professional guidelines and technical standards.

## CHAPTER 6. TEST FAIRNESS

### TEST FAIRNESS

The concept of fairness as it relates to testing is applied by the *Standards* in four primary areas: fair and equitable treatment of all test takers during the testing process, issues of fairness in measurement quality, fairness as the absence of measurement bias, and fairness as access to the construct being measured (p. 51). One way of characterizing all of these areas is to consider that fairness in testing requires that individuals not be advantaged or disadvantaged in any facet of the testing process because of characteristics that are irrelevant to the construct being tested. Standards 3.1 and 3.4, below, should be understood within the context of individuals from the intended test population from diverse racial, ethnic, gender, age, socioeconomic, and educational backgrounds who have met the eligibility requirements to take the RDA Practical Examination.

### STANDARDS

The standards most relevant to test fairness, as applied by the *Standards* to credentialing or licensing examinations, are:

#### **Standard 3.1**

Those responsible for test development, revision, and administration should design all steps of the testing process to promote valid scores for the widest possible range of individuals and relevant groups in the intended population. (p. 63)

#### **Standard 3.4**

Test takers should receive comparable treatment during the test administration and scoring process. (p. 65)

#### **Standard 9.14**

Test users should inform individuals who may need accommodations in test administration (e.g., older adults, test takers with disabilities, or English language learners) about the availability of accommodations and, when required, should see that these accommodations are appropriately made available. (p. 145)

### FINDINGS

Candidates are informed in the Board's "Registered Dental Assistant Examination Instructions" that they may call the Board to request a special accommodations packet, which must be submitted with their application. In addition, they are informed that if their religious beliefs preclude them from being examined on Saturday or Sunday, they must include a note indicating the day on which they cannot take the examination and

the reason why. The Board approves any necessary accommodations under the Americans with Disabilities Act.

In addition, as noted previously in Chapter 4, the Board has policies and procedures for standardizing the test administration. These procedures contribute to fairness in that all candidates receive the same instructions in the same way. There are opportunities for candidates to ask questions in a group setting so that all candidates present hear the question and the response together. These candidate "orientations" serve to ensure that all candidates have the opportunity to hear the instructions and to hear the test administration's facilitators clarify areas where there may be confusion.

**Finding 6:** The Board takes measures to ensure that the examination is fair for all candidates with regard to special accommodations and equitable treatment.

## **CONCLUSIONS**

Given the findings, the Board's process appears to meet professional guidelines and technical standards with regard to test fairness.

## CHAPTER 7. STAKEHOLDER MEETINGS

OPES convened two stakeholder panel meetings to provide focused discussions on topics directly related to the practical examination. The purpose of the meetings was to allow stakeholders the opportunity to provide background information to OPES and to provide a forum in which to discuss controversial issues and current trends.

The first meeting was convened by OPES on January 26, 2017, to discuss key questions generated as a result of OPES' observation of the November 5, 2016, examiner training and practical examination administration held at the UCSF School of Dentistry in San Francisco. The Board, with direction from OPES, recruited nine stakeholders, consisting of kit renters and educators representing both northern and southern California to participate in the meeting. Kit renters supply "kits" with the typodont and other materials that candidates need to take the examination. The stakeholders completed security agreements and personal data forms, which are on file with OPES for documentation of stakeholder information.

An orientation provided by OPES stated the purpose of the meeting, the role of the stakeholders, and the project background leading to the meeting. Once the stakeholders understood the purpose of the meeting, they were provided with questions to stimulate thought and discussion in areas where stakeholder input might contribute to the review and update of the practical examination. Areas of discussion included test site conditions, the use of tooth #8 for fabrication of a temporary crown, the problem with some kit renter items, the use of different types of typodonts, and the use of different types of materials.

The second meeting was convened by OPES the following day on January 27, 2017. The Board recruited a different group of eight stakeholders, also comprised of kit renters and educators representing both northern and southern California. The purpose of this second meeting was to allow for additional stakeholder representation. The majority of the participants of both panel meetings indicated that they were simultaneously kit renters and educators. The stakeholders were provided with the same security agreements, personal data forms, orientation, and key questions for discussion as the previous meeting.

Information gathered from the two stakeholder meetings were transcribed and are summarized below:

### Stakeholder Comments regarding Scoring Criteria, Grading Considerations, and Examiner Calibration

- A more thorough clarification of the scoring criteria needs to be implemented to provide for more quantifiable measures. The scoring rubric should include pictures and better descriptions of what constitutes each score rating.

- Examiner qualifications need to be evaluated. Examiners should be current and experienced (at least five years) and performing the duties on a daily or weekly basis.
- Calibration needs to be improved so that examiners are consistent with their expectations of what constitutes entry-level performance. An RDA (not dentist) should be doing the training of examiners.
- Candidates should be reminded that using loops or lights are allowed during the examination. Some candidates use them and some do not.
- Climate can affect the setting time of material. This information should be taken into consideration during grading.
- Material for cementation in a real mouth sets faster because it is warm. On a typodont, however, it sets slower. This information should be taken into consideration during grading.
- Examiners should not tug on tooth #8 to ensure that it is cemented properly since it can affect what the next examiner sees.

#### Stakeholder Comments regarding Test Administration Sites

- The seating of candidates needs to be consistent across locations. Candidates are placed within close proximity of each other in Pomona and Fresno but are afforded more space at UCSF.
- The setting up of bench mounts needs to be consistent across locations. The bench mounts are pre-mounted in Northern California, but in Southern California the candidates set up the bench mounts themselves prior to the examination.
- There needs to be consistency between testing rooms within the same test site. In Southern California, bench mounts are pre-mounted in some rooms, but not in others.
- Personal Protection Equipment (PPE) needs to be consistent with regard to what is allowable. For candidates who wear prescription glasses, there is inconsistency between whether face shields or side shields are required.

#### Stakeholder Comments regarding Typodonts

- Typodonts need to be standardized (i.e., Kilgore or only one type of Columbia).
- The Board should supply the typodonts to the candidates. If not, there needs to be criteria specifying the typodont's requirements. The typodonts should come ready to go.
- The Board should remove the task of calibrating/articulating the typodonts (i.e., making the typodonts close to check the bite with the paper) since this can affect tooth #8.
- Candidates should be allowed to screw in prep tooth #8 from the Board before the examination begins. During the examination, some candidates are

unable to strip the screw to take out the normal white tooth #8. This results in the candidate being escorted by a proctor to the kit renters to replace the upper arch from another typodont. This can affect the occlusion and fit, and consequently, the typodont's occlusion may not have the reasonable stability required.

#### Stakeholder Comments regarding General Examination Process Improvements

- Candidates need to be provided with a more specific response for why they failed. The language for failing is not congruent with the grading criteria. It was suggested that perhaps the Board keep a digital record of each candidate's work so that if a candidate fails, the candidate would know the reason for their failure based on the picture. There needs to be better overall communication between the Dental Board, the educators, kit renters, and candidates about why candidates failed.
- The Board needs to communicate whenever they are making a change. When an examination is cancelled, the Board needs to communicate the reasoning to the candidates. The Board also needs to notify the candidates about their application status when a test is cancelled and pushed to another date.
- The Board should provide first time versus repeat candidate statistics by school.
- The Board should keep records of each examiner's pass/fail rate for tracking purposes.
- The Board should look at the statistics to correlate when candidates graduated and when they take the examination. Do those who wait six months to one year after graduation typically pass the practical examination versus those who take the examination right after graduation?

## CHAPTER 8. SME REVIEW WORKSHOP

On February 17–18, 2017, OPES convened a two-day review workshop to provide recommendations for improving the practical examination and to link the practical examination to the 2016 occupational analysis (OA). The Board, with direction from OPES, recruited 10 SMEs, who consisted of RDAs and practical examiners. The attending SMEs represented both northern and southern California. The SMEs completed security agreements and personal data forms, which are on file with OPES for documentation of participant information.

An orientation provided by OPES stated the purpose of the meeting, the role of the SMEs, and the project background leading to the meeting. Once the SMEs understood the purpose of the meeting, they were asked for input regarding the practical examination and whether there was anything they would like to see changed and/or improved. The content of their discussions were very similar to the discussions held during the stakeholder meetings. Although the source of the problems and the responsible parties involved varied between the groups, they all agreed that improvement is needed in key areas. The areas of improvement are summarized as follows:

### SME Comments regarding Scoring Criteria, Grading Considerations, and Examiner Calibration

- The scoring criteria/scoring rubric is good, but it would be very beneficial for the Board to provide information about millimeters on the margins for improved clarification.
- The scoring sheet needs more applicable scenarios. “Incorrect procedure” does not provide candidates with enough information for why they failed the examination. More specific information is needed (i.e., prep is there, but the crown is not in place.) This will assist candidates to better prepare for the examination.
- The ability to grade the examination is very problematic if cementation is wrong. Performing one procedure right on top of another is not good. If the candidate fails the first procedure (fabricating a temporary crown), then they fail the second one as well (cementation). SMEs suggested that either cementation be removed as a tested procedure or a different tooth be chosen for cementation. For example, fabricate on temporary tooth #8, but cement on a posterior tooth.

- The setting time for cementation is a problem, which can affect scoring. If the cement is not set when the first examiner tugs at the tooth to ensure it is cemented properly, it can affect how the second examiner receives that tooth to grade. The examiners should no longer tug on the tooth, or the Board should allot more time for the material to set prior to examiner grading. (The examiners informed OPES that in the past, they were not allowed to touch the typodonts during scoring. They were required to score based on what they saw visually. Consequently, they may have been passing candidates for cementation because the tooth appeared cemented in place and stable, but when in fact, it may not have been. This could explain the more recent failure rates since examiners are now allowed to touch the typodonts to ensure proper cementation.)
- Calibration needs to be improved so that examiners are consistent with their expectations of what constitutes entry-level performance. The SMEs believe that the dentists who are involved with the practical examination have set the bar for minimum competency above what they would consider minimum competency. Therefore, the examiners need new training on minimum competency and calibration. The SMEs support OPES' recommendation of conducting SME workshops to develop anchoring/calibration materials (slides and typodonts) for new and improved examiner orientation/training sessions. In addition, the SMEs think that the dentists should be present at the practical examination as consultants only, rather than providing the calibration training or performing as a scoring examiner.
- There is confusion over what the word "stable" indicates with regard to cementation. This term needs to be operationally defined and discussed in depth during calibration training.

#### SME Comments regarding Test Administration Sites

- The seating of candidates needs to be consistent across locations.
- The setting up of bench mounts needs to be consistent across locations.
- The use of overhead lighting needs to be consistent across locations. UCSF allows the use of overhead lighting, but there are none available in the southern California sites.

The SMEs indicated that northern California candidates have always performed better on the practical examination than southern California candidates even when the examination was held at University of California, Los Angeles (UCLA) and University of Southern California (USC), which were similar to the test site at UCSF. Therefore, the SMEs believe that it is a matter of education the candidates are receiving in southern California that explains the higher failure rate compared to northern California rather than due to any other factor.

### SME Comments regarding Typodonts and Explorers

- Typodonts need to be standardized (i.e., Kilgore).
- Explorers need to be standardized because there are differences in explorers. The examiners use the pig tail, which is thinner, but some of the kits come with explorers that are thicker.

There were four topics of discussion in which the stakeholders (kit renters and educators), RDA SMEs, and the dentists differed:

1. The stakeholders indicated that there is inconsistency with regard to allowable PPE, but the SMEs indicated that this is not a problem.
2. The stakeholders indicated that the Board should remove the task of calibrating/articulating the typodonts since this can affect tooth #8. However, the SMEs indicated that this should continue to be done in order to make sure there is occlusion.
3. The stakeholders indicated that expired materials or missing kit items is not a problem. However, the SMEs indicated that it is a problem.
4. The dentists who were involved with the practical examination indicated that tooth #8 is problematic since the way that the tooth is trimmed makes it not shaped correctly. Therefore, the dentists believe that prep tooth #8 should be replaced or fixed. However, the SMEs indicated that the candidates are told the margin is supragingival in the candidate guide. The educators should be aware and be teaching candidates to expect this situation. Therefore, according to the SMEs, tooth #8 is not a problem since the candidates are provided this information.

## CHAPTER 9. LINKAGE OF PRACTICAL EXAMINATION CONTENT WITH 2016 OCCUPATIONAL ANALYSIS RESULTS

In order to verify the content validity of the skills and abilities tested on the present practical examination, the SMEs in the February 17-18, 2017 workshop were provided with a list of the 12 ability statements that had been developed during the 2016 RDA Occupational Analysis (OA). The 12 ability statements reflected the central dental assisting skills that define the RDA scope of practice. In conducting their review, the SMEs decided to add an additional ability statement for a total of 13 ability statements for an RDA (see Appendix B).

Overall, the SMEs concluded that the 13 ability statements were accurate and complete in describing the principle dental assisting tasks that define the RDA scope of practice. For the purpose of this report, these 13 ability statements will be referred to as the “RDA Abilities.”

The SMEs were also asked to review the relationship between the RDA Abilities and the tasks and knowledge from the 2016 RDA OA. To accomplish this task, the SMEs reviewed the linkage identified in the OA workshops. The SMEs concurred with the OA findings. The linkage between the task and knowledge statements of the 2016 RDA OA can be found in Appendix D.

The SMEs were then asked to rate each of the 13 ability statements using the following “acquired” rating scale:

- 0 - **Does not apply to my job; Not required** – This job knowledge does not apply to my job; it is not required for job performance.
- 1 - **Acquired before licensure** – I acquired the ability to apply this knowledge before licensure.
- 2 - **Acquired mostly before licensure** – I acquired most of the ability to apply this knowledge before licensure.
- 3 - **Acquired mostly after licensure** – I acquired most of the ability to apply this knowledge after licensure.
- 4 - **Acquired after licensure** – I acquired the ability to apply this knowledge after licensure.

The purpose was to assess whether the RDA Abilities are learned before or after licensure. Appendix C depicts the ratings provided by each SME and the average ratings for each ability statement. The results indicate that RDAs acquire most of the ability to apply the *related knowledge* before, or mostly before, licensure.

During the February 2017 discussion of the results, the SMEs went on to describe that the RDA candidate typically learns the *techniques and procedures* for applying the RDA Abilities while in school and during on the job training. This is congruent with the SME

discussions during the 2016 OA workshops, and similar results were reported by the RDA sample responding to the OA questionnaire. In the OA questionnaire, when respondents were asked to indicate the top three sources of experience to become an RDA, 59% indicated on the job from the supervising dentist, 31% from a private career school, and 29% on the job from an experienced RDA or RDA Extended Functions (RDAEF).

The SMEs further noted that the actual proficiency in applying the RDA Abilities occurs after licensure. The SMEs indicated that a certain degree of ability is gained by the completion of school, but proficiency takes time and practice to be achieved, especially in relation to taking accurate impressions, fabricating dental provisionals, placing temporary filling material, and the cementation of provisionals. These areas are associated with the following RDA Abilities:

|      |  |
|------|--|
| A4.  | Ability to fabricate acrylic temporary restoration with proper margins, tooth contours, and acrylic finish lines.  |
| A5.  | Ability to adjust acrylic temporary restoration with proper tooth contours, appropriate occlusal and proximal surfaces, and appropriate embrasures and contacts. |
| A7.  | Ability to cement temporary restoration, leaving restoration stable and in place without excess cement.  |
| A11. | Ability to place temporary restoration with proper occlusion, no excess O/B/L, and correct proximal box form (anatomically and margins).                         |

Finally, the SMEs were asked to review the three procedures evaluated by the current practical examination and to identify the tasks and knowledge from the 2016 OA measured by each of the three procedures. In addition, the SMEs were asked to identify which of the thirteen RDA Abilities were measured by each of the three procedures evaluated by the practical examination. The results of this review can be found in Appendix A.

## FINDINGS

The three procedures evaluated by the current practical examination are procedures that reflect principle dental assisting tasks that define the RDA scope of practice.

The results of the SME review conducted for this study reflect the findings of the 2016 RDA OA in the following areas:

- Much of the techniques and procedures related to the RDA Abilities are learned by the candidates in school and on the job prior to licensure.
- Applying the knowledge related to the RDA Abilities is also learned by the candidates in school and on the job prior to licensure.
- Proficiency in performing the RDA Abilities occurs after licensure and is related to the RDAs gaining further practice and experience in applying the RDA Abilities.
- The supervising dentist is the ultimate judge and arbiter of the extent to which the

RDA demonstrates sufficient proficiency to perform the RDA duties in the dentist's office (See B&P Code section 1752.4.(c)).

## CHAPTER 10. CONCLUSIONS AND RECOMMENDATIONS

Information was gathered about the RDA Practical Examination from Board staff, RDA educators, RDA examination kit renters, RDA examiners, dentists, and RDAs working in the industry. Their feedback, coupled with OPES' observation of a test administration, elicited serious concerns about the present practical examination.

OPES recommends that the Board immediately suspend the administration of the practical examination. [REDACTED]

The most critical issue identified is the need to clearly define minimum competence for the RDA procedures measured in the examination. OPES' analysis determined that the procedures that are being assessed are necessary for entry-level licensure and appropriate for a practical examination. However, the level of minimum acceptable competence for each procedure needs to be identified through a series of workshops involving dentists, RDAs, and testing professionals. The Board has a history of struggling with this issue, as the practical examination examiner training has in the past been conducted by an RDA and then more recently conducted by a dentist. Because dentists are ultimately responsible for the work of RDAs, both dentists and RDAs must be involved in determining the level of performance acceptable for entry-level RDA practice.

One factor adding to the complexity of defining minimum competence is the multiple pathways to RDA prelicensure training and the variety of materials that are used in different dental offices. The 2016 OA results indicated that RDAs typically learn the basic skills and techniques prelicensure and then receive additional training and techniques with specific materials under direct supervision of RDAs, RDAEFs, or dentists. This issue makes defining the correct level of minimum competence for some procedures more difficult. However, it is important to note that RDAs are closely supervised by dentists until they are determined to have the necessary skills and abilities to work under indirect supervision, therefore suspending the practical examination does not appear to increase the risk of public harm.

The second most critical issue identified is the need to improve the scoring criteria and calibration procedures. The current process does not meet professional guidelines and technical standards, and is causing unnecessary confusion for examiners, candidates, and instructors, as shown in the multitude of comments by stakeholders and SMEs. To correct this process, a series of SME workshops needs to be conducted to develop anchoring/calibration procedures and materials (slides and typodonts) for examiner orientation/training sessions. Ongoing examiner orientation/training sessions will need to be provided to ensure minimum competency and to maintain calibration standards. Each examiner's ratings will need to be tracked to assess their pass/fail scores over time (i.e., across administrations) and to monitor inter-rater reliability.

The third most critical issue is the lack of standardization. All test sites and all testing rooms must ensure consistency as much as possible (e.g., with candidate seating, bench mount setup, overhead lighting, and allowable personal protection equipment). Controversial issues with regard to the tooth used, the cementation process, the type of typodont and explorer need to be resolved. Ensuring that all equipment used by candidates is consistent, in working order, and that materials are not expired is important for reducing unnecessary stress to candidates and improving test reliability.

Finally, the potential conflict of interest of instructors providing kits and then participating in the discussion of updating the practical examination needs to be acknowledged and explored.

Addressing each issue and implementing the suggested changes to improve the RDA Practical Examination will require a great deal of time, ongoing commitment, and resources from the Board and industry. Implementing the recommendations to ensure the examination is in compliance with professional guidelines and technical standards could take one to two years. Given the amount of time, fiscal and staffing resources needed to enact change to the RDA Practical Examination, and the relatively low risk of public harm from its suspension, OPES recommends that the Board evaluate means other than a practical examination for assessing RDA competency to perform clinical procedures necessary for licensure.

## APPENDIX A: RDA PRACTICAL EXAMINATION OUTLINE

### I. Fabrication of a Temporary Crown

#### **TASK STATEMENTS**

- T21.** Take impressions for direct and indirect provisional restorations.  
**T18.** Fabricate and adjust direct and indirect provisional restorations.

#### **KNOWLEDGE STATEMENTS**

- K34.** Knowledge of irregularities in margins that affect direct and indirect provisional restorations.  
**K35.** Knowledge of techniques used to eliminate open margins when placing restorative materials.  
**K36.** Knowledge of methods for identifying improper occlusal contacts, proximal contacts, or embrasure contours of provisional restorations.  
**K37.** Knowledge of techniques and procedures for mitigating the effects of improper occlusal contacts, proximal contacts, or embrasure contours of provisional restorations.  
**K41.** Knowledge of types of impression materials and techniques and procedures for their application and placement.  
**K42.** Knowledge of techniques and procedures used to mix and place provisional materials.  
**K43.** Knowledge of techniques and procedures for bonding provisional veneers.  
**K69.** Knowledge of laws and regulations pertaining to infection control procedures related to "Dental Healthcare Personnel" (DHCP) environments.  
**K74.** Knowledge of protocols and procedures for purging dental unit waterlines and hand pieces (DUWL).  
**K84.** Knowledge of procedures and protocols for the disposal of biological hazardous waste and Other Potentially Infectious Materials (OPIM).

## **I. Fabrication of a Temporary Crown (continued)**

### **ABILITY STATEMENTS**

- A1.** Ability to take an accurate impression.
- A2.** Ability to prepare non-monomer acrylic resin material to fabricate an indirect restoration.
- A3.** Ability to fabricate acrylic temporary restoration without fractures, cracks, or voids.
- A4.** Ability to fabricate acrylic temporary restoration with proper margins, tooth contours, and acrylic finish lines.
- A5.** Ability to adjust acrylic temporary restoration with proper tooth contours, appropriate occlusal and proximal surfaces, and appropriate embrasures and contacts.
- A6.** Ability to prepare bonding agent and apply it to temporary restoration for cementation.
- A7.** Ability to cement temporary restoration, leaving restoration stable and in place without excess cement.
- A8.** Ability to mix, place, and contour sedative filling material.
- A9.** Ability to prepare tooth surface for placement of temporary restoration.
- A10.** Ability to place temporary restoration with a smooth surface without voids.
- A11.** Ability to place temporary restoration with proper occlusion, no excess O/B/L, and correct proximal box form (anatomically and margins).
- A12.** Ability to apply infection control procedures.
- A13.** Ability to place Tofflemire matrix and wedge.

## II. Cementation of a Temporary Crown

|  |
|--|
| <b>TASK STATEMENTS</b>   |
| <b>T19.</b> Perform cementation procedure for direct and indirect provisional restorations.                                |
| <b>KNOWLEDGE STATEMENTS</b>  |
| <b>K48.</b> Knowledge of types of cements and the techniques and procedures for their application, placement, and removal. |
| <b>ABILITY STATEMENTS</b>  |
| <b>A6.</b> Ability to prepare bonding agent and apply it to temporary restoration for cementation.                         |
| <b>A7.</b> Ability to cement temporary restoration, leaving restoration stable and in place without excess cement.         |
| <b>A9.</b> Ability to prepare tooth surface for placement of temporary restoration.  |
| <b>A12.</b> Ability to apply infection control procedures.   |

### III. Placement of a Temporary Restoration

| <b>TASK STATEMENTS</b>  |
|---|
| <p><b>T14.</b> Place matrices and wedges.</p> <p><b>T15.</b> Place temporary filling material.</p> <p><b>T18.</b> Fabricate and adjust direct and indirect provisional restorations.</p>  |
| <b>KNOWLEDGE STATEMENTS</b>   |
| <p><b>K29.</b> Knowledge of types of wedges and the techniques and procedures for their use.</p> <p><b>K30.</b> Knowledge of techniques and procedures for using matrix bands with or without band retainers.</p> <p><b>K31.</b> Knowledge of types of temporary filling materials and the techniques and procedures to mix, place, and contour them.</p> <p><b>K34.</b> Knowledge of irregularities in margins that affect direct and indirect provisional restorations.</p> <p><b>K35.</b> Knowledge of techniques used to eliminate open margins when placing restorative materials.</p> <p><b>K36.</b> Knowledge of methods for identifying improper occlusal contacts, proximal contacts, or embrasure contours of provisional restorations.</p> <p><b>K37.</b> Knowledge of techniques and procedures for mitigating the effects of improper occlusal contacts, proximal contacts, or embrasure contours of provisional restorations.</p> <p><b>K42.</b> Knowledge of techniques and procedures used to mix and place provisional materials.</p> <p><b>K43.</b> Knowledge of techniques and procedures for bonding provisional veneers.</p> |
| <b>ABILITY STATEMENTS</b>   |
| <p><b>A1.</b> Ability to take an accurate impression.</p> <p><b>A2.</b> Ability to prepare non-monomer acrylic resin material to fabricate an indirect restoration.</p> <p><b>A3.</b> Ability to fabricate acrylic temporary restoration without fractures, cracks, or voids.</p> <p><b>A4.</b> Ability to fabricate acrylic temporary restoration with proper margins, tooth contours, and acrylic finish lines.</p> <p><b>A5.</b> Ability to adjust acrylic temporary restoration with proper tooth contours, appropriate occlusal and proximal surfaces, and appropriate embrasures and contacts.</p>  |

### III. Placement of a Temporary Restoration (continued)

| <b>ABILITY STATEMENTS (continued)</b> |  |
|---------------------------------------|--|
| <b>A6.</b>                            | Ability to prepare bonding agent and apply it to temporary restoration for cementation.  |
| <b>A7.</b>                            | Ability to cement temporary restoration, leaving restoration stable and in place without excess cement.                                  |
| <b>A8.</b>                            | Ability to mix, place, and contour sedative filling material.  |
| <b>A9.</b>                            | Ability to prepare tooth surface for placement of temporary restoration.   |
| <b>A10.</b>                           | Ability to place temporary restoration with a smooth surface without voids.  |
| <b>A11.</b>                           | Ability to place temporary restoration with proper occlusion, no excess O/B/L, and correct proximal box form (anatomically and margins). |
| <b>A12.</b>                           | Ability to apply infection control procedures.   |
| <b>A13.</b>                           | Ability to place Tofflemire matrix and wedge.  |

## APPENDIX B: RDA ABILITY STATEMENTS

|   |
|---|
| <b>A1.</b> Ability to take an accurate impression.  |
| <b>A2.</b> Ability to prepare non-monomer acrylic resin material to fabricate an indirect restoration.  |
| <b>A3.</b> Ability to fabricate acrylic temporary restoration without fractures, cracks, or voids.  |
| <b>A4.</b> Ability to fabricate acrylic temporary restoration with proper margins, tooth contours, and acrylic finish lines.  |
| <b>A5.</b> Ability to adjust acrylic temporary restoration with proper tooth contours, appropriate occlusal and proximal surfaces, and appropriate embrasures and contacts. |
| <b>A6.</b> Ability to prepare bonding agent and apply it to temporary restoration for cementation.  |
| <b>A7.</b> Ability to cement temporary restoration, leaving restoration stable and in place without excess cement.  |
| <b>A8.</b> Ability to mix, place, and contour sedative filling material.  |
| <b>A9.</b> Ability to prepare tooth surface for placement of temporary restoration.   |
| <b>A10.</b> Ability to place temporary restoration with a smooth surface without voids.   |
| <b>A11.</b> Ability to place temporary restoration with proper occlusion, no excess O/B/L, and correct proximal box form (anatomically and margins).                        |
| <b>A12.</b> Ability to apply infection control procedures.  |
| <b>A13.</b> Ability to place Tofflemire matrix and wedge.   |

APPENDIX C: RDA ABILITY STATEMENT RATINGS BY SME

|     | SME<br>1 | SME<br>2 | SME<br>3 | SME<br>4 | SME<br>5 | SME<br>6 | SME<br>7 | SME<br>8 | SME<br>9 | SME<br>10 | AVG |
|-----|----------|----------|----------|----------|----------|----------|----------|----------|----------|-----------|-----|
| A1  | 1        | 1        | 2        | 2        | 2        | 1        | 2        | 1        | 2        | 2         | 1.6 |
| A2  | 1        | 1        | 2        | 1        | 2        | 1        | 2        | 1        | 1        | 2         | 1.4 |
| A3  | 2        | 2        | 2        | 1        | 2        | 1        | 2        | 2        | 2        | 1         | 1.7 |
| A4  | 2        | 2        | 2        | 2        | 2        | 1        | 2        | 3        | 2        | 2         | 2   |
| A5  | 3        | 3        | 2        | 2        | 2        | 2        | 2        | 3        | 2        | 2         | 2.3 |
| A6  | 1        | 1        | 2        | 2        | 2        | 2        | 1        | 2        | 1        | 1         | 1.5 |
| A7  | 2        | 2        | 3        | 2        | 2        | 2        | 2        | 2        | 2        | 2         | 2.1 |
| A8  | 2        | 2        | 3        | 1        | 2        | 1        | 2        | 2        | 2        | 1         | 1.8 |
| A9  | 1        | 1        | 2        | 2        | 2        | 2        | 2        | 1        | 1        | 2         | 1.6 |
| A10 | 1        | 2        | 2        | 2        | 2        | 1        | 2        | 2        | 2        | 1         | 1.7 |
| A11 | 2        | 2        | 3        | 3        | 2        | 1        | 2        | 3        | 2        | 2         | 2.2 |
| A12 | 1        | 1        | 1        | 1        | 2        | 1        | 1        | 1        | 1        | 1         | 1.1 |
| A13 | 1        | 3        | 2        | 2        | 2        | 1        | 2        | 3        | 1        | 2         | 1.9 |

Rating Scale: 0 - Does not apply to my job; Not required, 1 - Acquired before licensure; 2 - Acquired mostly before licensure; 3 - Acquired mostly after licensure; 4 - Acquired after licensure.

APPENDIX D: LINKAGE BETWEEN RDA PROCEDURES AND OA  
RESULTS

**PROCEDURE: Taking Impressions (Direct/Indirect Restorations)**

| Task/Ability Statement   | KSAs Required to Perform Task   |
|--|---|
| <p>T21. Take impressions for direct and indirect provisional restorations.</p> <p>A1. Ability to take an accurate impression.</p> <p>A12. Ability to apply infection control procedures.</p> | <p>K41. K of types of impression materials and techniques and procedures for their application and placement.</p> <p>K69. K of laws and regulations pertaining to infection control procedures related to "Dental Healthcare Personnel" (DHCP) environments.</p> <p>K74. K of protocols and procedures for purging dental unit waterlines and hand pieces (DUWL).</p> <p>K84. K of procedures and protocols for the disposal of biological hazardous waste and Other Potentially Infectious Materials (OPIM).</p> |

**PROCEDURE: Direct and Indirect Restorations (Place matrices and wedges)**

| Task/Ability Statement   | KSAs Required to Perform Task  |
|--|--|
| <p>T14. Place matrices and wedges</p> <p>A12. Ability to apply infection control procedures.</p> <p>A13. Ability to place Tofflemire matrix and wedge.</p> | <p>K29. K of types of wedges and the techniques and procedures for their use.</p> <p>K30. K of techniques and procedures for using matrix bands with or without band retainers</p> |

**PROCEDURE: Fabricating Dental Provisional**

| Task/Ability Statement  | KSAs Required to Perform Task   |
|---|---|
| <p>T18. Fabricate and adjust direct and indirect provisional restorations.</p> <p>A1. Ability to take an accurate impression.</p> <p>A2. Ability to prepare non-monomer acrylic resin material to fabricate an indirect restoration.</p> <p>A3. Ability to fabricate acrylic temporary restoration without fractures, cracks, or voids.</p> <p>A4. Ability to fabricate acrylic temporary restoration with proper margins, tooth contours, and acrylic finish lines.</p> <p>A5. Ability to adjust acrylic temporary restoration with proper tooth contours, appropriate occlusal and proximal surfaces, and appropriate embrasures and contacts.</p> <p>A6. Ability to prepare bonding agent and apply it to temporary restoration for cementation.</p> <p>A7. Ability to cement temporary restoration, leaving restoration stable and in place without excess cement.</p> <p>A8. Ability to mix, place, and contour sedative filling material.</p> <p>A9. Ability to prepare tooth surface for placement of temporary restoration.</p> <p>A10. Ability to place temporary restoration with a smooth surface without voids.</p> <p>A11. Ability to place temporary restoration with proper occlusion, no excess O/B/L, and correct proximal box form (anatomically and margins).</p> <p>A12. Ability to apply infection control procedures.</p> <p>A13. Ability to place Tofflemire matrix and wedge.</p> | <p>K34. K of irregularities in margins that affect direct and indirect provisional restorations.</p> <p>K35. K of techniques used to eliminate open margins when placing restorative materials.</p> <p>K36. K of methods for identifying improper occlusal contacts, proximal contacts, or embrasure contours of provisional restorations.</p> <p>K37. K of techniques and procedures for mitigating the effects of improper occlusal contacts, proximal contacts, or embrasure contours of provisional restorations.</p> <p>K42. K of techniques and procedures used to mix and place provisional materials.</p> <p>K43. K of techniques and procedures for bonding provisional veneers.</p> |

**PROCEDURE: Direct and Indirect Restorations (Place bases and liners)**

| Task/Ability Statement  | KSAs Required to Perform Task   |
|---|---|
| <p>T13. Place bases and liners.</p> <p>A8. Ability to mix, place, and contour sedative filling material.</p> <p>A9. Ability to prepare tooth surface for placement of temporary restoration.</p> <p>A12. Ability to apply infection control procedures.</p> | <p>K28. K of types of base and liner materials and the techniques and procedures for their application and placement.</p> |

**PROCEDURE: Direct and Indirect Restorations (Place bonding agent)**

| Task/Ability Statement  | KSAs Required to Perform Task   |
|---|---|
| <p>T17. Place bonding agent</p> <p>A6. Ability to prepare bonding agent and apply it to temporary restoration for cementation.</p> <p>A9. Ability to prepare tooth surface for placement of temporary restoration.</p> <p>A12. Ability to apply infection control procedures.</p> | <p>K5. K of indications and contraindications for the use of bonding agents</p> <p>K32. K of types of bonding agents and the techniques and procedures for their application and placement.</p> <p>K43. K of techniques and procedures for bonding provisional veneers.</p> |

**PROCEDURE: Direct and Indirect Restorations (Cementation procedures)**

| Task/Ability Statement   | KSAs Required to Perform Task   |
|--|---|
| <p>T19. Perform cementation procedure for direct and indirect provisional restorations.</p> <p>A6. Ability to prepare bonding agent and apply it to temporary restoration for cementation.</p> <p>A7. Ability to cement temporary restoration, leaving restoration stable and in place without excess cement.</p> <p>A9. Ability to prepare tooth surface for placement of temporary restoration.</p> <p>A12. Ability to apply infection control procedures.</p> | <p>K48. K of types of cements and the techniques and procedures for their application, placement, and removal</p> |

**PROCEDURE: Direct and Indirect Restorations (Place temporary filling material)**

| Task/Ability Statement   | KSAs Required to Perform Task  |
|--|--|
| <p>T15. Place temporary filling material.</p> <p>A8. Ability to mix, place, and contour sedative filling material.</p> <p>A9. Ability to prepare tooth surface for placement of temporary restoration.</p> <p>A10. Ability to place temporary restoration with a smooth surface without voids.</p> <p>A11. Ability to place temporary restoration with proper occlusion, no excess O/B/L, and correct proximal box form (anatomically and margins).</p> <p>A12. Ability to apply infection control procedures.</p> <p>A13. Ability to place Tofflemire matrix and wedge.</p> | <p>K29. K of types of wedges and the techniques and procedures for their use.</p> <p>K30. K of techniques and procedures for using matrix bands with or without band retainers</p> <p>K31. K of types of temporary filling materials and the techniques and procedures to mix, place, and contour them</p> |

**PROCEDURE: Direct and Indirect Restorations (Apply etchant)**

|  |  |
|--|--|
| <p>T16. Apply etchant to tooth surface (tooth dentin or enamel) for direct and indirect restorations.</p> <p>A9. Ability to prepare tooth surface for placement of temporary restoration.</p> <p>A12. Ability to apply infection control procedures.</p> | <p>K33. K of types of etchants and the techniques and procedures for their application and placement</p> <p>K46. K of indications and contraindications for the use of etching agents.</p> |
|--|--|

**PROCEDURE: Direct and Indirect Restorations (Removing indirect provisional restorations)**

|  |  |
|--|--|
| <p>T22. Remove indirect provisional restorations.</p> <p>A9. Ability to prepare tooth surface for placement of temporary restoration.</p> <p>A12. Ability to apply infection control procedures.</p> | <p>K33. K of types of etchants and the techniques and procedures for their application and placement</p> <p>K46. K of indications and contraindications for the use of etching agents.</p> |
|--|--|

# DENTAL BOARD OF CALIFORNIA

## REVIEW OF THE REGISTERED DENTAL ASSISTANT IN EXTENDED FUNCTIONS CLINICAL AND PRACTICAL EXAMINATIONS



OFFICE OF PROFESSIONAL EXAMINATION SERVICES



# DENTAL BOARD OF CALIFORNIA

## REVIEW OF THE REGISTERED DENTAL ASSISTANT IN EXTENDED FUNCTIONS CLINICAL AND PRACTICAL EXAMINATIONS

This report was prepared and written by the  
Office of Professional Examination Services  
California Department of Consumer Affairs

January 2018

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## EXECUTIVE SUMMARY

The Dental Board of California (Board) requested that the Department of Consumer Affairs' Office of Professional Examination Services (OPES) complete a comprehensive review of the Registered Dental Assistant in Extended Functions (RDAEF) Clinical and Practical Examinations. The purpose of the review was to determine whether the Board's RDAEF Clinical and Practical Examinations meet professional guidelines and technical standards.

Licensing boards and bureaus within the California Department of Consumer Affairs (DCA) are required to ensure that their examination programs comply with psychometric and legal standards. The public must be reasonably confident that an individual passing a licensing examination has the requisite knowledge and skills to competently and safely practice in the corresponding profession.

On October 7, 2017, OPES staff observed the RDAEF Clinical and Practical Examinations held at the University of California, Los Angeles (UCLA) School of Dentistry in Los Angeles. On October 14, 2017, OPES staff observed the examiner training and scoring of the RDAEF Clinical and Practical Examinations held at the University of California, San Francisco (UCSF) School of Dentistry in San Francisco.

The observations included discussions with Board staff, testing staff, dentists (examiners), and the RDAEF chief examiner. The purpose of the observations was to evaluate the process of the clinical and practical examinations with regard to reliability of measurement, examiner training and test scoring, administration, and test security and fairness to determine if the examinations meet professional guidelines and technical standards.

Based on the discussions and observations, OPES has concluded that, in general, the examinations meet professional guidelines and technical standards. However, OPES recommends that the Board implement additional slides during examiner training to enhance the level of examiner calibration, and that the Board institute minor improvements to the testing procedures and the testing environment to further improve the test administration process for all candidates. OPES believes that these small recommendations would increase the reliability and validity of the examinations.

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# CHAPTER 1. INTRODUCTION

## PURPOSE OF THE REVIEW

Licensing boards and bureaus within the California Department of Consumer Affairs (DCA) must ensure that their examination programs comply with psychometric and legal standards. The public must be reasonably confident that an individual passing a licensing examination has the requisite knowledge and skills to competently and safely practice in the corresponding profession.

The Office of Professional Examination Services (OPES) performed a review of the California Dental Board's (Board) Registered Dental Assistant in Extended Functions (RDAEF) Clinical and Practical Examinations. The purpose of the review was to determine whether the RDAEF Clinical and Practical Examinations meet the professional guidelines and technical standards outlined in section 139 of the California Business and Professions (B&P) Code and the Standards for Educational and Psychological Testing (2014) (Standards).<sup>1</sup>

## CALIFORNIA LAW AND POLICY

Section 139 (a) of the California B&P Code states:

The Legislature finds and declares that occupational analyses and examination validation studies are fundamental components of licensure programs.

It further requires that DCA develop a policy to address the minimum requirements for psychometrically sound examination validation, examination development, and occupational analyses, including standards for the review of state and national examinations.

DCA policy, OPES 12-01, specifies the *Standards*<sup>1</sup> as the most relevant technical and professional standards to be followed to ensure that examinations used for licensure in California are psychometrically sound, job-related, and legally defensible.

## FORMAT OF THE REPORT

The chapters of this report provide the relevant standards related to various aspects of the RDAEF Clinical and Practical Examinations and contain the findings and recommendations of OPES.

<sup>1</sup> *Standards* references information taken from: American Educational Research Association, American Psychological Association, and National Council on Measurement in Education. (2014). *Standards for Educational and Psychological Testing*. Washington, DC: American Educational Research Association.

## CHAPTER 2. RELIABILITY OF MEASUREMENT

### OBSERVATION OF CLINICAL AND PRACTICAL EXAMINATIONS

OPES observed two administrations of the Board's RDAEF Clinical and Practical Examinations to determine whether the examination programs meet professional guidelines and technical standards. On October 7, 2017, OPES staff observed the RDAEF Clinical and Practical Examinations held at the University of California, Los Angeles (UCLA) School of Dentistry in Los Angeles. On October 14, 2017, OPES staff observed the examiner training and scoring of the RDAEF Clinical and Practical Examinations held at the University of California, San Francisco (UCSF) School of Dentistry in San Francisco.

The observations included discussions with Board staff, testing staff, and dentists (examiners) involved with the clinical and practical examinations, as well as with the RDAEF Chief Examiner. The purpose of the observations was to evaluate the process of the clinical and practical examinations with regard to reliability of measurement, examiner training and test scoring, administration, test security, and fairness.

The following standards are most relevant to reliability and precision of measurement for licensing examinations, as referenced in the *Standards*.

### STANDARDS

#### **Standard 2.1**

The range of replications over which reliability/precision is being evaluated should be clearly stated, along with a rationale for the choice of this definition, given the testing situation. (p. 42)

Comment: For any testing program, some aspects of the testing procedure (e.g., time limits and availability of resources such as books, calculators, and computers) are likely to be fixed, and some aspects will be allowed to vary from one administration to another (e.g., specific tasks or stimuli, testing contexts, raters, and, possibly, occasions). Any test administration that maintains fixed conditions and involves acceptable samples of the conditions that are allowed to vary would be considered a legitimate replication of the testing procedure. As a first step in evaluating the reliability/precision of the scores obtained with a testing procedure, it is important to identify the range of conditions of various kinds that are allowed to vary, and over which scores are to be generalized.

#### **Standard 11.14**

Estimates of the consistency of test-based credentialing decisions should be provided in addition to other sources of reliability evidence. (p. 182)

## FINDINGS

The Board typically administers the RDAEF Clinical and Practical Examinations five or more times per year in two or more locations. On each administration date, the clinical examination is administered once in the morning while the practical examination is administered once in the afternoon. Examiner training occurs simultaneously with examination administration.

On October 7, 2017 the Board held one administration of the RDAEF Clinical and Practical Examinations at UCLA School of Dentistry, with simultaneous examiner training. On October 14, 2017, the Board held one administration of the RDAEF Clinical and Practical Examinations at UCSF School of Dentistry, with simultaneous examiner training. OPES could not be physically present at both examination administrations and both examiner trainings to compare them directly. At UCLA, OPES staff observed the test administrations; at UCSF, OPES staff observed the examiner training.

However, based on observations at both test locations, it appears that the locations are equal with regard to standardized check-in and registration procedures, candidate instructions, examination administration, test security protocols, and examiner training and scoring. OPES staff was able to reach this conclusion for the following reasons:

- OPES staff was able to observe the site and layout of both testing environments.
- OPES staff was able to observe the scoring of the examinations at both testing environments.
- The same individuals (Board staff and testing staff) administer the Board's examinations at both locations.
- At both locations, examiner training is conducted by the same Chief Examiner.

**Finding 1:** The standardization of administrations with regard to replicating the administrations of the tests between multiple site locations meets professional guidelines and technical standards.

## CHAPTER 3. EXAMINER TRAINING AND TEST SCORING

### STANDARDS

The following standards are most relevant to examiner training and test scoring for licensing examinations, as referenced in the *Standards*.

#### **Standard 4.20**

The process for selecting, training, qualifying, and monitoring scorers should be specified by the test developer. The training materials, such as the scoring rubrics and examples of test takers' responses that illustrate the levels on the rubric score scale, and the procedures for training scorers should result in a degree of accuracy and agreement among scorers that allows the scores to be interpreted as originally intended by the test developer. Specifications should also describe processes for assessing scorer consistency and potential drift over time in raters' scoring. (p. 92)

#### **Standard 4.21**

When test users are responsible for scoring and scoring requires scorer judgement, the test user is responsible for providing adequate training and instruction to the scorers and for examining scorer agreement and accuracy. The test developer should document the expected level of scorer agreement and accuracy and should provide as much technical guidance as possible to aid test users in satisfying this standard. (p. 92)

#### **Standard 6.8**

Those responsible for test scoring should establish scoring protocols. Test scoring that involves human judgment should include rubrics, procedures, and criteria for scoring. When scoring of complex responses is done by computer, the accuracy of the algorithm and processes should be documented. (p. 118)

### FINDINGS

#### Examiner Orientation/Training

On October 14, 2017, the examiner orientation/training session at the UCSF test site occurred twice – once for the clinical examination in the morning, and once for the practical examination in the afternoon. Both training sessions included clear instructions for how to perform candidate scoring. The grading sheets and the criteria for grading were discussed in detail. In addition, the RDAEF Chief Examiner provided information about what to look for during scoring

Both morning and afternoon training sessions included standard exercises for the training of examiners on scoring procedures and for the anchoring/calibrating of examiners.

[REDACTED]

[REDACTED]

[REDACTED] Thus, the Chief Examiner ensured that all examiners met the minimum standards for being allowed to score candidate performance.

**Finding 2:** Standard exercises for training examiners on scoring procedures, for anchoring/calibrating examiners, and for assessing the results of examiner training and calibration were evidenced.

### Test Scoring

Before the scoring process, examiners were instructed to follow the scoring protocols and to direct questions to designated staff or to the Chief Examiner as needed.

[REDACTED]

[REDACTED] Examiners were also instructed that scoring should be performed based on the specific scoring criteria and should not be based on what is “perfect” or on a given examiner’s opinion.

[REDACTED]

[REDACTED] Therefore, it appeared that the scoring process met professional guidelines and technical standards.

**Finding 3:** The scoring criteria are applied equitably to ensure the validity and reliability of the examination results. The test scoring process meets professional guidelines and technical standards.

[REDACTED]

## RECOMMENDATIONS

Although there was evidence of standard exercises for training examiners on scoring procedures, for anchoring/calibrating examiners, and for assessing the results of examiner training and calibration, more exercises should be included. [REDACTED]

[REDACTED]

**Recommendation 1:** Include more slides during examiner training to improve calibration [REDACTED]

[REDACTED]

[REDACTED]

**Recommendation 2:** Include a few visual examples for each scale point [REDACTED]

[REDACTED]

## CHAPTER 4. TEST ADMINISTRATION

### STANDARDS

The following standards are most relevant to standardizing the test administration process for licensing examinations, as referenced in the *Standards*.

#### **Standard 3.4**

Test takers should receive comparable treatment during the test administration and scoring process. (p. 65)

#### **Standard 4.15**

The directions for test administration should be presented with sufficient clarity so that it is possible for others to replicate the administration conditions under which the data on reliability, validity, and (where appropriate) norms were obtained. Allowable variations in administration procedures should be clearly described. The process for reviewing requests for additional testing variations should also be documented. (p. 90)

#### **Standard 4.16**

The instructions presented to test takers should contain sufficient detail so that test takers can respond to a task in the manner that the test developer intended. When appropriate, sample materials, practice or sample questions, criteria for scoring, and a representative item identified with each item format or major area in the test's classification or domain should be provided to the test takers prior to the administration of the test, or should be included in the testing material as part of the standard administration instructions. (p. 90)

#### **Standard 6.1**

Test administrators should follow carefully the standardized procedures for administration and scoring specified by the test developer and any instructions from the test user. (p. 114)

#### **Standard 6.3**

Changes or disruptions to standardized test administration procedures or scoring should be documented and reported to the test user. (p. 115)

#### **Standard 6.4**

The testing environment should furnish reasonable comfort with minimal distractions to avoid construct-irrelevant variance. (p. 116)

#### **Standard 6.5**

Test takers should be provided appropriate instructions, practice, and other support necessary to reduce construct-irrelevant variance. (p. 116)

## FINDINGS

### Test Administration – Directions and Instructions to Candidates

The *Registered Dental Assistant in Extended Functions Candidate Handbook* is mailed to each candidate. This handbook provides candidates with information regarding RDAEF examination requirements and prohibitions, general descriptions and examination administration procedures, required materials, grading and scoring criteria, and appeals.

Throughout the administration process, candidates are presented with standardized instructions from testing staff. Testing staff and proctors are strategically placed in specific areas on the floor to assist candidates and to provide instructional information during candidate check-in registration. Once candidates are checked in, they are escorted into an orientation room along with their patients and employer dentists, and they are provided with a scripted orientation speech. Following orientation, the candidates, patients, and dentists proceed to the examination clinic. In the examination clinic, the candidates are provided with scripted instructions over the PA system. The candidates are also notified over the PA system when they have a specific amount of time remaining to complete the examination and when they must stop. These instructions are provided in a clear and uniform manner consistently in both clinical and practical testing sessions.

**Finding 4:** The directions and instructions provided to candidates appear straightforward. The information available to candidates is detailed and thorough, clearly stating the Board's policies where necessary.

### Test Administration – Standardized Procedures

Testing staff and proctors follow standardized scripts, instructions, and checklists throughout the test administration process. Responses to candidate questions are standardized, where applicable. Checklists are used to evaluate site preparedness, to document candidate compliance with infection control procedures (i.e., personal protection equipment [PPE]), and to document candidate apparel and equipment. Operating procedures are also in place, if needed, for emergency preparedness, sexual harassment/misconduct, and other unprofessional conduct – including candidate and examiner/staff dismissal.

The test facility has some signage directing candidates where to go, and the directions to the check-in area are minimally marked and monitored. Additional signage could help further guide candidates because the examinations are administered on very large college campuses.

The testing staff maintain a professional appearance and demeanor. Their roles and responsibilities are well-evidenced, and the check-in process is well-organized. However, candidates should be reminded about prohibited items during check-in. They receive a reminder during the orientation speech, but they should be given an earlier reminder at check-in before entering the orientation room. In addition, even though

patients are reminded to keep their phones off or on silent during the clinical examination, they should be reminded during orientation to keep their phones out of sight during the entire examination.

The timing schedule for test administration is objective and standard, and candidates are able to monitor time remaining. However, the practical examination room at UCLA only has one clock. Additional clocks should be provided in the practical examination room so that all candidates can easily monitor the time remaining.

**Finding 5:** The policies and procedures established for the test administration process meet professional and technical standards and guidelines. However, minor additions to the existing procedures could benefit the candidates.

### Test Administration – Testing Environment

The testing environment was well-lit and set at a comfortable temperature. However, at UCLA the temperature felt slightly warmer in the practical examination room than in the clinical examination room.

Candidate testing stations are identical for each candidate and are evenly spaced to permit confidential performance between candidates. The testing stations allow for the proper placement and anchoring of typodonts in the practical examination, and there is sufficient room to perform the procedures and to place the armamentaria in both the clinical and practical examinations. Testing staff are easily able to monitor communication between candidates, and proctors are able to walk through the testing area to make unobtrusive observations.

**Finding 6:** The testing environment meets professional guidelines and technical standards.

## RECOMMENDATIONS

Although the RDAEF Clinical and Practical Examinations meet professional and technical standards and guidelines with regard to the testing environment and to the policies and procedures for test administration processes, the examinations could benefit from some minor improvements.

**Recommendation 3:** In the test facility, include more signage directing candidates where to go, and more signage indicating areas that are restricted to candidates and testing personnel only.

**Recommendation 4:** Remind candidates during check-in about prohibited items, and remind patients during orientation about keeping phones out of sight throughout the entire clinical examination.

**Recommendation 5:** Provide additional clocks in the practical examination room to ensure all candidates can see a clock.

**Recommendation 6:** Check the temperature of the testing environment and if possible, adjust as needed to ensure comfort.

## CHAPTER 5. TEST SECURITY

### STANDARDS

The following standards are most relevant to the test security of licensing examinations, as referenced in the *Standards*.

**Standard 6.6**

Reasonable efforts should be made to ensure the integrity of test scores by eliminating opportunities for test takers to attain scores by fraudulent or deceptive means. (p. 116)

**Standard 6.7**

Test users have the responsibility of protecting the security of test materials at all times. (p. 117)

**Standard 8.9**

Test takers should be made aware that having someone else take the test for them, disclosing confidential test material, or engaging in any other form of cheating is unacceptable and that such behavior may result in sanctions. (p. 136)

**Standard 9.21**

Test users have the responsibility to protect the security of tests, including that of previous editions. (p. 147)

### FINDINGS

During test administration, the following security policies, procedures, and protocols are adhered to and implemented:

- Candidates must provide a current and valid government-issued photo identification for entry into the test site.
- Candidates are prohibited from bringing any personal belongings into the testing rooms other than the required materials.
- Candidate identification numbers are used to designate candidates on all examination and scoring materials and testing stations.
- Areas of the test facility are marked, blocked, or monitored by staff (i.e., only candidates and designated staff are allowed in the testing area).
- Testing staff and proctors are clearly identified (i.e., badges, attire).
- Examiners remain in a separate room away from candidates during testing and do not intermingle with candidates outside the testing area.

- Testing area layout permits the monitoring and observation of candidates.
- All scoring materials remain in a secure, designated area.
- Candidate score sheets are maintained in a confidential and secure manner.
- Only designated staff have access to testing and scoring materials.
- Procedures for candidate dismissal upon completion prevent sharing of information between candidates.
- Candidates leaving the test area during the exam are monitored, and procedures are followed with regard to candidate movement and activity.
- Following administration, all test and scoring materials are accounted for, secured, and prepared for conveyance.

In addition to these security measures, the Board's *Registered Dental Assistant in Extended Functions Candidate Handbook* also provides information to candidates regarding general requirements and prohibitions during the examination.

**Finding 7:** The Board, through its internal test administration and security protocols, provides a robust framework of test site and examination security policies and procedures.

## CHAPTER 6. TEST FAIRNESS

### TEST FAIRNESS

The concept of fairness as it relates to testing is applied by the *Standards* in four primary areas: fair and equitable treatment of all test takers during the testing process, fairness as the lack or absence of measurement bias, fairness as access to the construct being measured, and fairness as validity of individual test score interpretations for the intended use(s) (p. 51). One way of characterizing all of these areas is to consider that fairness in testing requires that individuals not be advantaged or disadvantaged in any facet of the testing process because of characteristics that are irrelevant to the construct being tested. Standards 3.1 and 3.4, below, should be understood within the context of individuals from the intended test population from diverse racial, ethnic, gender, age, socioeconomic, and educational backgrounds who have met the eligibility requirements to take the RDAEF Clinical and Practical Examinations.

### STANDARDS

The following standards are most relevant to test fairness for licensing examinations, as referenced in the *Standards*.

#### **Standard 3.1**

Those responsible for test development, revision, and administration should design all steps of the testing process to promote valid scores for the widest possible range of individuals and relevant groups in the intended population. (p. 63)

#### **Standard 3.4**

Test takers should receive comparable treatment during the test administration and scoring process. (p. 65)

#### **Standard 9.14**

Test users should inform individuals who may need accommodations in test administration (e.g., older adults, test takers with disabilities, or English language learners) about the availability of accommodations and, when required, should see that these accommodations are appropriately made available. (p. 145)

### FINDINGS

Special accommodation requests are included in the Board's individual letter to candidates for admittance to the examination. Candidates are informed that they may also call the Board to request a special accommodation. In addition, they are informed that if their religious beliefs preclude them from taking the examination on Saturday or Sunday, they must include a note indicating the day on which they cannot take the

examination and the reason why. The Board approves any necessary accommodations under the Americans with Disabilities Act.

In addition, as noted previously in Chapter 4, the Board has policies and procedures for standardizing the test administration. These procedures contribute to fairness in that all candidates receive the same instructions in the same way. Candidates have opportunities to ask questions in a group setting so that all candidates present hear the question and the response together. The candidate orientation prior to the examination, as well as the scripted instructions provided during the examination, ensure that all candidates have the opportunity to hear the instructions and to hear any clarifications by the administration's facilitators of potential areas of confusion.

**Finding 8:** The Board takes measures to ensure that the examination is fair for all candidates with regard to special accommodations and equitable treatment.

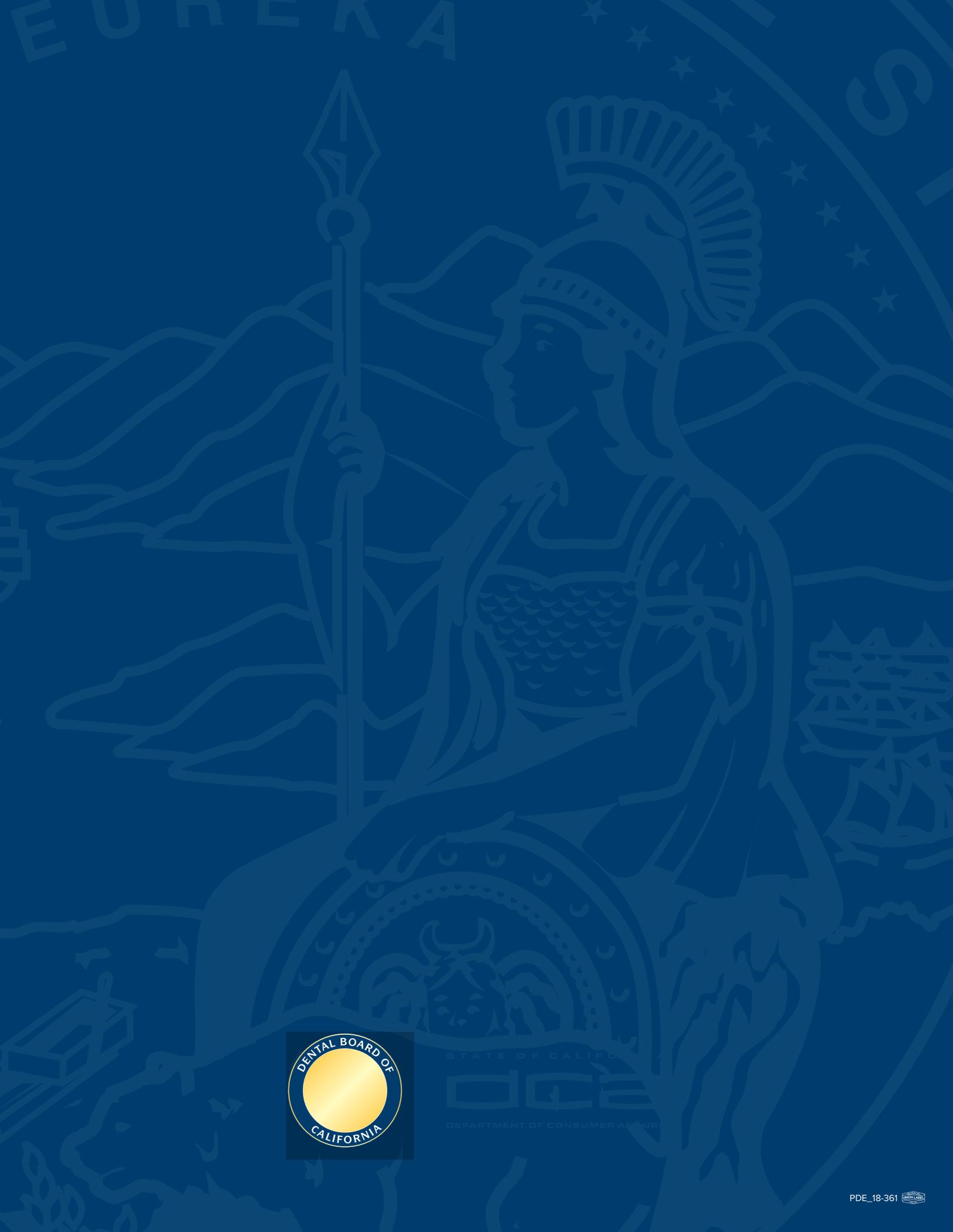
## CHAPTER 7. CONCLUSIONS

Information about the RDAEF Clinical and Practical Examinations was gathered from Board staff, testing staff, dentists (examiners), and the RDAEF Chief Examiner. This information, coupled with OPES' observation of two test administrations at two different locations, established that the examinations meet professional guidelines and technical standards with regard to reliability of measurement, examiner training and scoring, test administration, test security, and fairness.

However, OPES recommends that the Board include additional slides during examiner training to enhance the level of examiner calibration, and that the Board institute a few minor improvements to the testing procedures and the testing environment to further improve the test administration process for all candidates (i.e., provide additional signage and clocks, provide additional reminders about prohibited items during check-in, and check room temperature). OPES believes that these small recommendations would increase the reliability and validity of the examinations.

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