

PEDIATRIC ANESTHESIA STUDY

DECEMBER 2016



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OF CALIFORNIA**

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TABLE OF CONTENTS

Executive Summary	1
Introduction	2
Background	2
Definitions Used in Dental Sedation and Anesthesia	5
Dental Board General Anesthesia, Conscious Sedation and Oral Conscious Sedation Permit Programs	7
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	8
Current California Sedation and Anesthesia Laws	8
Dental Sedation and Anesthesia Laws in Other States	9
Comparison of California Laws With Laws in Other States	10
Advanced Educational Programs that Include Sedation Training	13
Summary of Comparison of California Laws and Regulations to Other States.	19
Discussion of Differences	20
Professional Dental Association Guidelines, Position Papers and Policy Statements	21
Discussion of Differences and Similarities Between California Laws and the ADA	28
Summary of Differences and Similarities Between California Laws and the AADA and AAP-AAPD Guidelines	29
Discussion of Areas Where California Requirements are Different From Professional Guidance Documents	29
PART 2: Literature Review - Sedation and General Anesthesia for Pediatric Dental Patients	33
Dental Sedation and Anesthesia Outcomes Reports	47
Summary of Literature Review	46
PART 3: Dental Board of California - Data Related to Pediatric Sedation and Anesthesia	49
Notification of Pediatric Deaths	49
Appendix 1	57
Appendix 2	67

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.¹

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.

¹ Boynes, S.G., *A Guide to Dental Anesthesiology Rules and Regulations*, 5th 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 2006.² 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

² 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,³ ⁴ the American Dental Society of Anesthesia⁵ and the American Association of Oral and Maxillofacial Surgeons.⁶ These publications provide summaries of all laws and regulations relevant to general anesthesia and deep sedation as well as moderate and

³American Dental Association, "Statutory Requirements for General Anesthesia and Deep Sedation Permits," 2009. http://www.ada.org/en/~media/ADA/Advocacy/Files/anesthesia_general_permit

⁴ 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

⁵Boynes, S.G., *A Guide to Dental Anesthesiology Rules and Regulations*, 5th ed., Chicago, No-No Orchard Publishing, 2013. http://www.mediafire.com/download/b0p8rhh9imk4939/Fifth_Edition_Dental_Anesthesiology_Guide_to_the_Rules_and_Regulations.pdf

⁶ 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).⁷ 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^{8 9} and the educational standards of the Commission on Dental Accreditation of the American Dental Association,¹⁰ 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.

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

⁸ 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

⁹ 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

¹⁰ 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.¹¹

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.

¹¹ "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.¹² 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

¹² 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.¹³ 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:

¹³ 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 CO₂ 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).¹⁴ 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.^{15 16}

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*

¹⁴ 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>

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

¹⁶ 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.¹⁷ 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

¹⁷ 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.¹⁸ 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,¹⁹ 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.

¹⁸ 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.

¹⁹ 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.”²⁰ 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 Parameters²¹ 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

²⁰ 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

²¹ 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.²²

- 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.²³ 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.

²² 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>

²³ 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.²⁴

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.

²⁴ 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.²⁵

²⁵ 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.²⁶ 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**

²⁶ 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 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 (95% CI 7.4-9.0)	---
Gonzales et al	2001-2011	systematic review of 20 trials pediatric studies all ASA	0.41-13.4/10,000	---
Schiff et al	1999-2010	Core data set – national standardized tracking data base 1,374,678 anesthetics ASA I and II elective cases Secondary German hospitals	26.2/1,000,000 (95% CI 19.4-34.6)	7.3/1000,000 (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.²⁷ Cravero and others have reported the development of an integrated outcome database for pediatric anesthesia which holds great promise for the future.²⁸

Pediatric Sedation Studies

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

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

²⁸ 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.

²⁹ 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>

³⁰ 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.³¹ Lourenco-Matharau 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.³²

Lee³³ 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.³⁴ 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.

³¹ 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>

³² Lourenco-Matharau, L., Ashley, P. F., Furness, S., Lourenco-Matharau, 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>

³³ 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>

³⁴ 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 al³⁵ 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 literature³⁶ 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 Schiff³⁷ 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.

³⁵ 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.

³⁶ 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).

³⁷ 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 study³⁸ 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. Lagasse³⁹ 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.⁴⁰ 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. Shapiro⁴¹ 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%.⁴² Thirteen of 23 deaths were caused by pulmonary embolism. Studies of office based cosmetic procedures emphasize that there is inherent risk

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

³⁹ 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>

⁴⁰ 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)

⁴¹ 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>

⁴² 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.⁴³ 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.

Lee⁴⁴ 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

⁴³ 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.

⁴⁴ 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.

Perrott⁴⁵ 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.

Lee⁴⁶ 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.

⁴⁵ 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)

⁴⁶ 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 al⁴⁷ 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 al⁴⁸ 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

⁴⁷ 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>

⁴⁸ 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's⁴⁹ 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 study⁵⁰ includes outcomes from MAC in both inpatient and outpatient facilities making it difficult to draw conclusions about the safety of MAC in outpatient facilities.

Jimenez⁵¹ 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

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

⁵⁰ 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.

⁵¹ 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 Peskin⁵² 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.

Deegan⁵³ 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.

Nkansah⁵⁴ 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

⁵² 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.

⁵³ 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>

⁵⁴ 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 Chicka⁵⁵ 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.⁵⁶ 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

⁵⁵ 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.

⁵⁶ 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.⁵⁷

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.⁵⁸ 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

⁵⁷ 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)

⁵⁸ 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.⁵⁹

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.⁶⁰

Langhan et al reported the results a study of physiologic monitoring practices during pediatric sedation from the PSRC.⁶¹ 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.

⁵⁹ 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>

⁶⁰ 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>

⁶¹ 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.⁶² 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.

⁶² 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 al⁶³ indicate in their study of pediatric dental anesthesia morbidity and mortality that approximately 100,000-250,000 cases were performed annually as of 2005.

⁶³ 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 480-505⁶⁴ ⁶⁵ 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.

⁶⁴ 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>

⁶⁵ 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 (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)¹

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.

¹ 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 Anesthesiology² (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)

² 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>

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 Dentistry³ (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 sedation⁴

³ 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>

⁴ 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

TABLE OF CONTENTS

Comparison of California requirements for minimal, moderate and deep sedation/general anesthesia with American Dental Association Guidelines¹ and American Academy of Pediatrics – American Academy of Pediatric Dentistry Guidelines²

Table 1

California Definitions Compared to ADA and ADA-AAPD Guidelines 67

Table 2

Educational Requirements for Minimal, Moderate, Deep Sedation and General Anesthesia 71
Continuing Education – Comparison of State Requirements with Association Guidelines 76

Table 3

Pre-operative Evaluation for Minimal Sedation, Moderate Sedation, Deep Sedation, and General Anesthesia. 81

Table 4

Personnel Requirements – Clinical Guidelines – Comparison of CA, ADA, and AAP-AAPD Guidelines (updated Sept. 2016) 85
Sedation and Anesthesia Assisting Requirements in the 50 States 87

Table 5

Facility Requirements – Clinical Guidelines – Comparison of California, ADA and AAP-AAPD Guidelines 91

Table 6

Monitoring and Equipment – Clinical Guidelines for Minimal Sedation, Moderate Sedation, Deep Sedation, and General Anesthesia. 93
State Requirements. 97

Table 7

Record Requirements – Clinical Guidelines for Minimal Sedation, Moderate Sedation, Deep Sedation, and General Anesthesia. 99

Table 8

Emergency drugs – California sedation laws compared to ADA and ADA-AAPD Guidelines 101

Table 9

State Mandated Office Inspection Requirements 103
Summary of Requirements in 50 states 106

Table 10

Pediatric Sedation Laws for the 50 States – Summary 109

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 ADA¹ and ADA-AAPD Guidelines²

<p>California requirements for minimal sedation, moderate sedation and general anesthesia</p> <p>California law has specific requirements for pediatric patients for oral (moderate) conscious sedation only (under age 13).</p>	<p>ADA Guidelines for use of sedation and general anesthesia by dentists; For pediatric patients ADA supports AAP-AAPD Guidelines (age 12 and under)</p>	<p>AAP-AAPD Guidelines for monitoring and management of pediatric patients (age 21 and under)</p>
<p>Minimal Sedation</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>	<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>CA requires a pediatric oral (moderate) conscious sedation permit for children 13 or under.</p>	<p>Pediatrics 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>
<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>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>

(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/S0024615000072132>
- 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 Dentists¹	AAP-AAPD Guidelines for Monitoring and Management of Pediatric Patients²
<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. (see ADA Educational Guidelines)</p>	<p>Educational Requirements</p> <p>Minimal Sedation</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>Minimal sedation requires</p> <ol style="list-style-type: none"> 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 An equivalent advanced education program accredited by the ADA Commission on Dental Accreditation. <p>Enteral and/or Combination Inhalation-Enteral Minimal Sedation Course Duration:</p> <p>Current certification in Basic Life Support for Healthcare Providers</p> <ol style="list-style-type: none"> Completion of a nitrous oxide competency course. 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. <p><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><i>continued on next page</i></p>

Minimal Sedation (continued)	
<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	
<p>California Moderate Enteral Sedation Courses for Adults and Minors</p> <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 24 hours 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; this course in moderate enteral sedation is not designed for the management of children (aged 12 and under). 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>Moderate Enteral Sedation</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>

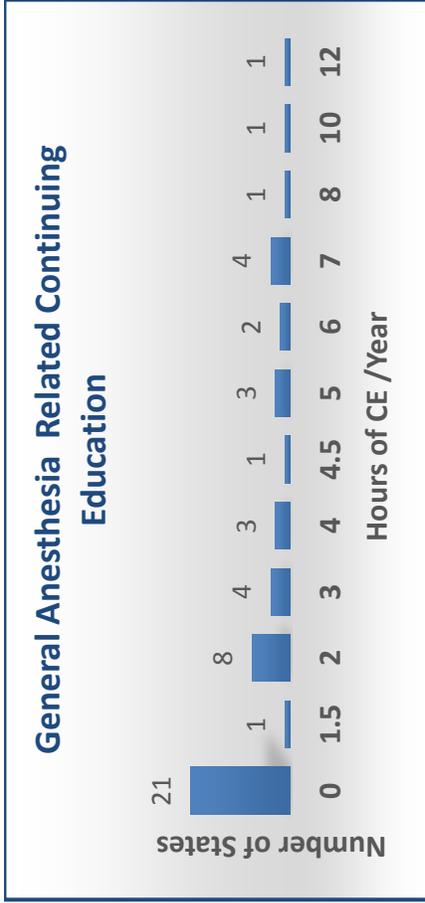
Conscious Sedation (Moderate IV Sedation)	Moderate Parenteral Sedation	Moderate Sedation
<p>At least 60 hours of instruction. Satisfactory completion of at least 20 cases of administration of conscious sedation for a variety of dental procedures.</p> <p>Course must comply with the requirements of the 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).</p> <p>(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.</p> <p>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>C. Deep Sedation or General Anesthesia</p> <ol style="list-style-type: none"> 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 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. 	<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>

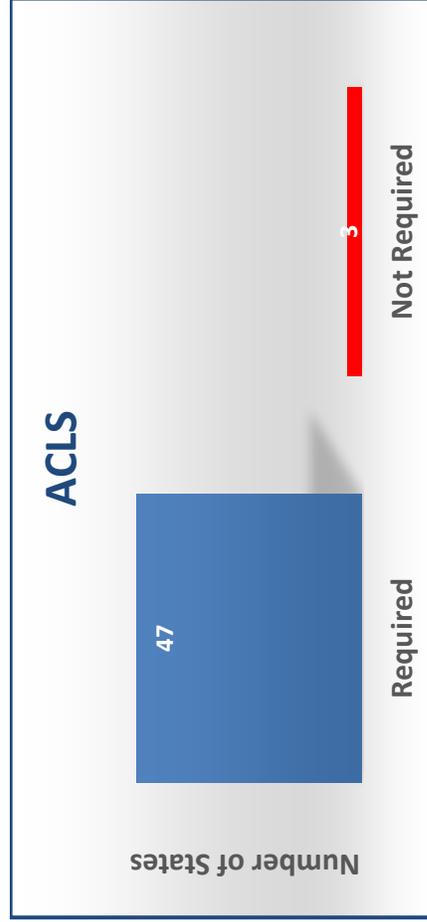
(Footnotes)

- 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>

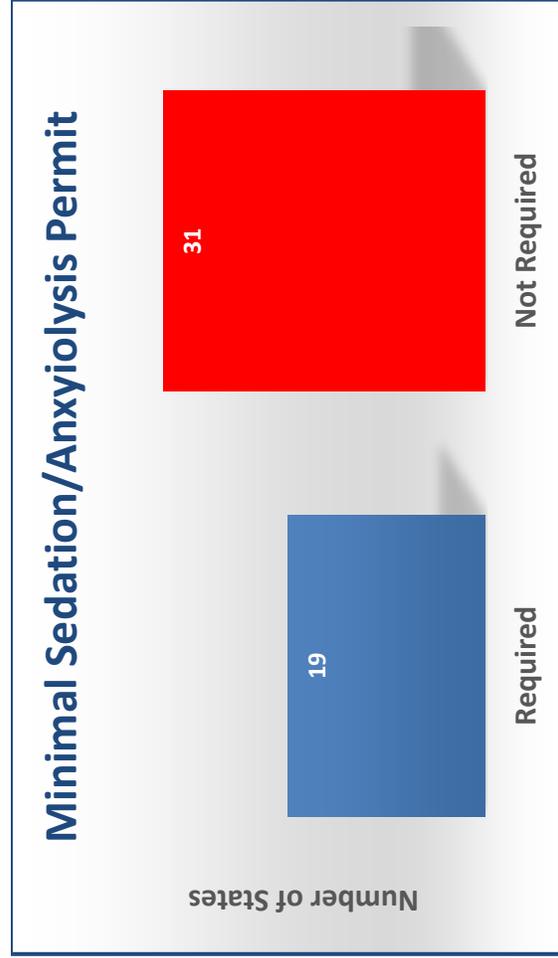
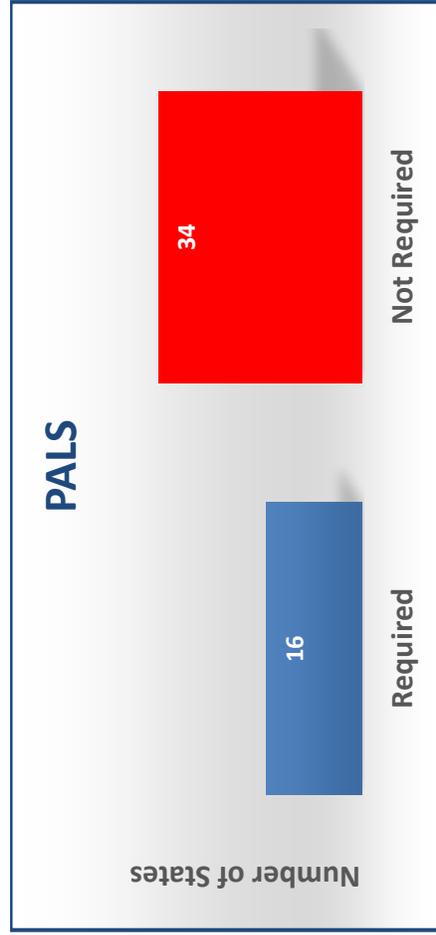
Continuing Education – State Requirements



ACLS for General Anesthesia Permits

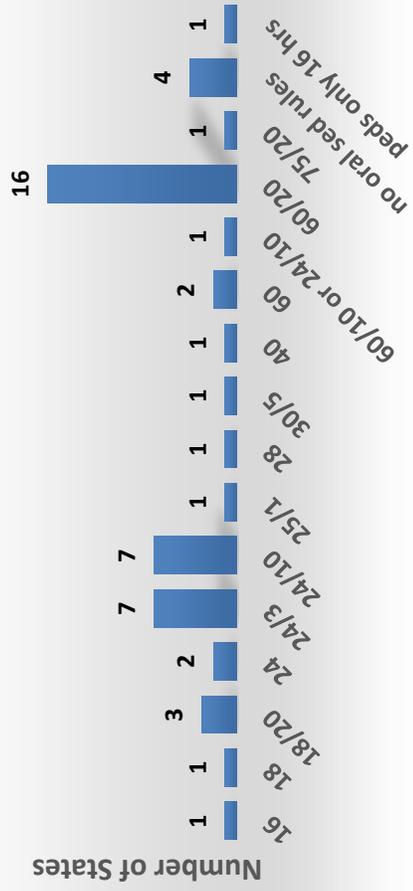


Pediatric Advanced Life Support for General Anesthesia Permit Holders



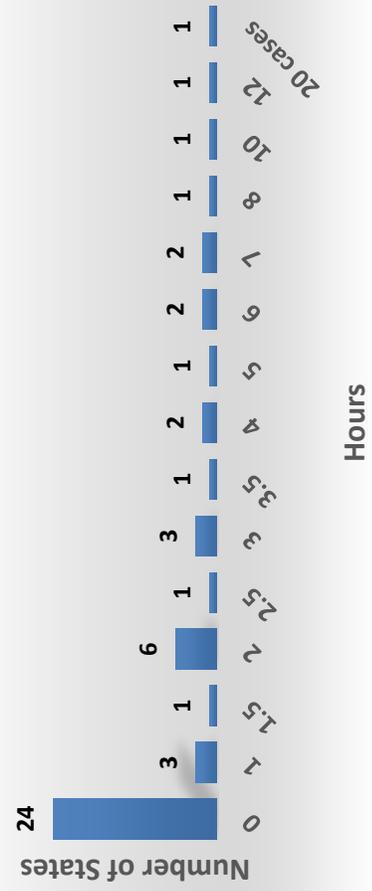
Moderate Oral Sedation Course Requirements

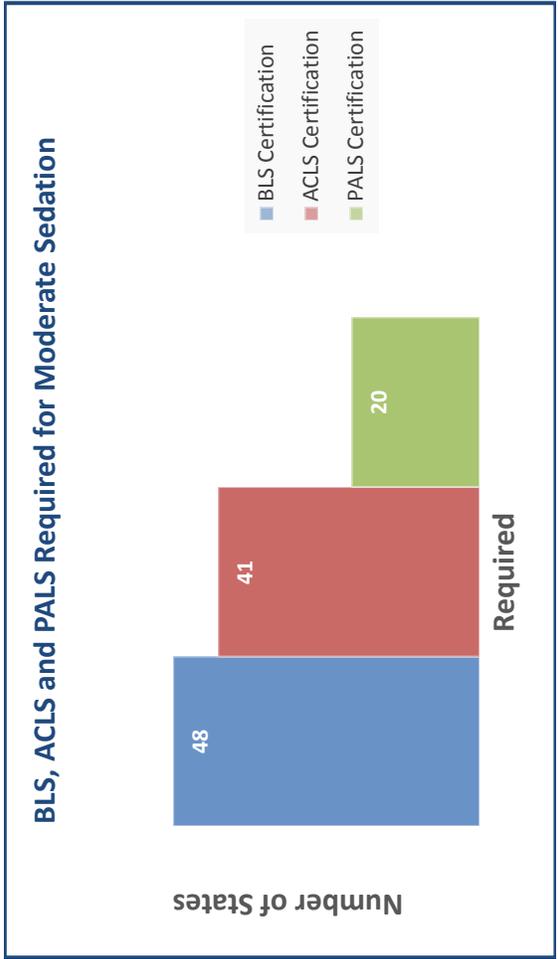
hours/cases



Sedation Related Continuing Education

Hours/Year





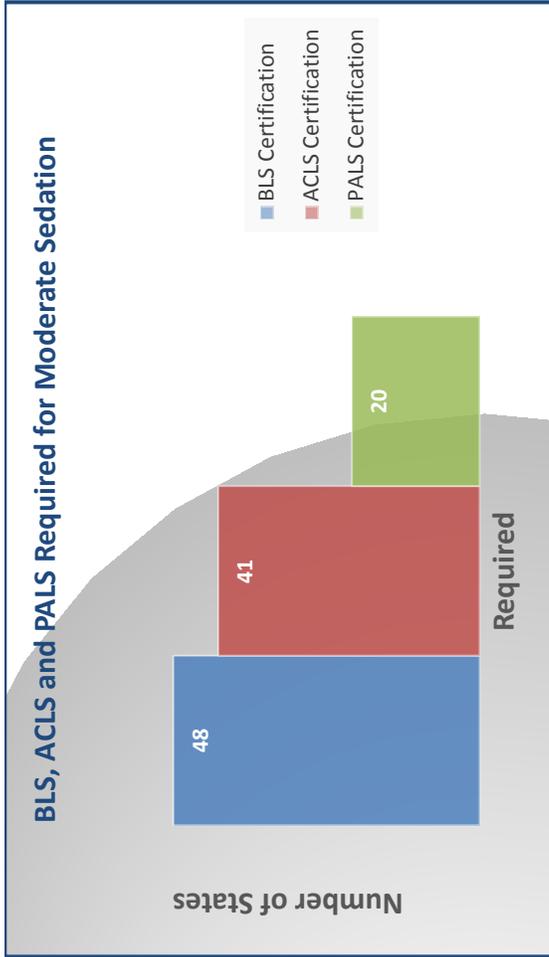


TABLE 3
Pre-operative Evaluation for Minimal Sedation, Moderate Sedation, Deep Sedation, and General Anesthesia

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>Pre-operative evaluation 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>Pre-operative evaluation and preparation</p> <ol style="list-style-type: none"> 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. Pre-operative preparation <ul style="list-style-type: none"> 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. Determination of adequate oxygen supply and equipment necessary to deliver oxygen under positive pressure must be completed. Baseline vital signs must be obtained unless the patient's behavior prohibits such determination. A focused physical evaluation must be performed as deemed appropriate. Pre-operative dietary restrictions must be considered based on the sedative technique prescribed. Pre-operative verbal and written instructions must be given to the patient, parent, escort, guardian, or caregiver. 	<p>Health evaluation</p> <p>Age and weight.</p> <ul style="list-style-type: none"> 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. 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. Physical examination, including a focused evaluation of the airway (tonsillar hypertrophy, abnormal anatomy). Physical status evaluation [ASA classification]. Name, address, and telephone number of the child's medical home. <p>Dietary precautions: 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 (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>Patient Evaluation</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"> • 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. • Determination of adequate oxygen supply and equipment necessary to deliver oxygen under positive pressure must be completed. • Baseline vital signs must be obtained unless the patient's behavior prohibits such determination. • A focused physical evaluation must be performed as deemed appropriate. • Pre-operative dietary restrictions must be considered based on the sedative technique prescribed. • Pre-operative verbal or written instructions must be given to the patient, parent, escort, guardian, or caregiver. 	

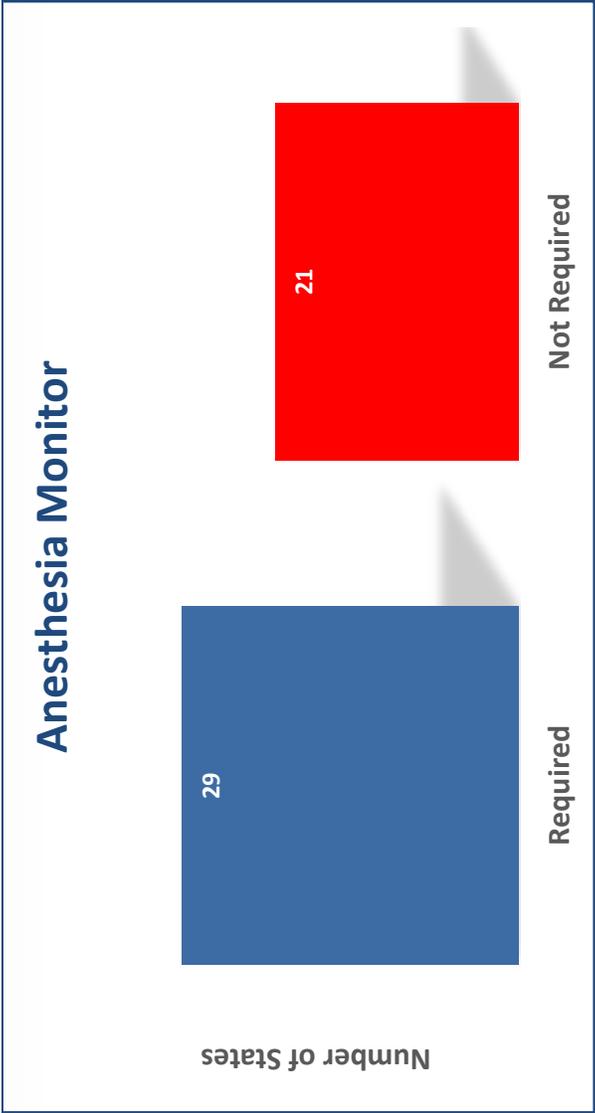
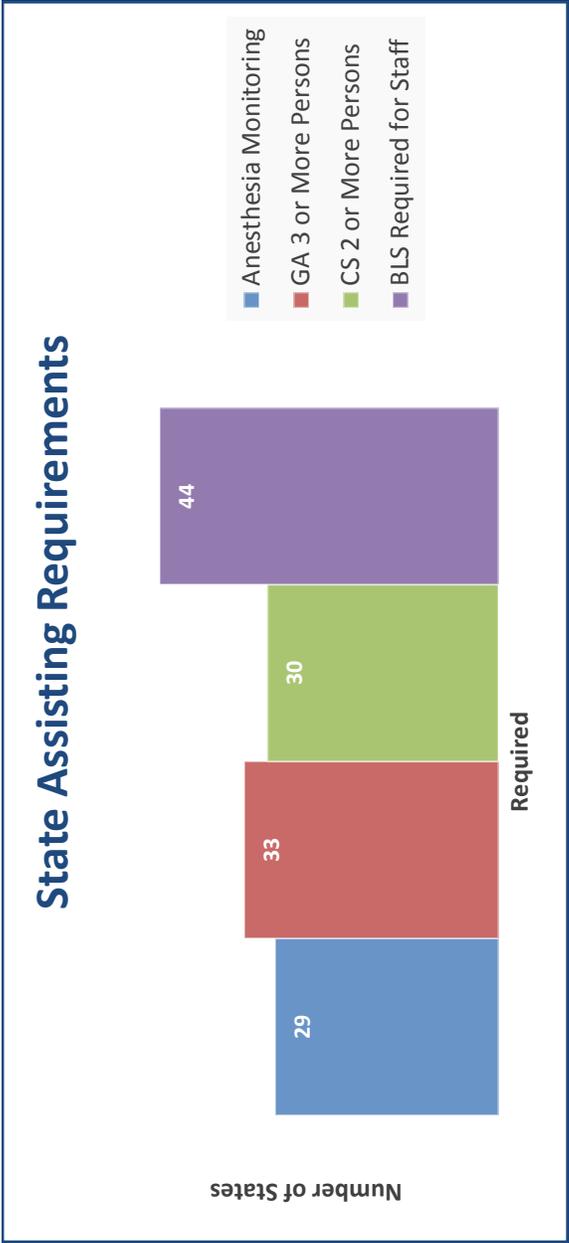
General Anesthesia	Deep Sedation or General Anesthesia	Deep Sedation
<p>No specific dietary restrictions.</p> <p>Equipment for an IV must be available, but does not need to be established. Dentist discretion advised for cases where it may be difficult or impossible to establish IV access.</p>	<p>Patient Evaluation</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"> • 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. • Determination of adequate oxygen supply and equipment necessary to deliver oxygen under positive pressure must be completed. • Baseline vital signs must be obtained unless the patient's behavior prohibits such determination. • A focused physical evaluation must be performed as deemed appropriate. • Pre-operative dietary restrictions must be considered based on the sedative/anesthetic technique prescribed. • Pre-operative verbal and written instructions must be given to the patient, parent, escort, guardian, or caregiver. • 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>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)**

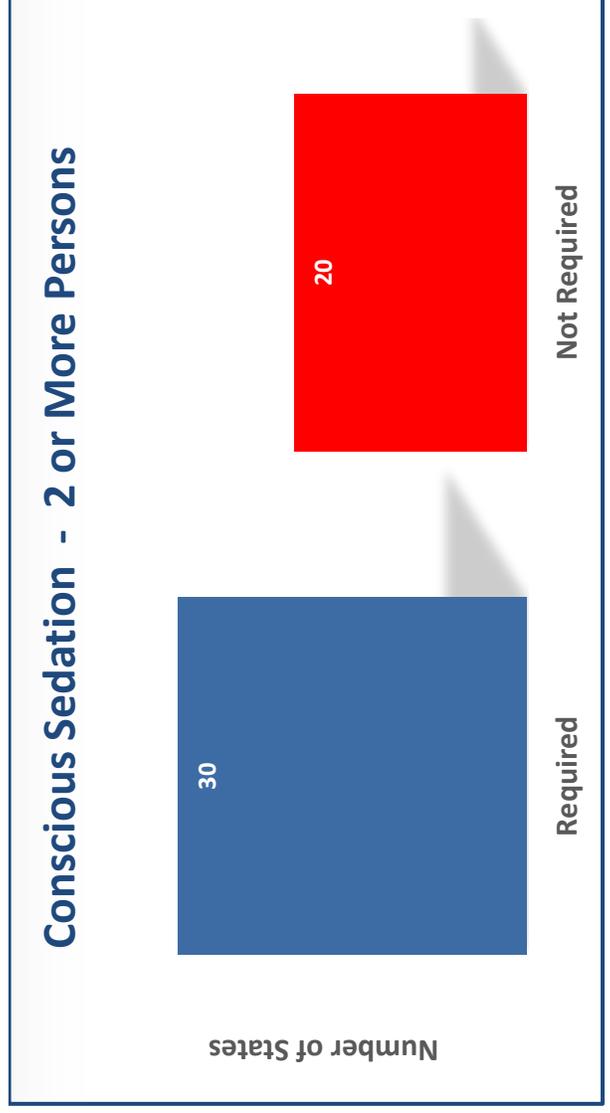
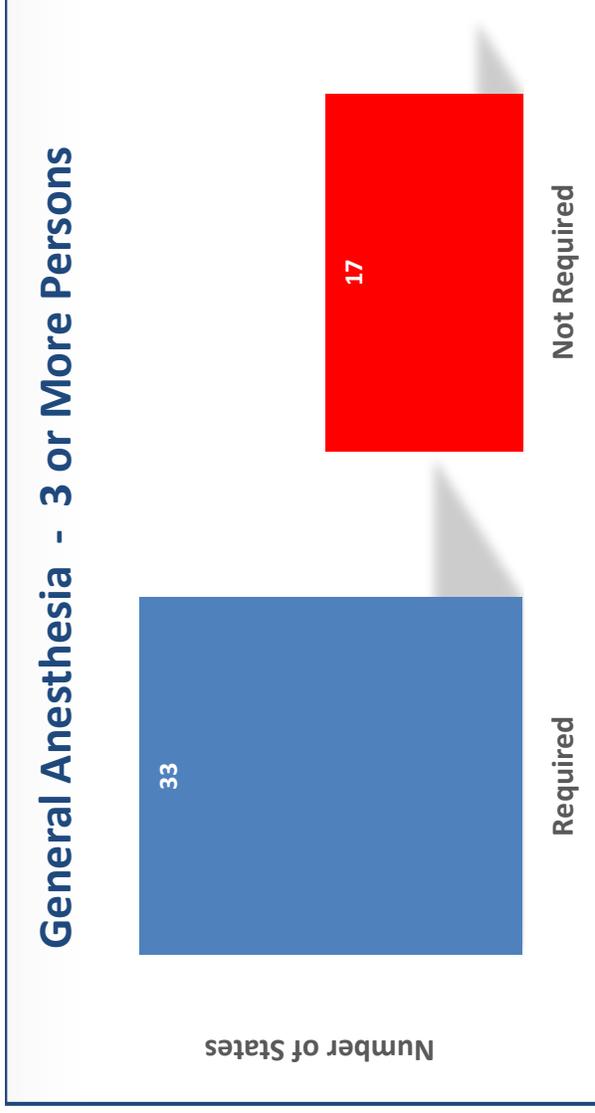
California	ADA Guidelines	AAP-AAPD Guidelines
Minimal Sedation		
	At least one additional person trained in BLS + dentist.	Children who have received minimal sedation generally will not require more than observation and intermittent assessment of their level of sedation. Some children will become moderately sedated despite the intended level of minimal sedation; should this occur, then the guidelines for moderate sedation apply.
Moderate Sedation		
<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)	
	<p>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.</p> <p>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.</p> <p>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.</p>
Deep Sedation/General Anesthesia	
<p>Same as moderate sedation</p>	<p>A minimum of three (3) individuals must be present.</p> <ul style="list-style-type: none"> • 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. <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.</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.</p> <p>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> <p>(updated to 2016 Guidelines)</p>

Sedation and Anesthesia Assisting Requirements in the 50 States



Sedation and Anesthesia Assisting Requirements in the 50 States



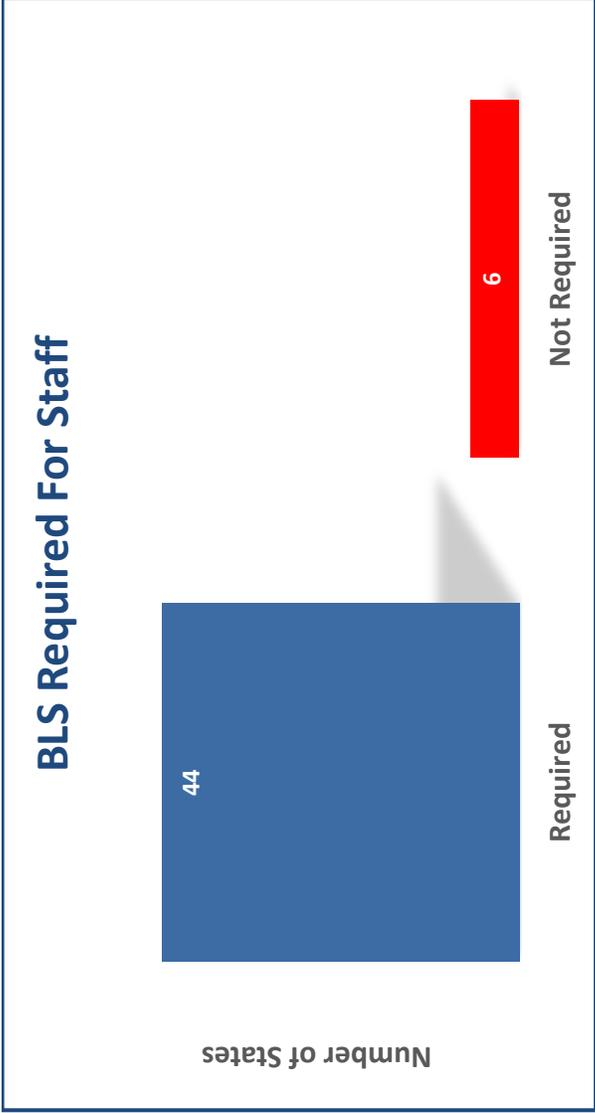


TABLE 5
Facility Requirements — Comparison of California, ADA and AAP-AAPD Guidelines

California Requirements	ADA Guidelines	AAP-AAPD Guidelines
<p>Facilities 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"> (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. (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 theater. 	<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"> • 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. • An appropriate scavenging system must be available if gases other than oxygen or air are used. 	<p>Facilities 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

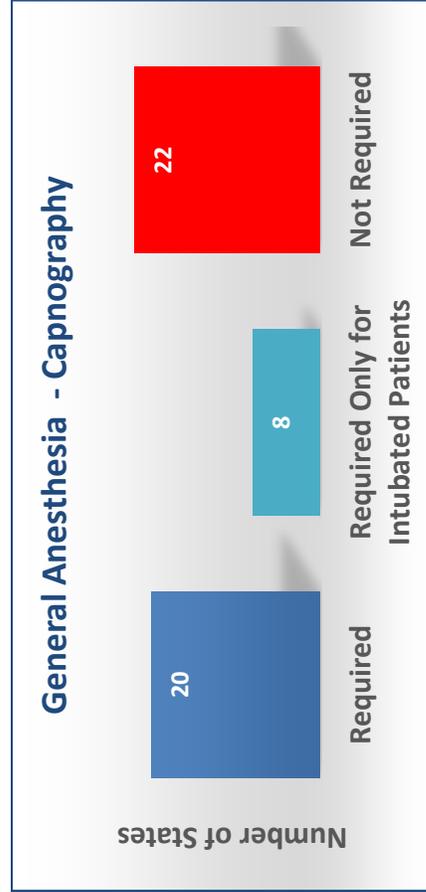
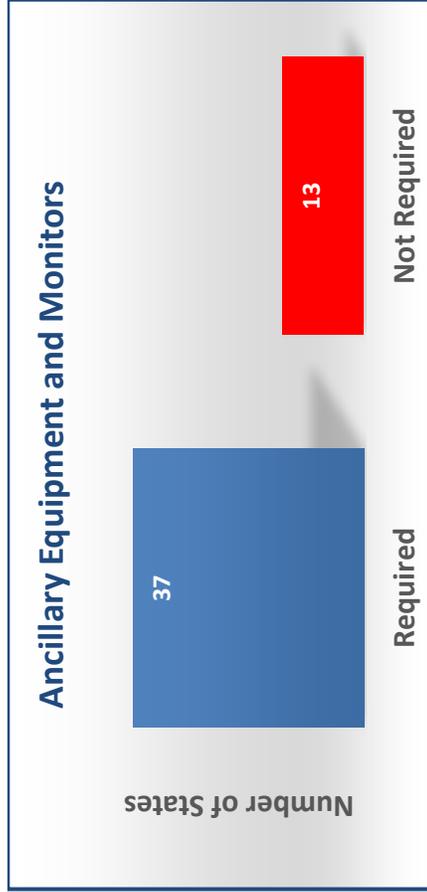
California Requirements	ADA Guidelines	AAP-AAPD Guidelines
<p>Oral Conscious Sedation</p> <p>CCR 1044: An emergency cart or kit shall be available and readily accessible and shall include the necessary and appropriate drugs and age- and size-appropriate equipment to resuscitate a nonbreathing and unconscious 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"> (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 	<p>Minimal Sedation</p> <p>Monitoring: 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>Oxygenation:</p> <ul style="list-style-type: none"> • Color of mucosa, skin or blood must be evaluated continually. • Oxygen saturation by pulse oximetry may be clinically useful and should be considered. <p>Ventilation:</p> <ul style="list-style-type: none"> • The dentist and/or appropriately trained individual must observe chest excursions continually. • The dentist and/or appropriately trained individual must verify respirations continually. <p>Circulation:</p> <ul style="list-style-type: none"> • 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). 	<p>All Levels of Sedation</p> <p>On-site monitoring and rescue equipment 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, cricthyrotomy 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>Monitoring:</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>Consciousness:</p> <ul style="list-style-type: none"> Level of consciousness (e.g., responsiveness to verbal command) must be continually assessed. <p>Oxygenation:</p> <ul style="list-style-type: none"> Color of mucosa, skin or blood must be evaluated continually. Oxygen saturation must be evaluated by pulse oximetry continuously. <p>Ventilation:</p> <ul style="list-style-type: none"> The dentist must observe chest excursions continually. The dentist must monitor ventilation. This can be accomplished by auscultation of breath sounds, monitoring end-tidal CO₂ or by verbal communication with the patient. <p>Circulation:</p> <ul style="list-style-type: none"> 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). Continuous ECG monitoring of patients with significant cardiovascular disease should be considered. 	<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>Intravenous Equipment</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	Intravenous Equipment (continued)
		<p>Assorted IV needles (eg, 25-, 22-, 20-, and 18-gauge)</p> <p>Intraosseous bone marrow needle</p> <p>Sterile gauze pads</p> <p>Airway Management Equipment</p> <p>Face masks (infant, child, small adult, medium adult, large adult)</p> <p>Breathing bag and valve set</p> <p>Oropharyngeal airways (infant, child, small adult, medium adult, large adult)</p> <p>Nasopharyngeal airways (small, medium, large)</p> <p>Laryngeal mask airways (1, 1.5, 2, 2.5, 3, 4, and 5)</p> <p>Laryngoscope handles (with extra batteries)</p> <p>Laryngoscope blades (with extra light bulbs)</p> <p>Straight (Miller) No. 1, 2, and 3</p> <p>Curved (Macintosh) No. 2 and 3</p> <p>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)</p> <p>Stylettes (appropriate sizes for endotracheal tubes)</p> <p>Surgical lubricant</p> <p>Suction catheters (appropriate sizes for endotracheal tubes) Yankauer-type suction</p> <p>Nasogastric tubes</p> <p>Nebulizer with medication kits</p> <p>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> <p>(K) Laryngoscope complete with adequate selection of blades and spare batteries and bulb. (This equipment is not required for conscious sedation.)</p> <p>(L) Endotracheal tubes and appropriate connectors. (This equipment is not required for conscious sedation.)</p> <p>(M) Emergency airway equipment (oral airways, laryngeal mask airways or combitubes, cricthyrotomy device).</p> <p>(N) Tonsillar or pharyngeal type suction tip adaptable to all office outlets.</p> <p>(O) Endotracheal tube forcep. (This equipment is not required for conscious sedation.)</p> <p>(P) Sphygmomanometer and stethoscope.</p> <p>(Q) Electrocardioscope and defibrillator. (This equipment is not required for conscious sedation.)</p> <p>(R) Adequate equipment for the establishment of an intravenous infusion.</p> <p>(S) Precordial/pretracheal stethoscope.</p> <p>(T) 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>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. Monitoring must include:</p> <p>Oxygenation:</p> <ul style="list-style-type: none"> • Color of mucosa, skin or blood must be continually evaluated. • Oxygenation saturation must be evaluated continuously by pulse oximetry. <p>Ventilation:</p> <ul style="list-style-type: none"> • Intubated patient: End-tidal CO2 must be continuously monitored and evaluated. • Non-intubated patient: Breath sounds via auscultation and/or end-tidal CO2 must be continually monitored and evaluated. • Respiration rate must be continually monitored and evaluated. <p>Circulation:</p> <ul style="list-style-type: none"> • The dentist must continuously evaluate heart rate and rhythm via ECG throughout the procedure, as well as pulse rate via pulse oximetry. • The dentist must continually evaluate blood pressure. <p>Temperature:</p> <ul style="list-style-type: none"> • A device capable of measuring body temperature must be readily available during the administration of deep sedation or general <p>Anesthesia:</p> <ul style="list-style-type: none"> • The equipment to continuously monitor body temperature should be available and must be performed whenever triggering agents associated with malignant hyperthermia are administered <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>Equipment 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 (i.e., 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

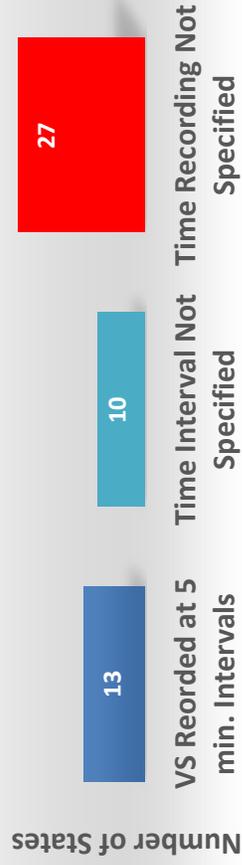


TABLE 7

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

California Record Requirements	ADA Guidelines	AAP-AAPD Guidelines
<p>Oral (Moderate) Conscious Sedation</p> <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>Minimal Sedation</p> <p>Documentation: An appropriate sedative record must be maintained, including the names of all drugs administered, including local anesthetics, dosages, and monitored physiological parameters.</p>	<p>All Levels of Sedation</p> <p>Documentation prior to treatment — see pre-operative evaluation</p> <p>Documentation during treatment 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>Documentation after treatment 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 re-sedation, some patients might benefit from a longer period of less-intense observation (e.g., a step-down observation area) before discharge from medical supervision.¹³³ 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>

<p>Conscious Sedation and General Anesthesia</p> <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>Moderate Sedation</p> <p>Documentation: 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"> • Pulse oximetry, heart rate, respiratory rate, blood pressure and level of consciousness must be recorded continually. 	
	<p>Deep Sedation or General Anesthesia</p> <p>Documentation: 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"> • Pulse oximetry and end-tidal CO₂ measurements (if taken), heart rate, respiratory rate, and blood pressure must be recorded continually. 	

TABLE 8
Emergency drugs — California sedation laws compared to ADA and ADA-AAPD Guidelines

California — Required Emergency Drugs	ADA Guidelines	AAP-AAPD Guidelines
<p>Pediatric and Adult Oral Conscious Sedation (CCR 1044.5)</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> <ol style="list-style-type: none"> (1) Epinephrine (2) Bronchodilator (3) Appropriate drug antagonists (4) Antihistaminic (5) Anticholinergic (6) Anticonvulsant (7) Oxygen (8) Dextrose or other antihypoglycemic 	<p>Minimal Sedation</p> <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>All Levels of Sedation</p> <p>Appendix C. Drugs That May Be Needed to Rescue a Sedated Patient*</p> <p>Albuterol for inhalation</p> <p>Ammonia spirits</p> <p>Atropine</p> <p>Diphenhydramine</p> <p>Diazepam</p> <p>Epinephrine (1:1000, 1:10 000)</p> <p>Flumazenil</p> <p>Glucose (25 percent or 50 percent)</p> <p>Lidocaine (cardiac lidocaine, local infiltration)</p> <p>Lorazepam</p> <p>Methylprednisolone</p> <p>Naloxone</p> <p>Oxygen</p> <p>Fosphenytoin</p> <p>Racemic epinephrine</p> <p>Rocuronium</p> <p>Sodium bicarbonate</p> <p>Succinylcholine</p> <p>* The choice of emergency drugs may vary according to individual or procedural needs</p>

Conscious Sedation and General Anesthesia (CCR 1043.3)	Moderate Sedation	
<p>Drugs: Emergency drugs of the following types shall be available:</p> <ol style="list-style-type: none"> (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 	<ul style="list-style-type: none"> • 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. 	
	<p style="text-align: center;">Deep Sedation General Anesthesia</p>	
	<ul style="list-style-type: none"> • 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. 	

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

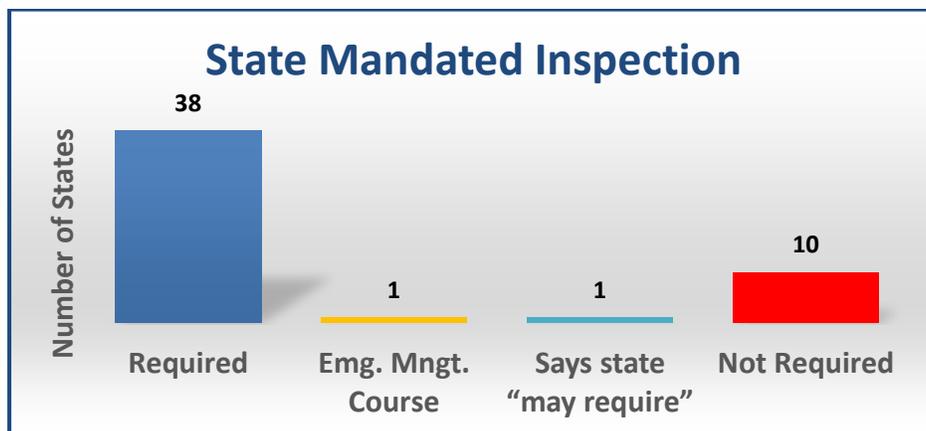
Note: Authority cited: Section 1614, Business and Professions Code. Reference: Sections 1647.10, 1647.16, 1647.22 and 1647.24, Business and Professions Code.

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

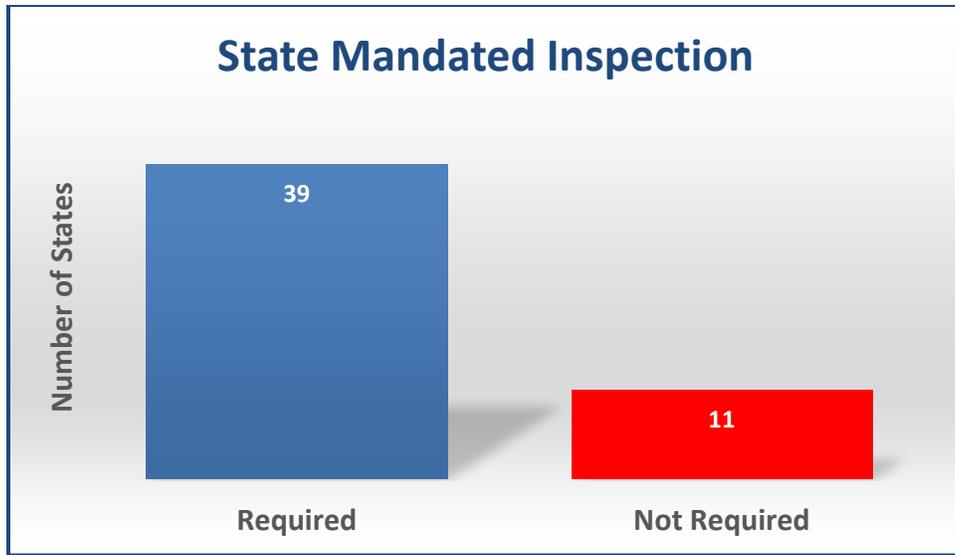


Table 10.

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.

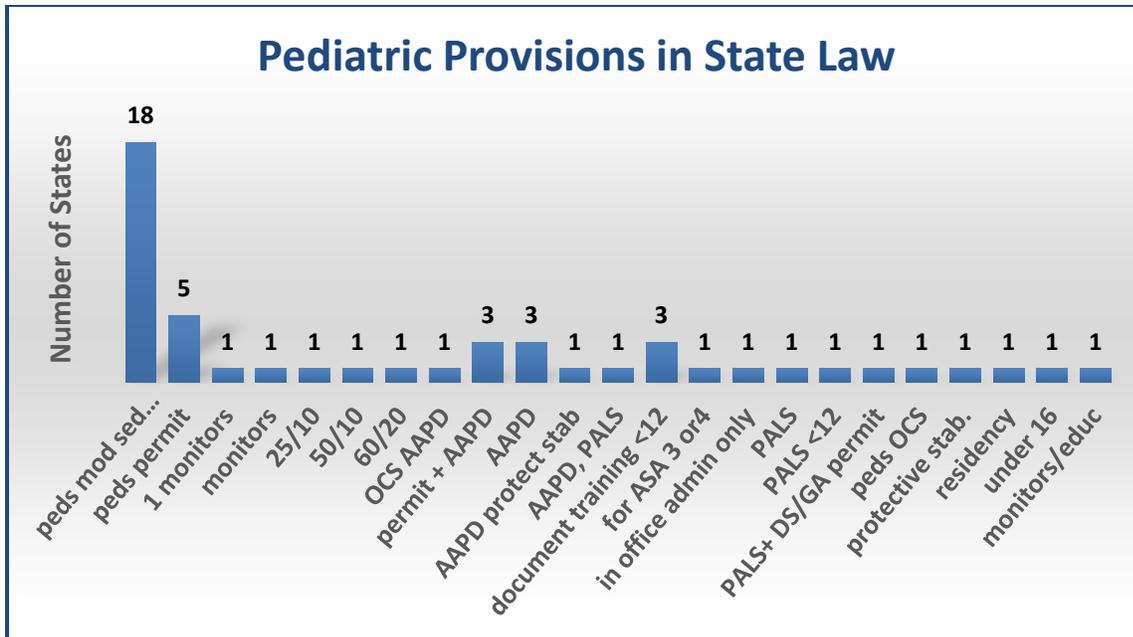
Ten states (California, Colorado, Florida, Georgia, Kentucky, Louisiana, Missouri, Mississippi, North Carolina and Oklahoma) require permits for sedating pediatric patients.

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

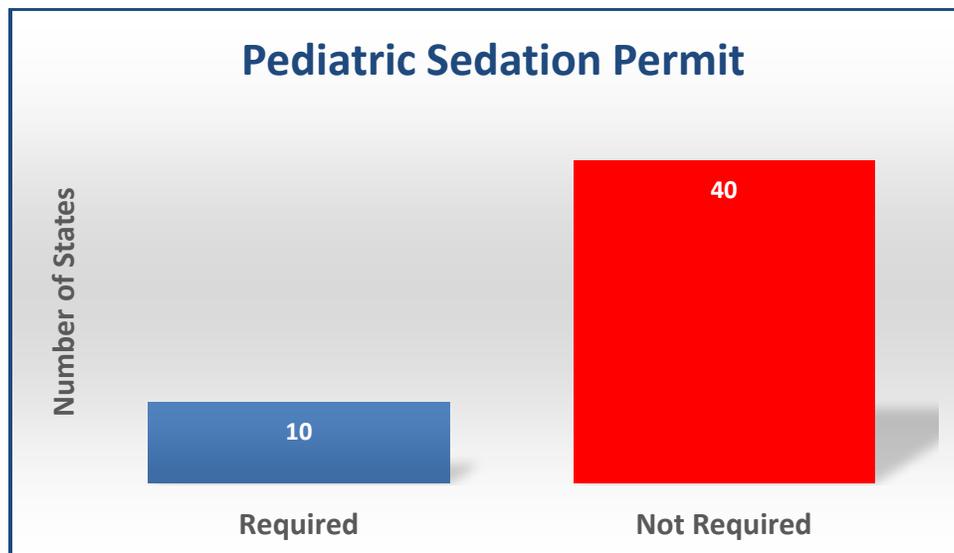
Approximately twenty nine states have specific requirements for pediatric sedation administered by the oral route.

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



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